

**CORPORATE INTEGRITY AGREEMENT**  
**BETWEEN THE**  
**OFFICE OF INSPECTOR GENERAL**  
**OF THE**  
**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**AND**  
**FOREST LABORATORIES, INC.**

**I. PREAMBLE**

Forest Laboratories, Inc. hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance by Forest Laboratories, Inc., and its U.S. subsidiaries (Forest Pharmaceuticals, Inc., Forest Research Institute, Inc., FL Cincinnati Inc., Inwood Laboratories, Inc., and Cerexa, Inc.) (collectively “Forest”) with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements) and with the statutes, regulations, and written directives of the Food and Drug Administration (FDA requirements). **Contemporaneously with this CIA, Forest Laboratories, Inc. and Forest Pharmaceuticals, Inc. are entering into a Settlement Agreement and Release with the United States.** Forest Laboratories, Inc. and Forest Pharmaceuticals, Inc. will also enter into settlement agreements with various States (Medicaid State Settlement Agreements) and Forest Laboratories, Inc.’s agreement to this CIA is a condition precedent to those agreements.

Prior to the Effective Date of this CIA (as defined below), Forest established a voluntary compliance program applicable to all Forest employees (Compliance Program). Forest’s Compliance Program includes a Chief of Compliance who reports directly to the Board of Directors and the President and Chief Operating Officer, and a Compliance Committee. The Compliance Program also includes a Code of Conduct (known as “Code of Business Conduct & Ethics”) applicable to all employees that is regularly reviewed and disseminated, written policies and procedures, educational and training initiatives, a Disclosure Program that allows for the confidential disclosure and investigation of potential compliance violations and appropriate disciplinary procedures, and regular monitoring and internal auditing procedures.

Forest shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. Forest may modify its

Compliance Program as appropriate, but, at a minimum, Forest shall ensure that during the term of this CIA, it shall comply with the obligations set forth herein.

## **II. TERM AND SCOPE OF THE CIA**

A. The period of the compliance obligations assumed by Forest under this CIA shall be five years from the Effective Date of this CIA, unless otherwise specified. The effective date shall be the date on which the final signatory of this CIA executes the document (Effective Date). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a “Reporting Period.”

B. Sections VII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Forest's final Annual Report; or (2) any additional materials submitted by Forest pursuant to OIG's request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. “Covered Persons” includes:

a. all owners of Forest who are natural persons (other than shareholders who (i) have an ownership interest of less than 5%; and (ii) acquired the ownership interest through public trading);

b. all directors of Forest Laboratories, Inc.;

c. except as carved out below in this Section II.C.1, (1) all U.S.-based officers, directors, and employees of Forest, and (2) all officers, directors, and employees of Forest who are based outside the United States and who have responsibilities relating to Promotional and Product Related Functions or Regulatory Related Functions; and

d. except as carved out below in this Section II.C.1, all contractors, subcontractors, agents, and other persons who perform Promotional and Product Related Functions or Regulatory Related Functions (as defined below in Section II.C.4) on behalf of Forest.

Notwithstanding the above, the term “Covered Persons” does not include: (i) employees, contractors, subcontractors, agents, or other personnel of Forest who perform only building and facilities functions (i.e., facilities maintenance, grounds maintenance, and food service functions); (ii) part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become “Covered Persons” at the point when they work more than 160 hours during the calendar year; or (iii) employees of Inwood Laboratories, Inc. or Cerexa, Inc. so long as they do not have responsibilities relating to Promotional and Product Related Functions or Regulatory Related Functions.

2. “Relevant Covered Persons” includes all Covered Persons whose job responsibilities relate to Promotional and Product Related Functions or Regulatory Related Functions.
3. “Government Reimbursed Products” refers to all Forest pharmaceutical products promoted or sold by Forest in the United States that are reimbursed by Federal health care programs.
4. The term “Promotional and Product Related Functions” includes: (a) the selling, detailing, marketing, advertising, promoting, or branding of Government Reimbursed Products; (b) the development, approval, preparation, or dissemination of materials or information about, or the provision of services relating to, Government Reimbursed Products including those functions relating to review committees and Forest’s Medical Information and Communication Department (“MIC Department”); (c) authorship, publication, and dissemination of clinical study results for Government Reimbursed Products; and (d) contracting with healthcare professionals (HCPs) or healthcare institutions (HCIs) in the United States to conduct postmarketing and other clinical studies of Government Reimbursed Products, and the authorship, publication, and disclosure of results relating to such studies.
5. The term “Regulatory Related Functions” includes: (a) activities associated with all FDA requirements and guidance (collectively “requirements”) relating to determinations about the status or classification of a Forest product and any changes in such status or

classification (including, but not limited to, a determination that a product is a “new drug”), including all reporting requirements and all requirements relating to the tracking or distribution of the product; and (b) activities associated with the tracking, collection, verification, reporting, or updating of: i) product or product-related information; ii) pricing information; or iii) utilization information, for purposes of the Medicaid Drug Rebate Program (codified at 42 U.S.C. § 1396r-8), the Medicare program (codified at 42 U.S.C. § 1395-1395hhh), and other Federal health care programs, including the reporting or updating of information in connection with any determinations about the status or classification of a Government Reimbursed Product and any changes in such status or classification (including information about the status of a product as a covered outpatient drug.)

6. The term “Third Party Educational Activity” shall mean any continuing medical education (CME), disease awareness, or other scientific, educational, or professional program, meeting, or event sponsored by Forest, including but not limited to, sponsorship of symposia at medical conferences.
7. The term "Third Party Personnel" shall mean personnel of the entities with whom Forest or any Forest subsidiary has or may in the future (during the term of this CIA) enter into agreements to co-promote a Government Reimbursed Product in the United States or engage in joint promotional activities in the United States relating to such a product. Forest has represented that: (1) the Third Party Personnel are employed by entities independent of Forest; (2) Forest does not control Third Party Personnel; and (3) it would be commercially impracticable to compel the compliance of Third Party Personnel with the requirements set forth in this CIA. Forest agrees to promote compliance by Third Party Personnel with Federal health care program and FDA requirements by complying with the provisions set forth below in Sections III.B.2, V.A.7, and V.B.7 related to Third Party Personnel who meet the definition of Covered Persons. Provided that Forest complies with the requirements of Sections III.B.2, V.A.7, and V.B.7, Forest shall not be required to fulfill the other CIA obligations that would otherwise apply to Third Party Personnel who meet the definition of Covered Persons.

### **III. CORPORATE INTEGRITY OBLIGATIONS**

Forest shall establish and maintain a Compliance Program throughout the term of this CIA that includes the following elements:

#### **A. Compliance Officer and Compliance Committee.**

1. *Compliance Officer.* Prior to the Effective Date, Forest appointed a Compliance Officer (known as “Chief of Compliance”), and Forest shall maintain a Compliance Officer during the term of the CIA. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements and FDA requirements. The Compliance Officer shall be a member of senior management of Forest, shall report directly to the Chief Operating Officer and President, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Forest, or a Committee of the Board, and shall be authorized to report on such matters to the Board of Directors, or a Committee of the Board, at any time. The Compliance Officer shall not be, or be subordinate to, the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Forest as well as for any reporting obligations created under this CIA. Any non-compliance-related job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer’s ability to perform the duties outlined in this CIA.

Forest shall report to OIG, in writing, any changes in the identity or position description of the Compliance Officer, or any actions or changes that would affect the Compliance Officer’s ability to perform the duties necessary to meet the obligations in this CIA, within five days after such a change.

2. *Compliance Committee.* Prior to the Effective Date, Forest established a Compliance Committee, and Forest shall maintain a Compliance Committee during the term of this CIA. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as Legal, Compliance, Finance, Marketing, Internal Audit, Human Resources, Sales, Regulatory Affairs, and Medical.) The Compliance Officer shall chair the Compliance Committee, and the Compliance Committee shall support the Compliance Officer in fulfilling his/her

responsibilities under the CIA (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly.

Forest shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

3. *Board of Directors Compliance Obligations.* The Board of Directors of Forest Laboratories, Inc. (Board), or a Committee of the Board, shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA. The Board, or a Committee of the Board, shall, at a minimum, be responsible for the following:

a. The Board, or a Committee of the Board, shall meet at least quarterly to review and oversee Forest's Compliance Program, including but not limited to the performance of the Compliance Officer and other Compliance personnel.

b. The Board, or a Committee of the Board, shall arrange for the performance of a review of the effectiveness of Forest's Compliance Program (Compliance Program Review) by the Compliance Expert (described below) for each Reporting Period of the CIA. The Board, or a Committee of the Board, shall review the Compliance Program Review Report (described below) as part of its review and assessment of Forest's Compliance Program. A copy of the Compliance Program Review Report shall be provided to OIG in each Annual Report submitted by Forest.

c. The Board, or a Committee of the Board, shall retain an independent individual or entity with expertise in compliance with Federal health care program and FDA requirements (Compliance Expert). The Compliance Expert shall create a work plan for the Compliance Program Review, oversee the performance of the Compliance Program Review, and prepare a written report about the Compliance Program Review and the results of the review. The written report (Compliance Program Review Report) shall include a description of the review and shall include recommendations with respect to the Compliance Program. This report shall also include a certification that the Compliance Expert has evaluated its professional independence and objectivity, as appropriate to the nature of the engagement with regard to the Compliance Program Review and concluded that it is, in fact, independent and objective.

d. For each Reporting Period of the CIA, the Board, or a Committee of the Board, shall adopt a resolution, signed by each individual member of the Board or the Committee, summarizing its review and oversight of Forest's compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA.

At minimum, the resolution shall include the following language:

“The Board of Directors [or a Committee of the Board] has made a reasonable inquiry into the operations of Forest's Compliance Program, including, but not limited to, evaluating its effectiveness and receiving updates about the performance of the Compliance Officer and other Compliance personnel for the time period **[insert time period]**. In addition, the Board [or a Committee of the Board] has retained a Compliance Expert with expertise in compliance with the Federal health care program and FDA requirements to support the Board's responsibilities. The Board [or a Committee of the Board] also has arranged for the performance of, and reviewed the results of, the Compliance Program Review, including the Compliance Program Review Report. Based on all of these steps, the Board [or a Committee of the Board] has concluded that, to the best of its knowledge, Forest has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the CIA.”

If the Board, or a Committee of the Board, is unable to provide such a conclusion in the resolution, the Board or the Committee shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at Forest.

Forest shall report to OIG, in writing, any changes in the composition of the Board or the Committee of the Board described above, or any actions or changes that would affect the ability of the Board, or the Committee of the Board to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

4. *Management Accountability and Certifications:* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Forest officers or employees (“Certifying Employees”) are each specifically expected to monitor and oversee activities within their areas of authority and shall annually provide the certification in Section III.A.4, below, with regard to the Forest business area(s) under

their authority. These Certifying Employees shall include, at a minimum, the following: Chief Executive Officer, Forest Laboratories, Inc. (FLI); President and Chief Operating Officer (FLI); Executive Vice-President of Global Marketing (FLI); Senior Vice-President and Chief Commercial Officer(FLI); Vice-President of Marketing Services, Forest Pharmaceuticals, Inc. (FPI); Vice-President of Managed Markets, Government and Policy (FLI); Vice-President of Marketing and Product Management (FLI); Vice-President of New Products (FPI); Corporate Vice-President of Business Development and Strategic Planning (FLI); Corporate Vice President (FLI) and President, Forest Research Institute, Inc. (FRI); President of Cerexa Administration; Senior Vice-President of Finance and Chief Financial Officer (FLI); Corporate Vice-President of Human Resources (FLI); Senior Vice-President of Sales (FPI); Vice-President (FRI) and Chief of Compliance (FLI); Executive-Vice President of Trade Sales and Development (FLI); Vice-President of Information Systems & Manufacturing/Operational Informatics (FLI); Vice-President of Regulatory Affairs (FRI), and, to the extent that a Forest business unit performs sales, marketing, promotion, pricing, contracting, regulatory affairs, compliance, and medical affairs functions is not covered by the certifications of one of the above-listed individuals, such other appropriate Forest executives, vice-presidents, and directors as would be necessary to ensure that there is a certifying officer or employee covering each such business unit.

For each Reporting Period, each Certifying Employee shall sign a certification that states:

“I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department or functional area], an area under my supervision. My job responsibilities include ensuring compliance by the [insert name of the department or functional area] with all applicable Federal health care program requirements, FDA requirements, the obligations of the CIA, and Forest’s policies and I have taken steps to promote such compliance. To the best of my knowledge, except as otherwise described herein, the [insert name of department or functional area] of Forest is in compliance with all applicable Federal health care program requirements, FDA requirements, and the obligations of the CIA. I understand that this certification is being provided to and relied upon by the United States.”

If any Certifying Employee is unable to provide such a conclusion in the certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above and the steps being taken to address the issue(s) identified in the certification.

B. Written Standards.

1. *Code of Conduct.* Prior to the Effective Date, Forest developed, implemented, and distributed a written Code of Conduct (known as the “Code of Business Conduct & Ethics”) to all Covered Persons employed by Forest. Forest currently requires all newly employed Covered Persons to certify in writing or electronically, that they have received, read, understood, and shall abide by Forest’s Code of Conduct. Forest shall continue to make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employed Covered Persons.

