

October 23, 1986

To: Dr. M. W