The Code of Conduct sets forth and shall continue to set forth, at a minimum, the following:

- a. Forest’s commitment to full compliance with all Federal health care program and FDA requirements, including its commitment to comply with all requirements relating to Promotional and Product Related Functions and Regulatory Related Functions;
- b. Forest’s requirement that all of its Covered Persons shall be expected to comply with all Federal health care program and FDA requirements and with Forest’s own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA);
- c. the requirement that all of Forest’s Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by Forest, suspected violations of any Federal health care program and FDA requirements or of Forest’s own Policies and Procedures;
- d. the possible consequences to both Forest and Covered Persons of failure to comply with Federal health care program and FDA requirements and with Forest’s own Policies and Procedures and the failure to report such noncompliance; and
- e. the right of all individuals to use the Disclosure Program described in Section III.E, and Forest’s commitment to nonretaliation and to

maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

To the extent not already accomplished, within 120 days after the Effective Date, the Code of Conduct shall be distributed to each Covered Person and each Covered Person shall certify, in writing or electronically, that he or she has received, read, understood, and shall abide by Forest's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later.

Forest shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed within 30 days after any revisions are finalized. Each Covered Person shall certify, in writing or electronically, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

2. *Third Party Personnel.* Within 120 days after the Effective Date, and annually thereafter by the anniversary of the Effective Date, Forest shall send a letter to each entity employing Third Party Personnel. The letter shall outline Forest's obligations under the CIA and its commitment to full compliance with all Federal health care program and FDA requirements. The letter shall include a description of Forest's Compliance Program. Forest shall attach a copy of its Code of Conduct to the letter and shall request the entity employing Third Party Personnel to either: (a) make a copy of Forest's Code of Conduct and a description of Forest's Compliance Program available to its Third Party Personnel; or (b) represent to Forest that it has and enforces a substantially comparable code of conduct and compliance program for its Third Party Personnel.

3. *Policies and Procedures.* Prior to the Effective Date, Forest implemented written Policies and Procedures regarding the operation of the Compliance Program and Forest's compliance with Federal health care program and FDA requirements (Policies and Procedures). To the extent not already accomplished, within 120 days after the Effective Date, Forest shall ensure that the Policies and Procedures address or shall continue to address:

- a. the subjects set forth in the Code of Conduct identified in Section III.B.1;

- b. appropriate ways to conduct Promotional and Product Related Functions in compliance with all applicable Federal health care program requirements, including, but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b(b)), and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733);
- c. appropriate ways to conduct Promotional and Product Related Functions in compliance with all applicable FDA requirements;
- d. appropriate ways to conduct Regulatory Related Functions in accordance with all applicable Federal health care program requirements;
- e. appropriate ways to conduct Regulatory Related Functions in accordance with all applicable FDA requirements;
- f. the materials and information that may be distributed by Forest sales representatives and account managers about Forest's Government Reimbursed Products and the manner in which Forest sales representatives respond to requests for information about non-FDA approved (or "off-label") uses of Forest's Government Reimbursed Products. These Policies and Procedures shall require that sales representatives and account managers refer all requests for information about off-label uses of Government Reimbursed Products to Forest's MIC Department;
- g. the materials and information that may be distributed by Forest's MIC Department and the mechanisms through, and manner in which, the MIC Department receives and responds to requests for information about off-label uses of Forest's Government Reimbursed Products; the form and content of information disseminated by Forest in response to such requests; and the internal review process for the information disseminated.

The Policies and Procedures shall include a requirement that Forest maintain database(s) to track requests for information about Forest's products that are received by the MIC Department.

This database shall be referred to as the “MIC Inquiries Database.” The MIC Inquiries Database shall include the following items of information for each unique inquiry (Inquiry) received for information about Forest’s Government Reimbursed Products: 1) date of Inquiry; 2) form of Inquiry (*e.g.*, fax, phone, etc.); 3) name of the requesting HCP or HCI (in accordance with applicable privacy laws); 4) nature and topic of request (including exact language of the Inquiry if made in writing); 5) nature/form of the response from Forest (including a record of any materials provided to the HCP or HCI in response to the request); and 6) if applicable, the name of the Forest representative who called on or interacted with the HCP or HCI, if known;

- h. the manner and circumstances under which personnel from External Scientific Affairs participate in meetings or events with HCPs or HCIs (either alone or with sales representatives) and the role of External Scientific Affairs personnel at such meetings or events, as well as how they handle requests for information about off-label uses of Forest’s Government Reimbursed Products;
- i. the development, implementation, and review of call panels for sales representatives who promote Government Reimbursed Products. For each Government Reimbursed Product, the Policies and Procedures shall require that Forest review the call panels for the product and the bases upon, and circumstances under which HCPs and HCIs belonging to specified medical specialties or types of clinical practice are included in, or excluded from, the call panels. The Policies and Procedures shall also require that Forest modify the call panels as necessary to ensure that Forest is promoting its Government Reimbursed Products in a manner that complies with all applicable Federal health care program and FDA requirements. The call panel reviews shall occur at least annually and shall also occur each time the FDA approves a new or additional indication for a Government Reimbursed Product;

- j. the development, implementation, and review of plans for the distribution of samples of Forest's Government Reimbursed Products (Sample Distribution Plans). This shall include a review of the bases upon which, and circumstances under which, HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples from Forest (including, separately, from Forest sales representatives and/or directly from Forest's Quality Assurance Department). The Policies and Procedures shall also require that Forest modify the Sample Distribution Plans as necessary to ensure that Forest is promoting its products in a manner that complies with all applicable Federal health care program and FDA requirements;
- k. consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including, but not limited to, speaker programs, speaker training programs, presentations, consultant meetings, advisory boards, and ad hoc advisory activities, and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements. These Policies and Procedures shall be designed to ensure that the arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The Policies shall include requirements about the content and circumstances of such arrangements and events;
- l. programs to educate sales representatives, including but not limited to mentorships, preceptorships, or presentations by HCPs at sales meetings and experience-based learning activities. These Policies and Procedures shall be designed to ensure that the programs are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The Policies shall include requirements about the content and circumstances of such arrangements and events;
- m. sponsorship or funding of grants (including educational grants) or charitable contributions. These Policies and Procedures shall be designed to ensure that Forest's funding and/or sponsorship

complies with all applicable Federal health care program and FDA requirements;

- n. funding of, or participation in, any Third Party Educational Activity as defined in Section II.C.6 above. These Policies and Procedures shall be designed to ensure that Forest's funding and/or sponsorship of such programs satisfies all applicable Federal health care program and FDA requirements.

The Policies and Procedures shall require that: 1) Forest disclose its financial support of the Third Party Educational Activity and, to the extent feasible consistent with clause 5 of this paragraph, any financial relationships with faculty, speakers, or organizers at such Activity; 2) as a condition of funding, the third party agrees to disclose Forest's financial support of the Third Party Educational Activity and any financial relationships that Forest might have with faculty, speakers, or organizers at such Activity; 3) any faculty, speakers, or organizers at the Third Party Educational Activity agree to disclose any financial relationship with Forest; 4) the Third Party Educational Activity have an educational focus; 5) the content, organization, and operation of the Third Party Educational Activity be independent of Forest control; 6) Forest support only Third Party Educational Activity that is non-promotional in tone/nature; and 7) Forest support of a Third Party Educational Activity shall be contingent on the provider's commitment to provide information at the Educational Activity that is fair, balanced, accurate and not misleading;

- o. for all promotional and written materials and information related to Government Reimbursement Products intended to be disseminated outside Forest, the review of such materials by appropriate qualified personnel (such as regulatory, medical, and/or legal personnel) in a manner designed to ensure that legal, regulatory, and medical concerns are properly addressed during Forest's review and approval process and are elevated when appropriate. The Policies and Procedures shall be designed to ensure that such materials and information, when finally approved, comply with all applicable Federal health care program

and FDA requirements. The Policies and Procedures shall require that: 1) applicable review committees review all promotional materials prior to the distribution or use of such materials; and 2) deviations from the standard review committee practices and protocols (including timetables for the submission of materials for review) shall be documented and referred for appropriate follow-up;

- p. the review of all materials, information, requirements, and disclosures relating to Regulatory Related Functions. These Policies and Procedures shall be designed to ensure that Forest's activities pertaining to Regulatory Related Functions comply with all applicable Federal health care program and FDA requirements. The Policies and Procedures shall require that Forest annually review the FDA status and classification (e.g., new drug, less-than-effective) of all its products and all changes in the status and/or classification of each product. The Policies and Procedures shall also require that Forest annually review all product information (and changes to such information) reported to CMS for purposes of the Medicaid Drug Rebate Program and the Medicare program (including information about the status of a drug as a covered outpatient drug and product codes or classifications (including those related to the FDA's Drug Efficacy Study Implementation (DESI) program);
- q. sponsorship of post-marketing clinical studies or other post-marketing studies, including investigator-initiated trials (IITs), relating to Government Reimbursed Products, including the decision to provide financial or other support for the IITs; the manner in which such support is provided; and support for publication of information about the IITs, including the publication of information about the trial outcomes and results and the uses made of publications relating to IITs;
- r. authorship of any articles or other publications about Government Reimbursed Products or about therapeutic areas or disease states that may be treated with Government Reimbursed Products, including, but not limited to, the disclosure of any and all

relationships between the author and Forest, the identification of all authors or contributors (including professional writers) associated with a given publication, and the scope and breadth of research results made available to each author or contributor;

- s. compensation (including salaries and bonuses) for Relevant Covered Persons who are sales employees. These Policies and Procedures shall be designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in improper promotion, sales, and marketing of Forest's products; and
- t. disciplinary policies and procedures for violations of Forest's Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

To the extent not already accomplished, within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be made available to all Covered Persons whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), Forest shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be made available to all Covered Persons whose job functions relate to those Policies and Procedures.

### C. Training and Education.

Forest represents that it provides training to its employees on a regular basis concerning a variety of topics. The training covered by this CIA need not be separate and distinct from the regular training provided by Forest, but instead may be integrated fully into such regular training so long as the training covers the areas specified below.

1. *General Training.* Within 120 days after the Effective Date, Forest shall provide at least one hour of General Training to each Covered Person. This training, at a minimum, shall explain:

- a. Forest's CIA requirements; and
- b. Forest's Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

To the extent that Forest provided General Training to Covered Persons during the 180 days immediately prior to the Effective Date that satisfied the requirements set forth in Section III.C.1.b above, the OIG shall credit that training for purposes of satisfying Forest's General Training obligations of this Section III.C.1 for the first Reporting Period. Forest may satisfy its remaining General Training obligations for the Covered Persons who received the training described in the preceding sentence by notifying them within 120 days after the Effective Date in writing or in electronic format of the fact that Forest entered a CIA and providing an explanation of Forest's requirements and obligations under the CIA.

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. *Specific Training.* Within 120 days after the Effective Date, each Relevant Covered Person engaged in Promotional and Product Related Functions shall receive at least three hours of Specific Training applicable to their specific job functions in addition to the General Training required above. This Specific Training shall include a discussion of:

- a. all applicable Federal health care program requirements relating to Promotional and Product Related Functions, including but not limited to the requirements of the Federal anti-kickback statute, the Civil Monetary Penalties Law, and the Civil False Claims Act;
- b. all applicable FDA requirements relating to Promotional and Product Related Functions;

- c. all Forest Policies and Procedures and other requirements applicable to Promotional and Product Related Functions;
- d. the personal obligation of each individual involved in Promotional and Product Related Functions to comply with all applicable Federal health care program and FDA requirements and all other applicable legal requirements;
- e. the legal sanctions for violations of the applicable Federal health care program and FDA requirements; and
- f. examples of proper and improper practices related to Promotional and Product Related Functions.

Within 120 days after the Effective Date, each Relevant Covered Person engaged in Regulatory Related Functions shall receive at least three hours of Specific Training applicable to their specific job functions in addition to the General Training required above. This Specific Training shall include a discussion of:

- a. all applicable Federal health care program requirements relating to Regulatory Related Functions;
- b. all applicable FDA requirements relating to Regulatory Related Functions;
- c. all Forest Policies and Procedures and other requirements applicable to Regulatory Related Functions;
- d. the personal obligation of each individual involved in Regulatory Related Functions to comply with all applicable Federal health care program and FDA requirements and all other applicable legal requirements;
- e. the legal sanctions for violations of the applicable Federal health care program and FDA requirements; and

- f. examples of proper and improper practices related to Regulatory Related Functions.

To the extent that Forest provided Specific Training to Relevant Covered Persons during the 180 days immediately prior to the Effective Date that satisfied the requirements set forth in this Section III.C.2 above, the OIG shall credit that training for purposes of satisfying Forest's Specific Training obligations of this Section III.C.2 for the first Reporting Period.

New Relevant Covered Persons shall receive the applicable Specific training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 120 days after the Effective Date, whichever is later. A Forest employee who has completed the Specific Training shall review or supervise (as applicable) a new Relevant Covered Person's work, to the extent that the work relates to Promotional and Product Related Functions or Regulatory Related Functions (as applicable), until such time as the new Relevant Covered Person completes his or her Specific Training.

After receiving the initial Specific Training described in this Section, each Relevant Covered Person shall receive at least three hours of the applicable Specific Training in each subsequent Reporting Period.

3. *Board Member Training.* Within 120 days after the Effective Date, Forest shall provide at least one hour of training to each member of the Board of Directors, in addition to the General Training. This training shall address the responsibilities of board members and corporate governance.

New members of the Board of Directors shall receive the Board Member Training described above within 30 days after becoming a member or within 120 days after the Effective Date, whichever is later.

4. *Certification.* Each individual who is required to complete training shall certify, in writing or electronically, if applicable, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

5. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the subject area of the training, including applicable Federal health care program and FDA requirements. The training and education required under this Section III.C may be provided by supervisory employees, knowledgeable staff, Forest trainers, and/or outside consultant trainers selected by Forest, or may be satisfied by relevant continuing education programs provided they cover the topics outlined above in Section III.C.2.

6. *Update of Training.* Forest shall review the training annually, and, where appropriate, update the training to reflect changes in Federal health care program requirements, FDA requirements, any issues discovered during any internal audits or any IRO Review, and any other relevant information.

7. *Computer-based Training.* Forest may provide the training required under this CIA through appropriate computer-based training approaches. If Forest chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the Covered Persons receiving such training. In addition, if Forest chooses to provide computer-based General or Specific Training, all applicable requirements to provide a number of “hours” of training in this Section III.C may be met with respect to computer-based training by providing the required number of “normative” hours as that term is used in the computer-based training industry.

#### D. Review Procedures.

##### 1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 120 days after the Effective Date, Forest shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform reviews to assist Forest in assessing and evaluating its Promotional and Product Related Functions and certain of its Regulatory Related Functions. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

Each IRO engaged by Forest shall have expertise in applicable Federal health care program and FDA requirements as may be appropriate to the Review for which the IRO is retained. Each IRO shall assess, along with Forest, whether it can perform the engagement in a professionally independent and objective fashion, as appropriate to the nature of the review, taking into account any other business relationships or other engagements that may exist.

The IRO(s) shall conduct reviews that assess Forest's systems, processes, policies, procedures, and practices relating to Promotional and Product Related Functions and certain of its Regulatory Related Functions ("IRO Review").

*b. Frequency and Brief Description of Reviews.* As set forth more fully in Appendix B, the Promotional and Product Related Review shall consist of two components - a Systems Review and a Transactions Review. The Systems Review shall assess Forest's systems, processes, policies, and procedures relating to Promotional and Product Related Functions and Regulatory Related Functions. If there are no material changes in Forest's systems, processes, policies, and procedures relating to these Functions, the Promotional and Product Related Systems Review shall be performed for the periods covering the first and fourth Reporting Periods. If Forest materially changes its systems, processes, policies, and procedures, the IRO shall perform a Systems Review for the Reporting Period in which such changes were made in addition to conducting the Systems Review for the first and fourth Reporting Periods.

The Transactions Review shall be performed annually and shall cover each of the five Reporting Periods. The IRO(s) shall perform all components of each annual Transactions Review. As set forth more fully in Appendix B, the Transactions Review shall include several components, including a review relating to inquiries included in Forest's MIC Inquiries Database, a review of Forest's Call Panel Assessments, a review of "Sampling Events" (as defined in Appendix B) and a review of records relating to a sample of the Payments that are reported by Forest pursuant to Section III.M below.

In addition, each Transactions Review shall also include a review of up to three additional areas or practices of Forest identified by the OIG in its discretion (hereafter “Additional Items”).)

For purposes of identifying the Additional Items to be included in the Transactions Review for a particular Reporting Period, the OIG will consult with Forest and may consider internal audit work conducted by Forest, Forest’s Government Reimbursed Product portfolio, the nature and scope of Forest’s promotional practices and arrangements with HCPs and HCIs, and other information known to it. As set forth more fully in Appendix B, Forest may propose to the OIG that its internal audit(s) be partially substituted for one or more of the Additional Items that would otherwise be reviewed by the IRO as part of the Transactions Review. The OIG retains sole discretion over whether, and in what manner, to allow Forest’s internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO. The OIG shall notify Forest of the nature and scope of the IRO Review for each of the Additional Items not later than 150 days prior to the end of each Reporting Period. Prior to undertaking the review of the Additional Items, the IRO and/or Forest shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG.

*c. Retention of Records.* The IRO and Forest shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Forest) related to the reviews.

2. *IRO Review Reports.* The IRO(s) shall prepare a report (or reports) based upon each Review performed. The information and content to be included in the report is described in Appendix B, which is incorporated by reference.

3. *Validation Review.* In the event OIG has reason to believe that: (a) any IRO Review fails to conform to the requirements of this CIA; or (b) the IRO’s findings or Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the applicable IRO Review complied with the requirements of the CIA

and/or the findings or Review results are inaccurate (Validation Review). Forest shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of Forest's final Annual Report shall be initiated no later than one year after Forest's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Forest of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, Forest may request a meeting with OIG to: (a) discuss the results of any Review submissions or findings; (b) present any additional information to clarify the results of the applicable Review or to correct the inaccuracy of the Review; and/or (c) propose alternatives to the proposed Validation Review. Forest agrees to provide any additional information as may be requested by OIG under this Section III.D.3 in an expedited manner. OIG will attempt in good faith to resolve any Review issues with Forest prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Forest a certification or sworn affidavit that it has evaluated its professional independence and objectivity, as appropriate to the nature of the engagement, with regard to the applicable Review and that it has concluded that it is, in fact, independent and objective.

#### E. Disclosure Program.

Forest represents that it has a disclosure program designed to facilitate communications relating to compliance with Federal health care program and FDA requirements and with Forest's policies and procedures (the "Disclosure Program"). During the term of the CIA, Forest shall maintain a Disclosure Program that includes a mechanism (a toll-free compliance telephone line and/or on-line electronic reporting) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Forest's policies, conduct, practices, or procedures with respect to any Federal health care program or FDA requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. Forest shall continue to appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Forest shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be made available to OIG upon request.

F. Ineligible Persons.

1. *Definitions.* For purposes of this CIA:

- a. an “Ineligible Person” shall include an individual or entity who:
  - i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or
  - ii. has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
  
- b. “Exclusion Lists” include:
  - i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.oig.hhs.gov>); and

ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.gov>).

2. *Screening Requirements.* Forest shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

- a. As part of the hiring process, Forest shall screen all prospective Covered Persons who would be Forest employees against the Exclusion Lists prior to employing them and shall require such Covered Persons to disclose whether they are Ineligible Persons.
- b. Forest shall screen all current employed Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.
- c. Forest shall implement a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

With respect to current Covered Persons who are not Forest employees (such as contractors, subcontractors, agents, or other persons), Forest shall require that each current Covered Person or their employer represent and certify, in writing, to Forest within 90 days of the Effective Date, that the Covered Person has been screened against the Exclusion Lists and will be screened on an annual basis thereafter. Forest shall further require that any prospective Covered Person who is not a Forest employee be screened against the Exclusion List before conducting any work on behalf of Forest relating to its Government Reimbursed Products, and require that a certification of such screening be provided to Forest prior to such a prospective Covered Person performing work on behalf of Forest. Forest shall maintain a copy of all certifications related to the screening of all Covered Persons who are not Forest employees, and make such certifications available to the OIG, upon request.

Nothing in this Section affects the responsibility of (or liability for) Forest to (if applicable) refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person. Forest understands that items or

services furnished by Ineligible Person(s) are not payable by Federal health care programs and that Forest may be liable for overpayments (if applicable) and/or criminal, civil, and administrative sanctions for employing or contracting with an Ineligible Person(s) regardless of whether Forest meets the requirements of Section III.F.

3. *Removal Requirement.* If Forest has actual notice that a Covered Person has become an Ineligible Person, Forest shall remove such Covered Person from responsibility for, or involvement with, Forest's business operations related to the Federal health care programs and shall remove such Covered Person from any position for which the Covered Person's compensation or the items or services furnished, ordered, or prescribed by the Covered Person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the Covered Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If Forest has actual notice that a Covered Person is charged with a criminal offense that falls within the ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term, Forest shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the accuracy of any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, Forest shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Forest conducted or brought by a U.S.-based governmental entity or its agents involving an allegation that Forest has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Forest shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

H. Reporting.

1. *Reportable Events.*

a. *Definition of Reportable Event.* For purposes of this CIA, a "Reportable Event" means anything that involves:

- i. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program and/or applicable to any FDA requirements relating to the marketing, distribution, or promotion of Forest Government Reimbursed Products for which penalties or exclusion may be authorized; or
- ii. the filing of a bankruptcy petition by Forest.

A Reportable Event may be the result of an isolated event or a series of occurrences.

*b. Reporting of Reportable Events.* If Forest determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Forest shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:

- i. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program and/or FDA authorities implicated;
- ii. a description of Forest's actions taken to correct the Reportable Event; and
- iii. any further steps Forest plans to take to address the Reportable Event and prevent it from recurring.
- iv. If the Reportable Event involves the filing of a bankruptcy petition, the report to the OIG shall include documentation of the filing and a description of any Federal health care program authorities and/or FDA authorities implicated.
- v. Forest shall not be required to report as a Reportable Event any matter previously disclosed under section III.G.

## I. Notification of Communications with FDA.

Within 30 days after the date of any written report, correspondence, or communication between Forest and the FDA that materially discusses Forest's or a Covered Person's: i) actual or potential unlawful or improper promotion of Forest's products (including any improper dissemination of information about off-label indications); or ii) actual or potential violation of FDA requirements or guidance relating to the status or classification of, and/or distribution of, any Forest product, Forest shall provide a copy of the report, correspondence, or communication to the OIG. Forest shall also provide written notice to the OIG within 30 days after the resolution of any such disclosed matter, and shall provide the OIG with a description of the findings and/or results of the matter, if any.

## J. Field Force Monitoring and Review Efforts

To the extent not already accomplished, within 120 days after the Effective Date, Forest shall establish a Field Force Monitoring Program (FFMP) to evaluate and monitor various aspects of Forest's interactions with HCPs and HCIs, including interactions between sales representatives and HCPs and HCIs. The FFMP shall be a formalized process designed to directly and indirectly observe the appropriateness of sales representatives' interactions with HCPs and HCIs and to identify potential off-label promotional activities or other improper conduct. As set forth in more detail below, the FFMP shall include: 1) a Speaker Monitoring Program; 2) direct field observations (Observations) of sales representatives; and 3) the monitoring and review of other records relating to sales representatives' interactions with HCPs and HCIs (Records Reviews).

1. *Speaker Program Activities.* To the extent not already required, with regard to speaker programs, Forest shall maintain processes to require all speakers to complete training and enter written agreements that describe the scope of work to be performed, the speaker fees to be paid, and compliance obligations for the speakers (including requirements that the speaker may only use Forest-approved materials and may not directly or indirectly promote the product for off-label uses.) Forest and/or its designee shall maintain centralized systems or processes through which all speaker programs are administered. These systems or processes shall establish controls regarding eligibility and qualifications of speakers and venues for the programs and require that speakers are paid according to a centrally managed pre-set rate structure determined based on a fair-

market value analysis conducted by Forest. Forest shall maintain a comprehensive list of speaker program attendees through its centralized systems and processes. In addition, Forest shall track and review the aggregate amount (including speaker fees, travel, and other expenses) paid to each speaker in connection with speaker programs conducted during each Reporting Period. Forest shall require certified evaluations by sales representatives or other Forest personnel regarding whether a speaker program complied with Forest requirements, and in the event of non-compliance, Forest shall require the identification of the policy violation and ensure appropriate follow up activity to address the violation.

To the extent not already accomplished, Forest shall institute a Speaker Monitoring Program under which Forest Compliance or management personnel, or outside personnel acting on behalf of Forest, shall attend 175 speaker programs relating to Government Reimbursed Products during each Reporting Period and conduct live audits of those programs (Speaker Program Audits). Sixty percent of the programs subject to the Speaker Program Audits shall be in-office programs and forty percent shall be out-of-office programs. The programs subject to Speaker Program Audits shall be selected both on a risk-based targeting approach and on a sampling approach. For each program reviewed, personnel conducting the Speaker Program Audits shall review slide materials and other materials used as part of the speaker program, speaker statements made during the program, and Forest representative activities during the program to assess whether the programs were conducted in a manner consistent with Forest's Policies and Procedures. Forest shall maintain the controls around speaker programs as described above, and shall conduct its Speaker Program Audits as described above throughout the term of the CIA.

2. *Observations.* As a component of the FFMP, Forest Compliance personnel or other appropriately trained Forest personnel who are not currently working in the marketing or field sales organization shall conduct direct field observations (Observations) of sales representatives to assess whether the messages delivered and materials distributed to HCPs are consistent with Forest's Policies and Procedures. These Observations shall be full day ride-alongs with sales representatives, and each Observation shall consist of directly observing all meetings between a sales representative and HCPs and other representatives of HCIs during the workday. The Observations shall be scheduled throughout the year, randomly selected by Forest Compliance personnel and other appropriately trained Forest personnel as described above, include each therapeutic area and actively promoted Government Reimbursed Product, and be conducted across the United States. At the completion of each Observation, the employee responsible for conducting the Observation shall prepare a report (Observation Report) which includes:

- 1) the identity of the sales representative;
- 2) the identity of the Forest Compliance professional or other Forest personnel who conducted the Observation;
- 3) the date and duration of the Observation;
- 4) the product(s) promoted during the Observation;
- 5) an overall assessment of compliance with Forest policy;
- 6) the identification of any potential off-label promotional activity by the sales representative; and
- 7) the action(s) taken by Forest to address any identified issues.

Forest Compliance personnel or other appropriately trained Forest personnel who are not currently working in the marketing or field sales organization shall conduct at least 40 full-day Observations during each Reporting Period. The number of Observations conducted for each therapeutic area and product shall be proportional in number to the size of each therapeutic area and product, and shall be conducted across the United States.

3. *Records Reviews.* As a component of the FFMP, Forest shall review various types of records to assess sales representatives' interactions with HCPs and HCIs and to identify potential or actual compliance or legal violations. For each Reporting Period, Forest shall develop and implement a plan for conducting Records Reviews associated with at least three Government Reimbursed Products. The OIG shall have the discretion to identify the three Government Reimbursed Products to be reviewed for each Reporting Period. The OIG will select the products based on information about Forest's products provided by Forest, upon request by the OIG, no later than 60 days prior to the beginning of the Reporting Period and other information known to the OIG. If the OIG does not identify the Government Reimbursed Products to be reviewed during a given Reporting Period, Forest shall select the three products to be reviewed. The Records Reviews shall include a review of records relating to the activities of a sampling of sales representatives in each region who promoted one or more of the products under review.

These Records Reviews shall include the monitoring and review of selected: 1) records and systems relating to sales representatives' interactions with HCPs and HCIs relating to promotional speaker program activities, samples, meals, and other events or items (including records from the electronic detailing system (such as call notes) for the particular sales representative, sales communications from managers, and expense reports); 2) requests for medical information through the MIC Department; 3)

preceptorships; 4) message recall studies or other similar records (such as Verbatims) purporting to reflect the details of sales representatives' interactions with HCPs and HCIs; 5) sales representatives' e-mails and other electronic records; and 6) recorded results of the Observations, if any, of the sales representatives and applicable notes or information from the sales representatives' managers.

4. *Reporting and Follow-up.* Personnel conducting the Speaker Program Audits, Observations, and Records Reviews shall have access to all relevant records and information necessary to assess Forest's interactions with HCPs and HCIs and to identify potential or actual compliance violations. Results from FFMP audits, including the identification of potential violations of policies and/or legal requirements, shall be compiled and reported to the Compliance Officer for review and follow up as appropriate. In the event that a potential violation of Forest's Policies and Procedures and/or of legal or compliance requirements, including but not limited to potential off-label promotion, is identified during any aspect of the FFMP, Forest shall investigate the incident consistent with established Policies and Procedures for the handling of investigations and shall take all necessary and appropriate responsive action (including disciplinary action) and corrective action, including the disclosure of Reportable Events pursuant to Section III.H above, if applicable. Any compliance issues identified during a Speaker Program Audit, Observation and/or Records Review and any corrective action shall be recorded in the files of the Compliance Department.

Forest shall include a summary of the FFMP and the results of the FFMP as part of each Annual Report. As part of each Annual Report, Forest also shall provide the OIG with copies of the Observation Report for any instances in which it was determined that improper promotion occurred and a description of the action(s) that Forest took as a result of such determinations. Forest shall make the Observation Reports for all other Observations available to the OIG upon request.

K. Monitoring of Non-Promotional Activities.

To the extent not already accomplished, within 120 days after the Effective Date Forest shall develop and implement a monitoring program for the following types of activities: 1) consultant arrangement activities; 2) research-related activities; 3) publication activities; and 4) medical education grants. This monitoring program shall be referred to as the Non-Promotional Monitoring Program.

1. *Consultant Arrangement Activities.* To the extent that Forest engages U.S.-based HCPs or HCIs for services that relate to Promotional and Product Related Functions other than for speaker programs, research-related activities, or publication activities (e.g., as a member of an advisory board or to attend consultant meetings), such HCPs or HCIs shall be referred to herein as Consultants. Forest shall require all Consultants to enter written agreements describing the scope of work to be performed, the fees to be paid, and compliance obligations for the Consultants. Consultants shall be paid according to a centrally managed, rate structure which incorporates appropriate objective criteria and is determined based on a fair-market value analysis conducted by Forest.

To the extent not already accomplished, within 120 days after the Effective Date, Forest shall establish a process to develop annual budgeting plans that identify the business needs for, and the estimated numbers of, various Consultant engagements and activities to occur during the following year. The annual Consultant budgeting plans shall also identify the budgeted amounts to be spent on Consultant-related activities. Forest's Compliance personnel shall be involved in the review and approval of such budgeting plans, including any subsequent modification of an approved plan. The purpose of this review shall be to ensure that Consultant arrangements and related events are used for legitimate purposes in accordance with applicable Forest Policies and Procedures.

To the extent not already accomplished, within 120 days after the Effective Date, Forest shall establish a process to ensure that a needs assessment has been completed to justify the retention of a Consultant prior to the retention of the Consultant. The needs assessment shall identify the business need for the retention of the Consultant and provide specific details about the consulting arrangement (e.g., information about the numbers and qualifications of the HCPs or HCIs to be engaged, the agenda for the proposed meeting, and a description of the proposed work to be done and type of work product to be generated.) Any deviations from the Consultant budgeting plans shall be documented in the needs assessment form and shall be subject to review and approval by Forest Compliance personnel.

To the extent not already accomplished, within 120 days after the Effective Date, Forest shall amend its policies and procedures in a manner designed to ensure that each Consultant performs the work for which the Consultant is engaged and that, as applicable, Forest receives the work product generated by the Consultant.

Within 120 days after the Effective Date, Forest shall establish a Consultant Monitoring Program through which it shall conduct audits for each Reporting Period

(Consultant Program Audits) of at least 30 Consultant arrangements with HCPs. The Consultant Program Observations shall include live monitoring of at least 10 advisory board programs and monitoring of 20 other professional services agreements with HCPs. The Consultant Monitoring Program shall review Consultant arrangements both on a risk-based targeting approach and on a sampling approach. Forest personnel conducting the Consultant Program Audits shall review needs assessment documents, consultant contracts, and materials relating to the program or work of the Consultant (including work product resulting from any program or event), in order to assess whether the programs and arrangements were conducted in a manner consistent with Forest's Policies and Procedures. Results from the Consultant Program Audits, including the identification of potential violations of policies, shall be compiled and reported to the Compliance Department for review and follow-up as appropriate.

2. *Research-Related Activities.* To the extent that Forest engages or provides funding or other support to U.S.-based HCPs or HCIs to conduct Phase IV post-marketing clinical studies on Government Reimbursed Products, including, but not limited to, IITs, such HCPs and HCIs shall be referred to collectively as "Researchers." Forest shall require all Researchers to enter written agreements describing the scope of the clinical research or other work to be performed, the fees to be paid, and compliance obligations for the Researchers. Researchers shall be paid based on a fair-market value analysis conducted by Forest. This fair-market analysis shall be incorporated into guidelines that are used in the review, approval, and funding of Researchers' activities.

To the extent not already accomplished, within 120 days after the Effective Date, Forest shall establish an annual budgeting plan for Researchers that identifies the business and/or scientific need for, and the estimated numbers of, the various Researcher engagements and activities to occur during the year. The annual Researcher budgeting plan shall also identify the budgeted amounts to be spent on Researcher-related activities during the year. Forest Compliance personnel shall be involved in the review and approval of such budgeting plans, including any subsequent modification of an approved plan. The purpose of this review shall be to ensure that Research arrangements and related events are used for legitimate purposes in accordance with Forest Policies and Procedures.

To the extent not already accomplished, within 120 days after the Effective Date, Forest shall establish a process to ensure that a needs assessment has been completed to justify the retention of the Researcher prior to the retention of or the provision of funding or other support to the Researcher. The needs assessment shall identify the business

and/or scientific need for the information to be provided by the Researcher and provide specific details about the research arrangement (including, for example, information about the numbers and qualifications of the HCPs or HCIs to be engaged, a description of the proposed research to be done (including the research protocol) and type of work product to be generated). Any deviations from the Researcher budgeting plans shall be documented in the needs assessment form (or elsewhere, as appropriate) and shall be subject to review and approval by Forest Compliance personnel.

To the extent not already accomplished, within 120 days after the Effective Date, Forest shall amend its policies and procedures in a manner designed to ensure that each Researcher performs the work for which the Researcher is engaged.

Within 120 days after the Effective Date, Forest shall establish a Researcher Monitoring Program through which it shall conduct audits for each Reporting Period (Researcher Program Audits) of at least 30 Researcher arrangements with HCPs or HCIs. The Researcher Program Audits shall review at least 20 IITs and at least 10 other post-marketing Researcher arrangements. The Researcher Monitoring Program shall review Researcher arrangements both on a risk-based targeting approach and on a sampling approach. Forest personnel conducting the Researcher Program Audits shall review needs assessment documents, proposal and/or protocol documents, approval documents, contracts, and payments in order to assess whether the programs and arrangements were supported by Forest and performed by the Researchers in a manner consistent with Forest's Policies and Procedures. Results from the Researcher Program Audits, including identification of potential violations of policies, shall be compiled and reported to the Compliance Department for review and follow-up as appropriate.

3. *Publication Activities.* To the extent that Forest engages U.S.-based HCPs or HCIs to produce articles or other publications relating to Government Reimbursed Products (collectively "Publication Activities") such HCPs or HCIs shall be referred to as Authors. Forest shall require all Authors to enter written agreements describing the scope of work to be performed, any fees to be paid in connection with the Publication Activities, and compliance obligations of the Authors. Authors shall be paid according to a centrally managed rate structure which incorporates appropriate objective criteria and is determined based on a fair-market value analysis conducted by Forest.

To the extent not already accomplished, within 120 days after the Effective Date, Forest shall establish a process to develop annual plans that identify the business needs for and the estimated numbers of various Publication Activities (Publication Plans). The

annual Publication Plan shall also identify the budgeted amounts to be spent on Publication Activities. Forest's Compliance personnel shall be involved in the review and approval of such annual Publication Plans, including any modification of an approved plan. The purpose of this review shall be to ensure that Publication Activities and related events are used for legitimate purposes in accordance with Forest Policies and Procedures.

To the extent not already accomplished, within 120 days after the Effective Date, Forest shall establish a needs assessment process for Publication Activities. This process shall ensure that a needs assessment has been completed prior to the retention of an Author for a Publication Activity. The needs assessment shall provide specific details about Publication Activities to be performed (including a description of the proposed work to be done, type of work product to be generated, and the purpose for the work.) Any deviations from the Publication Plan shall be documented in the needs assessment form (or elsewhere, as appropriate) and shall be subject to review and approval by Forest Compliance personnel.

Within 120 days after the Effective Date, Forest shall establish a Publication Monitoring Program through which it shall conduct audits for each Reporting Period of at least 30 Publication Activities. The Publication Monitoring Program shall select publications for review both on a risk-based targeting approach and on a sampling approach. Personnel conducting the Publication Monitoring Program shall review needs assessment documents, proposal documents, approval documents, contracts, payments and materials relating to the Publication Activities (including work product resulting from the Activities), in order to assess whether the activities were conducted in a manner consistent with Forest's Policies and Procedures. Results from the Publication Monitoring Programs, including the identification of potential violations of policies, shall be compiled and reported to the Compliance Department for review and follow-up as appropriate.

4. *Industry Support Activities.* Forest represents that it has established an office within its Compliance Department as the exclusive mechanism through which requestors may seek or be awarded industry support, including grants for independent medical education activities, sponsorships, funding for awareness and advocacy programs and other industry support. Forest represents that its Sales and Marketing departments have no involvement in, or influence over, the review and approval of medical education grants. All funding requests for industry support are submitted through an on-line process (known as FRXIS) and requests are processed in accordance with standardized criteria

developed by the Medical Affairs Department. Forest shall continue the FRXIS process described above (or an equivalent process) throughout the term of the CIA, and shall notify the OIG in writing at least 60 days prior to the implementation of any new system subsequent to the Effective Date.

To the extent not already accomplished, within 120 days after the Effective Date, Forest shall establish a Grant Monitoring Program through which it shall conduct audits for each Reporting Period of at least 30 medical education grants and other types of industry support. The Grant Monitoring Program shall select grants and other industry support for review both on a risk-based targeting approach and on a sampling approach. The Grant Monitoring Program shall review medical education grants, sponsorships, advocacy/awareness grants and other support on a pro rata basis according to the number of such programs. Forest personnel conducting the Grant Monitoring Program shall review proposal documents (including grant requests), approval documents, contracts, payments and materials relating to the review of the requests, and documents and materials relating to the grants and any events or activities funded through the grants in order to assess whether the activities were conducted in a manner consistent with Forest's Policies and Procedures. Results from the Grant Monitoring Program, including the identification of potential violations of policies, shall be compiled and reported to the Compliance Department for review and follow-up as appropriate.

*5. Follow Up Reviews and Reporting.* In the event that a potential violation of Forest's Policies and Procedures or of legal or compliance requirements, including but not limited to potential off-label promotion, are identified during any aspect of the Non-Promotional Monitoring Program, Forest shall investigate the incident consistent with established Policies and Procedures for the handling of investigations and shall take all necessary and appropriate responsive action (including disciplinary action) and corrective action, including the disclosure of Reportable Events pursuant to Section III.H above, if applicable. Any compliance issues identified during any Non-Promotional Monitoring Program referenced above, and any corrective action, shall be recorded in the files of the Compliance Department.

Forest shall include a summary of the Non-Promotional Monitoring Program and the results of the Non-Promotional Monitoring Program as part of each Annual Report. As part of each Annual Report, Forest also shall provide the OIG with descriptions of any instances identified through the Non-Promotional Monitoring Program in which it was determined that improper promotion of Government Reimbursed Products occurred or the activities violated Forest's requirements or Policies and Procedures, and a description of

the action(s) that Forest took as a result of such determinations. Forest shall make the documents relating to the Non-Promotional Monitoring Program available to the OIG upon request.

L. Notice to Health Care Providers and Entities

Within 90 days after the Effective Date, Forest shall send, by first class mail, postage prepaid and return receipt requested, a notice containing the language set forth below to all HCPs and HCIs upon which Forest currently calls. This notice shall be dated and shall be signed by Forest's President. The body of the letter shall state the following:

As you may be aware, Forest Laboratories, Inc., (Forest) recently entered into a global civil, criminal, and administrative settlement with the United States and individual states in connection with the promotion and distribution of certain of its products.

This letter provides you with additional information about the settlement, explains Forest's commitments going forward, and provides you with access to information about those commitments. In general terms, the Government alleged that Forest improperly promoted the drugs Celexa and Lexapro between 1998 and 2005, including by promoting the drugs for a use not approved by the Food & Drug Administration (FDA), and that Forest improperly distributed a formulation of the drug Levothroid between 2001 and 2003 which is no longer marketed. To resolve the matters related to Celexa and Levothroid, Forest Pharmaceuticals, Inc., a subsidiary of Forest, agreed, among other things, to plead guilty to two misdemeanor criminal violations of the Federal Food, Drug & Cosmetic Act (FDCA) and to a felony charge of obstruction of a government agency proceeding. Forest did not admit any wrongful conduct related to Lexapro. Forest agreed to pay a total of \$313 million to the Federal Government and State Medicaid programs as part of the overall resolution of these matters. More information about this settlement may be found at the following: **[Forest shall include a link to the USAO, OCL, and Forest websites in the letter.]**

As part of the federal settlement, Forest also entered into a five-year corporate integrity agreement with the Office of Inspector General of the U.S. Department of Health and Human Services. The corporate integrity

agreement is available at <http://oig.hhs.gov/fraud/cia/index.html>. Under this agreement, Forest agreed to undertake certain obligations designed to promote compliance with Federal health care program and FDA requirements. We also agreed to notify healthcare providers about the settlement and inform them that they can report any questionable practices by Forest's representatives to Forest's Compliance Department or the FDA.

Please email Forest at **xxxxxx@frx.com** if you have questions about the settlement referenced above or to report any instances in which you believe that a Forest representative inappropriately promoted a product or engaged in other questionable conduct. Alternatively, you may report any such instances to the FDA's Division of Drug Marketing, Advertising, and Communications at 301-796-1200. You should direct medical questions or concerns about our products to **[insert a contact number]**.

We appreciate your time and attention. Forest is dedicated to ensuring that it brings you the scientific and medical information you need to make well-informed decisions about the use of Forest products for your patients.

The Compliance Officer (or a designee) shall maintain a log of all calls and messages received in response to the notice. The log shall include a record and summary of each call and message received (whether anonymous or not), the status of the call or message, and any corrective action taken in response to the call or message, if applicable. The disclosure log shall be made available to OIG upon request. As part of the Implementation Report and each Annual Report, Forest shall provide to the OIG a summary of the calls and messages received.

#### M. Reporting of Physician Payments

##### 1. Posting of Payment Information

Phase I Reporting: By January 1, 2011, Forest shall post in a prominent position on its website an easily accessible and readily searchable listing of all U.S.-based physicians and Related Entities (as defined below in Section III.M.2) who or which received any Phase I Payments (as defined below in Section III.M.2) directly or indirectly from Forest during the first three calendar quarters of 2010.

After the initial posting, 60 days after the end of each subsequent calendar quarter, Forest shall also post on its website a listing of updated information about all Phase I Payments made during the preceding calendar quarter. Thereafter, no later than March 1 of each calendar year, Forest shall also post on its website a report of the cumulative value of Phase I Payments provided to each physician and/or Related Entity during the preceding calendar year. The commencement of Phase II reporting will terminate the obligations of Phase I reporting.

**Phase II Reporting:** By May 1, 2012, Forest shall post in a prominent position on its website an easily accessible and readily searchable listing of all physicians and Related entities who or which received any Phase II Payments (as defined below in Section III.M.2) directly or indirectly from Forest during the first calendar quarter of 2012 and the aggregate value of such Payments. Thereafter, 60 days following the end of each calendar quarter, Forest shall also post on its website a listing of updated information about all Phase II Payments made during the preceding calendar quarter and the aggregate value of such Payments. No later than March 1, 2013, Forest shall also post on its website a report of the cumulative value of Phase II Payments provided to each physician and/or Related Entity during the preceding calendar year. Thereafter, on or before March 1 of each subsequent year, Forest shall post a report on the cumulative value of Phase II Payments provided to each physician and/or Related Entity during the preceding calendar year.

Each listing made pursuant to this Section III.M shall include a complete list of all individual physicians and Related Entities to whom or to which Forest directly or indirectly made Payments in the preceding calendar quarter(s) or year (as applicable). Each listing shall be arranged alphabetically according to the physicians' last name or the name of the Related Entity. The Payment amounts in the lists shall be reported in \$10,000 increments (*e.g.*, \$0 - \$10,000; \$10,001- \$20,000; *etc.*) or in the actual amount paid, provided, however, that the Payment amounts shall be listed in the same way (incrementally or in actual amounts) for all physicians and/or Related Entities on the listing. For each physician, the applicable listing shall include the following information: i) physician's full name; ii) name of Related Entity (if applicable); iii) city and state of the physician's practice or the Related Entity; iv) the purpose of the payment(s); and (v) the aggregate value of the payment(s) in the preceding quarter(s) or year (as applicable). Each quarterly and annual listing shall be easily accessible and readily searchable. If payments for multiple physicians have been made to one Related Entity, the aggregate value of all payments to the Related Entity will be the reported amount.

## 2. Definitions and Miscellaneous Provisions

Forest shall continue to make each annual listing and the most recent quarterly listing of Payment information available on its website at least throughout the term of this CIA. Forest shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and records related to all applicable Payments and to the annual and quarterly listings of Payments. Nothing in this Section III.M affects the responsibility of Forest to comply with (or liability for noncompliance with) all applicable Federal health care program requirements and state laws as they relate to all applicable Payments made to physicians or Related Entities.

For purposes of this Section III.M, the term “Phase I Payments” is defined to include all payments or transfers of value (whether in cash or in kind) made to physicians and/or to Related Entities in connection with medical education grants, awareness and advocacy initiatives, sponsorships, and contributions or general support of an organization.

For purposes of this Section III.M, the term “Phase II Payments” includes all Phase I Payments (as defined above) and all other “payments or transfers of value” as that term is defined in § 1128G(e)(10) under Section 6002 of the Patient Protection and Affordable Care Act (Public Law 111-148) (Affordable Care Act) and any regulations promulgated thereunder. The term Payments includes, by way of example, the types of payments or transfers of value enumerated in § 1128G(a)(1)(A)(vi) of the Affordable Care Act. The term Payments includes any payments or transfers of value made, directly by Forest or by a vendor retained by Forest to a physician or Related Entity in connection with, or under the auspices of, a co-promotion arrangement.

For purposes of its website posting of the quarterly and annual listings of Payments, and with regard only to payments made pursuant to product research or development agreements and clinical investigations as set forth in § 1128G(c)(E) of the Affordable Care Act, Forest may delay the inclusion of such payments on its website listing consistent with § 1128G(c)(E) of the Act and any subsequent regulations promulgated thereunder.

For purposes of this Section III.M, the term “Payment” as used in the definition of Phase I Payments and Phase II Payments does not include transfers of anything of value or other items that are not included in the definition of “Payment” or are excluded from

the definition of “Payment” by § 1128G(e)(1) under Section 6002 of the Act and any subsequent regulations promulgated thereunder.

For purposes of this Section III.M, the term “Related Entity” is defined to be any entity by or in which any physician receiving Payments is employed, has tenure, or has an ownership interest. Payments or transfers of value to Related Entities consist of those payments or transfers of value made to Related Entities on behalf of, at the request of, for the benefit or use of, or under the name of a physician for whom Forest would otherwise report a Payment if made directly to the physician.

N. Other Transparency/Disclosure Initiatives.

By January 1, 2011, Forest shall post on its company website the following information with respect to medical education grants and other industry support: 1) the recipient organization’s name; 2) a brief description of the program for which the grant or contribution was requested; and 3) the amount of the grant or contribution. After the initial posting, Forest shall continue to post (and provide updates to) the above-described information about grants and contribution on a quarterly basis throughout the term of this CIA. Forest shall notify the OIG in writing at least 60 days prior to any change in the substance of its policies regarding the funding of grants and contributions or posting of the above-referenced information relating to such funding.

Forest represents that it requires all Consultants to fully comply with all applicable disclosure obligations relating to their relationship with Forest that may be externally imposed on the Consultants based on their affiliation with formulary or P&T committees or committees associated with the development of treatment protocols or standards. Forest shall continue this requirement throughout the term of this CIA. Within 120 days after the Effective Date, Forest shall amend its policies relating to Consultants to explicitly state Forest’ requirement about full disclosure by Consultants consistent with the requirements of any HCI, medical committee, or other medical or scientific organization with which the Consultants are affiliated. In addition, for any amendment to its contracts with Consultants and in any new contracts with Consultants entered into after 120 days following the Effective Date, Forest shall include an explicit requirement that the Consultants fully comply with applicable disclosure requirements and disclose their relationship with Forest as required pursuant to their affiliation with any HCI, medical committee, or other medical or scientific organization.

Forest represents that it expects all Authors of biomedical manuscripts to fully comply with the International Committee of Medical Journal Editors (ICMJE) criteria regarding authorship and disclosure of their relationship with Forest and to disclose any potential conflicts of interest, including any financial or personal relationships that might be perceived to bias their work. Within 120 days after the Effective Date, Forest shall amend its policies relating to Authors to explicitly state Forest' requirement about full disclosure by Authors consistent with the requirements of any HCI, medical committee or other medical or scientific organization with which the Authors are affiliated. In addition, for any amendments to its contracts with Authors and in any new contracts with Authors entered into after 120 days following the Effective Date, Forest shall include an explicit requirement that Authors disclose in their manuscripts, journal submissions, and elsewhere as appropriate or required, any potential conflicts of interest, including their financial or personal relationship with Forest, the names of any individuals who have provided editorial support for any manuscript or other publication, and all funding sources for the study or publication.

Forest represents that it registers and reports the results of all Forest-sponsored clinical studies as required by applicable regulations on the National Institutes of Health (NIH) sponsored website ([www.clinicaltrials.gov](http://www.clinicaltrials.gov)). Forest shall continue to comply with applicable regulations relating to the posting of clinical study information throughout the term of this CIA. In addition, if there is a change in Federal health care program requirements, FDA requirements, or other applicable requirements relating to the reporting of clinical study information, Forest shall fully comply with such requirements.

Forest shall post information on its company website about postmarketing commitments (PMCs). The Forest website will provide access to general information about the PMC process, including study descriptions and information about the nature and status of FDA PMCs. Forest shall continue to post the above-described information about PMCs on its website throughout the term of this CIA.

#### **IV. CHANGES TO BUSINESS UNITS OR LOCATIONS**

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, Forest changes the location of or closes a business unit or location related to Promotional and Product Related Functions or Regulatory Related Functions, Forest shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change or closure of the location.

B. Purchase or Establishment of New Unit or Location. In the event that, after the Effective Date, Forest purchases or establishes a new business unit or location related to Promotional and Product Related Functions or Regulatory Related Functions, Forest shall notify OIG no later than five days after the date that the purchase or establishment is publicly disclosed by Forest. This notification shall include the address of the new business unit or location, phone number, fax number, Federal health care program provider or supplier number (if applicable), and the name and address of the contractor that issued each number (if applicable). Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements of this CIA.

C. Sale of Unit or Location. In the event that, after the Effective Date, Forest proposes to sell any or all of its business units or locations related to the Promotional and Product Services-Related Functions or Regulatory Related Functions, Forest shall notify OIG of the proposed sale no later than five days after the date the sale is publicly disclosed by Forest. This notification shall include a description of the business unit or location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of such business unit or location, unless otherwise determined and agreed to in writing by the OIG.

## V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the Effective Date, Forest shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A.1, and a summary of any job responsibilities unrelated to compliance that the Compliance Officer may have;
2. the names and positions of the members of the Compliance Committee required by Section III.A.2;
3. the names of the members of the Board of Directors referenced in Section III.A.3;

4. the names and positions of the Certifying Employees required by Section III.A.4;

5. a copy of Forest's Code of Conduct required by Section III.B.1;

6. the number of Covered Persons required to complete the Code of Conduct certification required by Section III.B.1, the percentage of Covered Persons who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

7. (a) a copy of the letter (including all attachments) required by Sections II.C.7 and III.B.2 sent to each party employing Third Party Personnel; (b) a list of all such existing agreements; and (c) a description of the entities' response to Forest's letter;

8. a summary of all Policies and Procedures required by Section III.B.3 (a copy of such Policies and Procedures shall be made available to the OIG upon request);

9. the following information regarding each type of training required by Section III.C:

a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

b. the number of Covered Persons required to be trained, percentage of Covered Persons actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request;

10. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; and (c) a summary and description of any and all current and prior engagements and agreements between Forest and the IRO;

11. a certification from the IRO regarding its professional independence and objectivity with respect to Forest;
12. a description of the Disclosure Program required by Section III.E;
13. a description of the process by which Forest fulfills the requirements of Section III.F regarding Ineligible Persons;
14. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken in response to the screening and removal obligations set forth in Section III.F;
15. a certification by the Compliance Officer that the notice required by Section III.L was mailed to each HCP and HCI, the number of HCPs and HCIs that received a copy of the notice, a sample copy of the notice required by Section III.L, and a summary of the calls or messages received in response to the notice;
16. if applicable, a certification from the Compliance Officer that information regarding Payments has been posted on Forest's website as required by Section III.M;
17. a list of all of Forest's locations (including locations and mailing addresses) at which it performs Promotional and Product Related Functions or Regulatory Related Functions; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal health care program provider or supplier number(s) (if applicable), and the name and address of each Federal health care program contractor to which Forest currently submits claims (if applicable);
18. a description of Forest's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and
19. the certifications required by Section V.C.

B. Annual Reports. Forest shall submit to OIG annually a report with respect to the status of, and findings regarding, Forest's compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. an explanation of any change in the identity, position description, or other job responsibilities unrelated to compliance of the Compliance Officer and any change in the membership of the Compliance Committee, the Board of Directors, or the group of Certifying Employees described in Sections III.A.2-4;
2. the following information regarding the Compliance Expert: (a) identity, address, and phone number; (b) a copy of the engagement letter; and (c) a summary and description of any and all current and prior engagements and agreements between Forest and the Compliance Expert;
3. a complete copy of the Compliance Review Report (including the certification from the Compliance Expert regarding its professional independence and objectivity with respect to Forest);
4. a copy of the Board of Directors' resolution required by Section III.A.3;
5. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B.3 and the reasons for such changes (e.g., change in applicable requirements);
6. the number of Covered Persons required to complete the Code of Conduct certification required by Section III.B.1, the percentage of Covered Persons who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
7. (a) a copy of the letter (including all attachments) required by Sections II.C.7 and III.B.2 sent to each entity employing Third Party Personnel; (b) a list of all such existing agreements; and (c) a description of the entities' response to Forest's letter;
8. the following information regarding each type of training required by Section III.C:
  - a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

b. the number of Covered Persons required to be trained, percentage of Covered Persons actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

9. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter (if different from what was submitted as part of the Implementation Report);

10. Forest's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.D;

11. a summary and description of any and all current and prior engagements and agreements between Forest and the IRO, if different from what was submitted as part of the Implementation Report;

12. a certification from the IRO regarding its professional independence and objectivity with respect to Forest;

13. a summary of the disclosures in the disclosure log required by Section III.E that relate to Federal health care programs or to FDA requirements;

14. any changes to the process by which Forest fulfills the requirements of Section III.F regarding Ineligible Persons;

15. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken by Forest in response to the screening and removal obligations set forth in Section III.F;

16. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

17. a summary of Reportable Events (as defined in Section III.H) identified during the Reporting Period and the status of any corrective and preventative action

relating to all such Reportable Events;

18. a summary describing any written communication with the FDA required to have been reported pursuant to Section III.I. This summary shall include a description of the matter and the status of the matter;

19. a summary of the FFMP and the results of the FFMP required by Section III.J, including copies of the Observation Report for any instances in which it was determined that improper promotion occurred and a description of the action(s) that Forest took as a result of such determinations;

20. a summary of the Non-Promotional Monitoring Program and the results of the program described in Section III.K, including detailed description of any identified instances in which it was determined that the activities reviewed violated Forest' policies or that improper promotion of Government Reimbursed Products occurred and a description of the action(s) Forest took as a result of such determinations;

21. a summary of the calls and messages received in response to the notice required by Section III.L and the disposition of those calls and messages;

22. a certification from the Compliance Officer that information regarding Payments has been posted on Forest's website as required by Section III.M;

23. a description of all changes to the most recently provided list of Forest's locations (including addresses) as required by Section V.A.17; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal health care program provider or supplier number(s) (if applicable), and the name and address of each Federal health care program contractor to which Forest currently submits claims (if applicable);

24. a listing of all Forest's Government Reimbursed Products; a listing of all Government Reimbursed Products for which the FDA determined that the products were "new drugs" or for which the FDA changed the status or classification of the product during the Reporting Period; and a description of the change and the effective date of the change; and

25. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications. The following certifications shall be included in the Implementation Report and Annual Reports:

1. Certifying Employees: In each Annual Report, Forest shall include the certifications of Certifying Employees as required by Section III.A.4;

2. Compliance Officer: In the Implementation Report and Annual Reports, Forest shall include the following individual certification by the Compliance Officer:

a. he or she has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information in the Report is accurate and truthful;

b. to the best of his or her knowledge, except as otherwise described in the applicable report, Forest is in compliance with the Federal health care program and FDA requirements and the obligations of the CIA;

c. to the best of his or her knowledge, Forest has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs;

d. Forest's: 1) Policies and Procedures as referenced in Section III.B.3 above; 2) templates for standardized contracts and other similar documents; and 3) the training materials used for purposes of Section III.C all have been reviewed by competent legal counsel and/or legal personnel working at their direction and have been found to be in compliance with all applicable Federal health care program and FDA requirements. In addition, Forest's promotional materials containing claims or information about Government Reimbursed Products and other materials and information intended to be disseminated outside Forest have been reviewed by competent regulatory, medical, and/or legal personnel in accordance with applicable Policies and Procedures to

ensure that legal, medical, and regulatory concerns are properly addressed and are elevated when appropriate, and that the materials and information when finally approved are in compliance with all applicable Federal health care program and FDA requirements. If the applicable legal requirements have not changed, after the initial review of the documents listed above, only material changes to the documents must be reviewed by competent regulatory, medical, and/or legal personnel. The certification shall include a description of the document(s) reviewed and approximately when the review was completed. The documentation supporting this certification shall be available to OIG, upon request;

e. Forest's call panels for Government Reimbursed Products were reviewed at least once during the Reporting Period (consistent with Section III.B.3.i) and, for each product, the call panels were found to be consistent with Forest's policy objectives as referenced above in Section III.B.3.i;

f. Forest: i) conducted a review of the FDA status and classification (e.g., new drug, lacking substantial evidence of effectiveness, etc.) of each of its Government Reimbursed Products; ii) conducted a review of the product information (including the status as a covered outpatient drug and all product codes or classifications) reported to CMS for each of its Government Reimbursed Products for purposes of the Medicaid Drug Rebate Program and the Medicare program; and iii) determined that the product information reported to CMS during the Reporting Period is true, accurate, and complete;

g. Forest complied with all FDA requirements and guidance (collectively "requirements") relating to any change in the status or classification of a Forest Government Reimbursed Product during the Reporting Period (including a determination that a product is a new drug or lacks evidence of effectiveness), including all reporting requirements and all requirements relating to the tracking or distribution of the product; and

h. Forest complied with all Federal health care program requirements relating to the tracking, collection, verification, reporting, and updating of product or product-related information in connection with any change in the status or classification of a Government Reimbursed Product during the Reporting Period, including, but not limited to, reporting obligations relating to product or product-related information for purposes of the Medicaid Drug Rebate Program and the Medicare program.

D. Designation of Information. Forest shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Forest shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

## **VI. NOTIFICATIONS AND SUBMISSION OF REPORTS**

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG: Administrative and Civil Remedies Branch  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services  
Cohen Building, Room 5527  
330 Independence Avenue, S.W.  
Washington, DC 20201  
Telephone: 202.619.2078  
Facsimile: 202.205.0604

Forest: Chief of Compliance  
Forest Laboratories, Inc.  
909 Third Avenue  
New York, NY 10022  
Telephone: 212.224.6786  
Facsimile: 212.504.3065

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that any such means provides proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by OIG, Forest may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), either instead of or in addition to a paper copy.

## **VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS**

Corporate Integrity Agreement  
Forest Laboratories, Inc.

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Forest's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Forest's locations for the purpose of verifying and evaluating: (a) Forest's compliance with the terms of this CIA; and (b) Forest's compliance with the requirements of the Federal health care programs in which it participates and with all applicable FDA requirements. The documentation described above shall be made available by Forest to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Forest's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Forest shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Forest's employees may elect to be interviewed with or without a representative of Forest present.

#### **VIII. DOCUMENT AND RECORD RETENTION**

Forest shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for six years (or longer if otherwise required by law) from the Effective Date.

#### **IX. DISCLOSURES**

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Forest prior to any release by OIG of information submitted by Forest pursuant to its obligations under this CIA and identified upon submission by Forest as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Forest shall have the rights set forth at 45 C.F.R. § 5.65(d).

## **X. BREACH AND DEFAULT PROVISIONS**

Forest is expected to fully and timely comply with all of its CIA obligations. The breach and default remedies available to the OIG under this Section X do not preempt or limit any actions that individual States may take against Forest under applicable legal authorities or under any applicable settlement agreement or consent decree between the State and Forest.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Forest and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as “Stipulated Penalties”) in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Forest fails to establish, implement, or accomplish any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. a resolution from the Board of Directors;
- d. a written Code of Conduct;
- e. written Policies and Procedures;
- f. the training of Covered Persons, Relevant Covered Persons, and Board Members;
- g. a Disclosure Program;
- h. Ineligible Persons screening and removal requirements;
- i. notification of Government investigations or legal proceedings;
- j. reporting of Reportable Events;

- k. notification of written communications with FDA;
- j. a Field Force Monitoring Program as required by III.J;
- k. a Non-Promotional Monitoring Program as required by III.K;
- k. notification of HCPs and HCIs as required by Section III.L; and
- l. posting of any Payments as required by Section III.M.

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Forest fails to engage a Compliance Expert as required in Section III.A.3 or an IRO as required in Section III.D and Appendices A-B.

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Forest fails to submit the Implementation Report or the Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Forest fails to submit the annual IRO Review Report(s) in accordance with the requirements of Section III.D and Appendices A-B.

5. A Stipulated Penalty of \$1,500 for each day Forest fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Forest fails to grant access.)

6. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Forest as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of \$1,000 for each day Forest fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Forest, stating the specific grounds for its determination that Forest has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Forest shall take to comply with

the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Forest receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-6 of this Section.

B. Timely Written Requests for Extensions. Forest may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Forest fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Forest receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter*. Upon a finding that Forest has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Forest of: (a) Forest's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter*. Within 10 days after the receipt of the Demand Letter, Forest shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Forest elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Forest cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment*. Payment of the Stipulated Penalties shall be made by

electronic funds transfer to an account specified by OIG in the Demand Letter.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Forest has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

1. *Definition of Material Breach.* A material breach of this CIA means:

- a. a failure by Forest to report a Reportable Event and take corrective action, as required in Section III.H;
- b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C;
- d. a failure to engage and use an IRO in accordance with Section III.D; or
- e. a failure of the Board of Directors to issue a resolution in accordance with Section III.A.3.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Forest constitutes an independent basis for Forest's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Forest has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Forest of: (a) Forest's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* Forest shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's

satisfaction that:

- a. Forest is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Forest has begun to take action to cure the material breach; (ii) Forest is pursuing such action with due diligence; and (iii) Forest has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Forest fails to satisfy the requirements of Section X.D.3, OIG may exclude Forest from participation in the Federal health care programs. OIG shall notify Forest in writing of its determination to exclude Forest (this letter shall be referred to hereinafter as the “Exclusion Letter”). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Forest’s receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Forest may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

#### E. Dispute Resolution

1. *Review Rights.* Upon OIG’s delivery to Forest of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Forest shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG’s determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be

made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Forest was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Forest shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Forest to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Forest requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

- a. whether Forest was in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Forest had begun to take action to cure the material breach within that period; (ii) Forest has pursued and is pursuing such action with due diligence; and (iii) Forest provided to OIG within that period a reasonable timetable for curing the material breach and Forest has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Forest, only after a DAB decision in favor of OIG. Forest's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Forest upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues

such a decision, notwithstanding that Forest may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Forest shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Forest, Forest shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

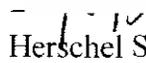
## **XI. EFFECTIVE AND BINDING AGREEMENT**

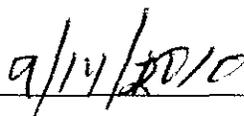
Forest and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns, and transferees of Forest;
- B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;
- C. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA;
- D. The undersigned Forest signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA; and
- E. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF FOREST LABORATORIES, INC.

/Herschel S. Weinstein/

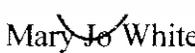
  
Herschel S. Weinstein  
Vice President--General Counsel  
Forest Laboratories, Inc.

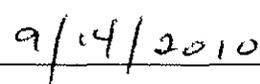
  
Date

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Paul E. Kalb  
Kristin Graham Koehler  
Sidley Austin LLP  
1501 K. Street N.W.  
Washington, D.C. 20005  
Counsel for Forest Laboratories, Inc.

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Date

/Christopher K. Tahbaz/

  
Mary Jo White  
Christopher K. Tahbaz  
Andrew J. Ceresney  
Kristin D. Kiehn  
Debevoise & Plimpton LLP  
919 Third Ave.  
New York, NY 10022  
Counsel for Forest Laboratories, Inc.

  
Date

**ON BEHALF OF FOREST LABORATORIES, INC.**

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Herschel S. Weinstein  
Vice President-General Counsel  
Forest Laboratories, Inc.

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Date

/Kristin Graham Koehler/

~~Paul E. Kaib~~  
Kristin Graham Koehler /  
Sidley Austin LLP  
1501 K. Street N.W.  
Washington, D.C. 20005  
Counsel for Forest Laboratories, Inc.

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9.14.10  
Date

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Mary Jo White  
Christopher K. Tahbaz  
Andrew J. Ceresney  
Kristin D. Kiehn  
Debevoise & Plimpton LLP  
919 Third Ave.  
New York, NY 10022  
Counsel for Forest Laboratories, Inc.

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Date

Corporate Integrity Agreement  
Forest Laboratories, Inc.

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL  
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

/Gregory E. Demske/

9/15/10

DATE

Gregory E. Demske  
Assistant Inspector General for Legal Affairs  
Office of Inspector General  
U. S. Department of Health and Human Services

Corporate Integrity Agreement  
Forest Laboratories, Inc.

## APPENDIX A

### INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.D of the CIA.

#### A. IRO Engagement

Forest shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Forest if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Forest may continue to engage the IRO.

If Forest engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Forest shall submit the information identified in Section V.A.10 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Forest if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Forest may continue to engage the IRO.

#### B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the IRO Review who have expertise in all applicable Federal health care program and FDA requirements relating to Promotional and Product Related Functions and Regulatory Related Functions. The assigned individuals shall also be knowledgeable about the general requirements of the Federal health care program(s) under which Forest products are reimbursed;
2. assign individuals to design and select the samples for the Transaction Reviews who are knowledgeable about the appropriate statistical sampling techniques; and
3. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

#### C. IRO Responsibilities.

The IRO shall:

1. perform each IRO Review in accordance with the specific requirements of the CIA;
2. follow all applicable Federal health care program and FDA requirements in making assessments in each IRO Review;
3. if in doubt of the application of a particular Federal health care program or FDA requirement, policy, or regulation, request clarification from the appropriate authority (e.g., CMS or FDA);
4. respond to all OIG inquiries in a prompt, objective, and factual manner; and
5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. IRO Independence and Objectivity.

The IRO must perform the IRO Review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and Forest .

E. IRO Removal/Termination.

1. *Forest Termination of IRO.* If Forest terminates its IRO during the course of the engagement, Forest must submit a notice explaining its reasons to OIG no later than 30 days after termination. Forest must engage a new IRO in accordance with Paragraph A of this Appendix.

2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and/or objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Forest to engage a new IRO in accordance with Paragraph A of this Appendix.

Prior to requiring Forest to engage a new IRO, OIG shall notify Forest of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Forest may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence or performance of its responsibilities and to present additional information regarding these matters. Forest shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with Forest prior to requiring Forest to terminate the IRO.

However, the final determination as to whether or not to require Forest to engage a new IRO shall be made at the sole discretion of OIG.

## **Appendix B to CIA Promotional and Product Related Review**

### **I. Promotional and Product Related Review, General Description**

As specified more fully below, Forest shall retain an Independent Review Organization (IRO) to perform reviews to assist Forest in assessing and evaluating its systems, processes, policies, procedures, and practices related to Forest's Promotional and Product Related Functions and Regulatory Related Functions ("IRO Review"). The IRO Review shall consist of two components - a systems review ("IRO Systems Review"), and a transactions review ("IRO Transactions Review") as described more fully below. Forest may engage, at its discretion, a single IRO to perform both components of the IRO Review provided that the entity has the necessary expertise and capabilities to perform both.

The IRO shall perform the IRO Systems Review for the first Reporting Period, and, if there are no material changes in Forest's systems, processes, policies, and procedures relating to Promotional and Product Related Functions or Regulatory Related Functions, the IRO shall perform the IRO Systems Review for the fourth Reporting Period. If Forest materially changes its systems, processes, policies, and procedures relating to Promotional and Product Related Functions or Regulatory Related Functions, the IRO shall perform an IRO Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Review for the first and fourth Reporting Periods. The additional IRO Systems Review(s) shall consist of: 1) an identification of the material changes; 2) an assessment of whether other systems, processes, policies, and procedures previously reported did not materially change; and 3) a review of the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the IRO Transactions Review for each Reporting Period of the CIA.

### **II. IRO Systems Review**

#### **A. Description of Reviewed Policies and Procedures**

The IRO Systems Review shall be a review of Forest's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to certain Promotional and Product Related Functions and Regulatory Related Functions. Where practical, Forest personnel may compile documentation, schedule and organize interviews, and undertake other efforts to assist the IRO in performing the Systems Review. The IRO is not required to undertake a de novo review of the information gathered or activities undertaken by Forest pursuant to the preceding sentence.

Specifically, the IRO shall review Forest's systems, processes, policies, and procedures associated with the following (hereafter “Reviewed Policies and Procedures”):

1. Forest's systems, policies, processes, and procedures applicable to the manner in which Forest representatives (including sales representatives, marketing personnel, and/or those in the Medical Information and Communication Department (the “MIC Department”) and the External Scientific Affairs Department (the “ESA Department”)) respond to requests or Inquiries relating to information about the uses of Forest's Government Reimbursed Products (including non-FDA-approved (i.e., off-label) uses) and the dissemination of materials relating to off-label uses of Forest's Government Reimbursed Products. This review includes:

- (a) the manner in which Forest personnel (including sales representatives, marketing personnel, and personnel in the MIC and ESA Departments) handle and respond to requests for information about off-label uses of Forest's Government Reimbursed Products (including tracking the requests and using pre-approved materials for purposes of responding to requests);
- (b) the form and content of information and materials related to Forest's Government Reimbursed Products disseminated to physicians, pharmacists, or other health care professionals (collectively “HCPs”) or health care institutions (HCIs) by Forest;
- (c) Forest's systems, processes, and procedures (including the MIC Inquiries Database) used to track requests for information about off-label uses of Forest's Government Reimbursed Products and responses to those requests;
- (d) the manner in which Forest collects and supports information reported in any systems used to track and respond to requests for product information, including the MIC Inquiries Database;
- (e) the processes and procedures by which Forest's Compliance Officer or a designee monitors and identifies situations in which it appears that improper off-label promotion may have occurred; and

- (f) Forest's processes and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for potential situations involving off-label promotion.

2. Forest's policies and procedures applicable to the manner and circumstances under which its medical personnel (including the ESA Department) participate in meetings or events with HCPs or HCIs (either alone or with sales representatives or account executives) and the role of the medical personnel at such meetings or events;

3. Forest's systems, policies, processes, and procedures relating to Forest's internal review and approval of information and materials related to Forest's Government Reimbursed Products disseminated to HCPs or HCIs by Forest;

4. Forest's systems, policies, processes and procedures relating to incentive compensation for Relevant Covered Persons who are sales representatives, with regard to whether the systems, policies, processes, and procedures are designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in the improper promotion, sales, and marketing of Forest's Government Reimbursed Products. This shall include a review of the bases upon which compensation is determined and the extent to which compensation is based on product performance;

5. Forest's systems, processes, policies, and procedures relating to the development and review of call panels for Forest's Government Reimbursed Products. This shall include a review of the bases upon which HCPs and HCIs belonging to specified medical specialties are included in, or excluded from, the call panels based on expected utilization of Forest Government Reimbursed Products for FDA-approved uses or non-FDA-approved uses;

6. Forest's systems, processes, policies, and procedures relating to the development, implementation, and review of Sample Distribution Plans. This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples from Forest (including, separately, from Forest sales representatives and Forest's Quality Assurance department);

7. Forest's systems, processes, policies, and procedures relating to all FDA requirements and guidance (collectively "requirements") relating to determinations about the status or classification of a Forest product and any

changes in such status or classification (including, but not limited to, a determination that a product is a “new drug”), including all reporting requirements and all requirements relating to the tracking or distribution of the product; and

8. Forest's systems, processes, policies, and procedures relating to the tracking, collection, verification, reporting and updating of: i) product or product-related information; ii) pricing information; or iii) utilization information for purposes of the Medicaid drug rebate program, the Medicare program, or other Federal health care programs, including the reporting or updating of information in connection with any determinations about the status or classification of a Government Reimbursed Product and any changes in such status or classification (including information about the status of a product as a covered outpatient drug).

## B. IRO Systems Review Report

The IRO shall prepare a report based upon each Systems Review. For each of the Reviewed Policies and Procedures identified in Section II.A above, the report shall include the following items:

1. a description of the documentation (including policies) reviewed and any personnel interviewed;
2. a detailed description of Forest's systems, policies, processes, and procedures relating to the items identified in Sections II.A.1-8 above, including a general description of Forest's control and accountability systems (e.g., documentation and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;
3. a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections II.A.1-8 above are made known or disseminated within Forest;
4. a detailed description of any system(s) used to track and respond to requests for off-label information submitted by sales representatives about Forest's Government Reimbursed Products;
5. a detailed description of Forest's incentive compensation system for Relevant Covered Persons who are sales representatives, including a description of the bases upon which compensation is determined and the extent to which compensation is based on product performance. To the extent that Forest may establish compensation differently for individual products, the IRO shall report separately on each such type of compensation arrangement;

6. findings and supporting rationale regarding any weaknesses in Forest's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and

7. recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

### III. IRO Transactions Review

As described more fully below in Sections III.A-F, the IRO Transactions Review shall include: (1) a review of a sample of Inquiries reflected in the MIC Inquiries Database; (2) a review of Forest's call panels and Forest's call panel review process; (3) a review of Sampling Events as defined below in Section III.C; (4) a review of records relating to a sample of the Payments that are reported by Forest pursuant to Section III.M of the CIA; and (5) a review of up to three Additional Items identified by the OIG in accordance with Section III.D.1.b of the CIA. The IRO shall report on all aspects of its reviews in the IRO Transactions Review Reports.

#### A. Review of MIC Inquiries Database

##### 1. Description of Inquiries Database

As set forth in Section III.B.3.g of the CIA, Forest shall maintain a database to track information relating to requests for information received by Forest about its products (hereafter "MIC Inquiries Database"). Specifically, Forest shall document and record in the MIC Inquiries Database all Inquiries submitted to the MIC Department based on requests from HCPs or HCIs regarding Forest's Government Reimbursed Products. Forest shall record in the MIC Inquiries Database the following information for each Inquiry received: 1) date of Inquiry; 2) form of Inquiry (e.g., fax, phone, medical information request form); 3) name of requesting HCP or HCI; 4) nature and topic of request (including exact language of the Inquiry if made in writing); 5) nature/form of the response from Forest (including a record of any materials provided in response to the request); and 6) if applicable, the name of the Forest representative who called upon or interacted with the HCP or HCI, if known.

##### 2. Internal Review of MIC Inquiries Database

On at least a semi-annual basis, Forest's Compliance Officer or designee shall review the MIC Inquiries Database and related information, as appropriate, and shall generate a report summarizing the items of information outlined in Section III.A.1 above for each Inquiry received during the preceding two quarters

("MIC Inquiries Database Report"). Forest's Compliance Officer or designee shall review the MIC Inquiries Database Report to assess whether the information contained in the report suggests that improper off-label promotion may have occurred in connection with any Inquiry(ies). If Forest's Compliance Officer or designee, in consultation with other appropriate Forest personnel, suspects that improper off-label promotion may have occurred in connection with any Inquiry, then Forest's Compliance Officer or designee shall undertake a follow-up review of the Inquiry (hereafter "Off-Label Review"), make specific findings based on the Off-Label Review, and take all appropriate corrective action (including disciplinary action of the Covered Person and reporting of the conduct, including disclosing Reportable Events pursuant to Section III.H of the CIA, if applicable).

### 3. IRO Review of Inquiries Reflected in the MIC Inquiries Database

The IRO shall select and review a random sample of 60 Inquiries from among the universe of all Inquiries reflected in the MIC Inquiries Database for each Reporting Period, except that up to 45 of the Inquiries reviewed by the IRO shall be Inquiries in connection with which Forest conducted an Off-Label Review. If Forest conducted an Off-Label Review of fewer than 45 Inquiries, additional Inquiries may be selected from among the universe of Inquiries reflected on the MIC Inquiries Database to reach a total of 60 Inquiries. For each Inquiry reviewed, the IRO shall determine:

- a) Whether each item of information listed above in Section III.A.1 is reflected in the MIC Inquiries Database for each reviewed Inquiry; and
- b) For each Inquiry for which Forest's Compliance Officer or designee conducted an Off-Label Review, the basis for suspecting that improper off-label promotion may have occurred; the steps undertaken as part of the Off-Label Review; the findings of the Forest's Compliance Office or designee as a result of the Off-Label Review; and any follow-up actions taken by Forest based on the Off-Label Review findings.

### B. IRO Review of Forest's Call Panels and Call Panel Review Process

The IRO shall conduct a review and assessment of Forest's review of its call panels for Government Reimbursed Products as set forth in Section III.B.3.i of the CIA. Forest shall provide the IRO with: i) a list of products promoted by Forest sales representatives during the Reporting Period; ii) information about the FDA-approved uses for each such product; and iii) one quarterly call panel for each such product. Forest shall also provide the IRO with information about the

reviews of call panels that Forest conducted during the Reporting Period and any modifications to the call panels made as a result of Forest's reviews.

For each call panel, the IRO shall select a sample of 50 of the HCPs and HCIs included on the call panel. For each call panel, the IRO shall compare the sampled HCPs and HCIs against the criteria (e.g., medical specialty or practice area) used by Forest in conducting its review and/or modification of the call panel in order to determine whether Forest followed its criteria and Policies and Procedures in reviewing and modifying the call panel.

The IRO shall note any instances in which it appears that the sampled HCPs and HCIs on a particular call panel are inconsistent with Forest's criteria relating to the call panel and/or Forest's Policies and Procedures. The IRO shall also note any instances in which it appears that Forest failed to follow its criteria or Policies and Procedures.

#### C. IRO Review of the Distribution of Samples of Forest's Government Reimbursed Products

The IRO shall conduct a review and assessment of the distribution of samples of Forest's Government Reimbursed Products to HCPs and HCIs. Forest shall provide the IRO with: i) a list of products for which Forest distributed samples during the Reporting Period; ii) information about the FDA-approved uses for each such product; and iii) information about Forest's policies and procedures relating to the distribution of samples of each product, including information showing which types of samples may be distributed by sales representatives to HCPs and HCIs of particular medical specialties or types of clinical practices. Forest shall also provide the IRO with information about: iv) the reviews of Forest's policies and procedures relating to the distribution of samples conducted during the Reporting Period in accordance with Section III.B.3.j of the CIA; and v) any modifications to the policies and procedures relating to distribution of samples that were made or corrective actions undertaken as a result of Forest's reviews, including investigating, documenting, resolving, and taking disciplinary action, if appropriate.

For each product for which Forest distributed samples during the Reporting Period, the IRO shall review 50 separate, randomly selected instances in which Forest provided samples of the product to HCPs or HCIs either through sales representative distribution or direct shipment. Each such instance shall be known as a "Sampling Event."

For each Sampling Event, the IRO shall review all documents and information relating to the distribution of the sample to the HCP or HCI, including

the sample card, direct shipment request form and/or the electronic call record (as applicable). The reviewed materials shall include information about the following: 1) the quantity, dosage, and form of the Forest product provided to the HCP or HCI; 2) the identity and type of medical specialty or clinical practice of the HCP or HCI; 3) if applicable, the identity of the individual Forest sales representative who accepted the sample request form or provided the sample to the HCP or HCI; 4) the manner and mechanism through which the sample was requested (*e.g.*, sample card or direct shipment request form); and 5) the manner and mechanism through which the request was fulfilled (*e.g.*, sales representative distribution or direct shipment).

For each Sampling Event, the IRO shall evaluate whether the sample was provided to an HCP or HCI whose medical specialty or clinical practice is consistent with the uses of the product approved by the FDA and whether the sample was distributed in a manner consistent with Forest's policies and procedures relating to the distribution of samples. To the extent that a sample was provided to an HCP or HCI by a Forest representative other than a sales representative, the IRO shall contact the HCP or HCI by letter. The letter shall request that the HCP or HCI: 1) verify that he/she/it received the quantity and type of samples identified by the IRO as the Sampling Event; 2) verify that he/she/it requested the samples provided during the Sampling Event; 3) explain or confirm its type of medical specialty or clinical practice; and 4) identify the basis for requesting the sample (*e.g.*, conversations with a Forest sales representative, conversation with a representative of Forest's MIC Department, independent research or knowledge of the HCP or HCI, *etc.*)

For each Sampling Event, the IRO shall compare the medical specialty and type of clinical practice of the HCP or HCI that received the sample with uses of the product approved by the FDA. The IRO shall note any instances in which it appears that the medical specialty or clinical practice of the HCP or HCI that received a sample during a Sampling Event was not consistent with the uses of the product approved by the FDA. For each such situation, the IRO shall note the process followed by Forest in determining that it was appropriate to provide a sample to such HCP or HCI and the basis for such determination (*e.g.*, in instances where unsolicited requests were made directly to the Quality Assurance Department). For each Sampling Event, the IRO shall also note any instances in which it appears that Forest failed to follow its policies and procedures relating to the distribution of samples for the product(s) provided during the Sampling Event and, if so, whether Forest already had taken corrective action, including investigating, documenting, resolving, and taking disciplinary action, if appropriate.

## D. IRO Review of Physician Payment Listings

### 1. Information Contained in Physician Payment Listings

As set forth in Section III.M of the CIA, Forest shall post quarterly and annual listings of physicians and Related Entities who received Phase I or II Payments, as defined in the CIA, directly or indirectly from Forest. For purposes of the IRO review as set forth in this Section III.D, each annual listing shall be referred to as the “Physician Payment Listing” or “Listing.” For each physician and Related Entity, each Physician Payment Listing shall include the following information: i) physician’s full name; ii) name of Related Entity (if applicable); iii) city and state that the physician or the Related Entity has provided to Forest for contact purposes; and (iv) the purpose of the payment(s); and (v) the aggregate value of the payment(s) in the preceding quarter(s) or year (as applicable). If payments for multiple physicians have been made to one Related Entity, the aggregate value of all payments to the Related Entity will be the reported amount.

For purposes of this IRO review, the term “Control Documents” shall include all relevant documents or electronic records sufficient to demonstrate the purpose of the payment and (where applicable) the performance of a service by the HCP and/or Related Entity associated with each Payment reflected in the Listing for the physician and/or Related Entity. For example, the term “Control Documents” includes, but is not limited to, documents relating to the nature, purpose, and amount of all Payments reflected in the Listing; contracts relating to the Payment(s) reflected in the Listing; documents relating to the occurrence of Payment(s) reflected in the Listing; documents reflecting any work product generated in connection with the Payment(s); documents submitted by sales representatives or headquarters personnel to request approval for the Payment(s); and business rationale or justification forms relating to the Payment(s).

### 2. Selection of Sample for Review

For each Reporting Period, the OIG shall have the discretion to identify up to 50 physicians or Related Entities from the applicable Physician Payment Listing that will be subject to the IRO review described below. If the OIG elects to exercise this discretion, it shall notify the IRO of the physicians and/or Related Entities subject to the IRO review. If the OIG elects not to exercise its discretion as described above, the IRO shall randomly select up to 50 physicians and/or Related Entities to be included in the review. For each selected physician and/or Related Entity, the IRO shall review the entry in the Physician Payment Listing and the Control Documents relating to Payments reflected in the Listing identified by the IRO as necessary and sufficient to validate the Payment information in the Listing.

3) IRO Review of Control Documents for Selected Physicians and/or Related Entities

For each physician and/or Related Entity selected as part of the sample, the IRO shall review the Control Documents identified by the IRO in each instance as necessary and sufficient to validate each Payment reflected in the Listing to evaluate the following:

- a) Whether Control Documents are available relating to each Payment reflected in the Listing for the sampled physician and/or Related Entity;
  - b) Whether the Control Documents were completed and archived in accordance with the requirements set forth in Forest's policies;
  - c) Whether the aggregate value of the Payment(s) as reflected in the Listing for the sampled physician or Related Entity is consistent with the value of the Payments(s) reflected in the Control Documents; and
  - d) Whether the Control Documents reflect that Forest's policies were followed in connection with Payment(s) reflected in the Listing (e.g., all written approvals for the activity were obtained in accordance with Forest's policies.)
- 4) Identification of Material Errors and Additional Review

A Material Error is defined as any of the following:

- a. A situation in which all required Control Documents relating to Payments reflected in the Listing for the sampled physician and/or Related Entity do not exist and:
  - i. no corrective action was initiated prior to the selection of the sampled physicians and/or Related Entities; or
  - ii. the IRO cannot confirm that Forest otherwise followed its policies and procedures relating to the entry in the Listing for the sampled physician or Related Entity, including its policies and

procedures relating to any Payment(s) reflected in the Listing.

- b. Information or data is omitted from key fields in the Control Documents that prevent the IRO from assessing compliance with Forest's policies and procedures, and the IRO cannot obtain this information or data from reviewing other Control Documents.

If a Control Document does not exist, but Forest has initiated corrective action prior to the selection of the sampled physicians and/or Related Entities, or if a Control Document does not exist but the IRO can determine that Forest otherwise followed its policies and procedures with regard to each entry in the Listing for a sampled physician or Related Entity, the IRO shall consider such a situation to be an exception (rather than a Material Error) and the IRO shall report the situation as such. The IRO shall note as exceptions any Control Documents for which non-material information or data is omitted.

If the IRO identifies any Material Errors, the IRO shall conduct such Additional Review of the underlying Payment associated with each Material Error as may be necessary to determine the root cause of the Material Error. For example, the IRO may need to review additional documentation and/or conduct interviews with appropriate personnel to identify the root cause of the Material Error(s) discovered.

#### E. IRO Review of Additional Items

As set forth in Section III.D.1.b of the CIA, for each Reporting Period, the OIG at its discretion may identify up to three additional items for the IRO to review (hereafter "Additional Items".) No later than 150 days prior to the end of the applicable Reporting Period, the OIG shall notify Forest of the nature and scope of the IRO review to be conducted for each of the Additional Items. Prior to undertaking the review of the Additional Items, the IRO and/or Forest shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG. The IRO shall include information about its review of each Additional Item in the Transactions Review Report (including a description of the review conducted for each Additional Item; the IRO's findings based on its review for each Additional Item; and the IRO's recommendations for any changes in Forest's systems, processes, policies, and procedures based on its review of each Additional Item.)

Forest may propose to the OIG that its internal audit(s) be partially substituted for one or more of the Additional Items that would otherwise be

reviewed by the IRO for the applicable Reporting Period. The OIG retains sole discretion over whether, and in what manner, to allow Forest's internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO.

In making its decision, the OIG agrees to consider, among other factors, the nature and scope of Forest's planned internal audit work, the results of the Transactions Review(s) during prior Reporting Period(s), and Forest's demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies Forest's request to permit its internal audit work to be substituted for a portion of the IRO's review of Additional Items in a given Reporting Period, Forest shall engage the IRO to perform the Review as outlined in this Section III.E.

If the OIG agrees to permit certain of Forest's internal audit work for a given Reporting Period to be substituted for a portion of Additional Items review, such internal work would be subject to verification by the IRO (Verification Review). In such an instance, the OIG would provide additional details about the scope of the Verification Review to be conducted by the IRO. However, for purposes of any Verification Review, the IRO shall review at least 20% of the sampling units reviewed by Forest in its internal audits.

#### F. IRO Transactions Review Report

For each Reporting Period, the IRO shall prepare a report based on its Transactions Review. The report shall include the following:

1. General Elements to Be Included in Report
  - a. Review Objectives: A clear statement of the objectives intended to be achieved by each part of the review;
  - b. Review Protocol: A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for each sample reviewed; and
  - c. Sources of Data: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Promotional and Product Related Transactions Review.
2. Results to be Included in Report

The following results shall be included in each IRO Review Report:

(Relating to the Review of Inquiries)

- a. in connection with the review of Inquiries, a description of each type of sample unit reviewed, including the number of each type of sample units reviewed (e.g., the number of Inquiries) and an identification of the types of documents and information reviewed for the Inquiries;
- b. for each Inquiry sample unit, the IRO shall summarize the information about the Inquiry contained in the MIC Inquiries Database;
- c. for each Inquiry sample unit, findings and supporting rationale as to whether: (i) each item of information listed in Section III.A.1 is reflected in the MIC Inquiries Database; and (ii) for each Inquiry for which an Off-Label Review was conducted, the basis for suspecting that improper off-label promotion may have occurred; the steps undertaken as part of the Off-Label Review; the findings of Forest's Compliance Office as a result of the Off-Label Review; and any follow-up actions taken by Forest as a result of Forest's Compliance Office findings;
- d. the findings and supporting rationale regarding any weaknesses in Forest's systems, processes, policies, procedures, and practices relating to the Inquiries, and the MIC Inquiries Database, if any; and
- e. recommendations for improvement in Forest's systems, processes, policies, procedures, and practices relating to the Inquiries and the MIC Inquiries Database, if any.

(Relating to the Call Panel Reviews)

- f. a list of the Government Reimbursed Products promoted by Forest during the Reporting Period and a summary of the FDA-approved uses for such products;
- g. for each Forest Government Reimbursed Product: i) a description of the criteria used by Forest in developing or

reviewing the call panels and for including or excluding specified types of HCPs or HCIs from the call panels; ii) a description of the review conducted by Forest of the call panels and an indication of whether Forest reviewed the call panels as required by Section III.B.3.i of the CIA; iii) a description of all instances for each call panel in which it appears that the HCPs and HCIs included on the call panel are inconsistent with Forest's criteria relating to the call panel and/or Forest's Policies and Procedures; and iv) a description of all instances in which it appears that Forest failed to follow its criteria or Policies and Procedures relating to call panels or the review of the call panels;

- h. the findings and supporting rationale regarding any weaknesses in Forest's systems, processes, policies, procedures, and practices relating to Forest's call panels or the review of the call panels, if any; and
- i. recommendations, if any, for changes in Forest's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to call panels or the review of the call panels.

(Relating to the Sampling Event Reviews)

- j. for each Government Reimbursed Product distributed during the Reporting Period: i) a description of Forest's policies and procedures relating to the distribution of samples (including whether sales representatives may provide samples of the product and, if so, to HCPs or HCIs of which medical specialty or type of clinical practice a sales representative may provide samples); ii) a detailed description of any instances from the reviews by the IRO in which it appears that the medical specialty or clinical practice of the HCPs or HCIs that received a sample during a Sampling Event were not consistent with the uses of the product approved by the FDA. This description shall include a description of the process followed by Forest in determining that it was appropriate to provide a sample to such HCP or HCI and the basis for such determination; and iii) a detailed description of any instances in which it appears that Forest failed to follow its policies and procedures relating to the distribution of

samples for the product(s) provided during the Sampling Event;

- k. the findings and supporting rationale regarding any weaknesses in Forest's systems, processes, policies, procedures, and practices relating to Forest's distribution of samples of Forest's Government Reimbursed Products, if any; and
- l. recommendations, if any, for changes in Forest's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to the distribution of samples.

(Relating to the Physician Payment Listing Reviews)

- m. a description of the entries in the Physician Payment Listing for each physician or Related Entity sampled and a description of Control Documents reviewed in connection with each selected physician or Related Entity;
- n. for each sampled physician or Related Entity, findings and supporting rationale as to whether: (i) all required Control Documents exist; (ii) each Control Document was completed in accordance with all of the requirements set forth in the applicable Forest policy; (iii) the aggregate value of the Payment(s) as reflected in the Listing for the sampled physician or entity is consistent with the value of the Payment(s) reflected in the Control Documents; (iv) each Control Document reflects that Forest's policies were followed in connection with the underlying activity reflected in the document (e.g., all required approvals were obtained); and (v) any corrective action or disciplinary action was undertaken in those instances in which Forest policies were not followed;
- o. for each sampled physician or Related Entity unit reviewed, an identification and description of all exceptions discovered. The report shall also describe those instances in which corrective action was initiated prior to the selection of the sampled physicians or Related Entities, including a

description of the circumstances requiring corrective action and the nature of the corrective action;

- p. if any Material Errors are discovered in any sample unit reviewed, a description of the error, the Additional Review procedures performed and a statement of findings as to the root cause(s) of the Material Error;
- q. the findings and supporting rationale regarding any weaknesses in Forest's systems, processes, policies, procedures, and practices relating to the Physician Payment Listing; and
- r. recommendations, if any, for changes in Forest's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Physician Payment Listing Review.

(Relating to Additional Items Reviews)

- s. for each Additional Item reviewed, a description of the review conducted;
- t. for each Additional Item reviewed, the IRO's findings based on its review;
- u. for each Additional Item reviewed, the findings and supporting rationale regarding any weaknesses in Forest's systems, processes, policies, procedures, and practices relating to the Additional Item, if any; and
- v. for each Additional Item reviewed, recommendations, if any, for changes in Forest's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.

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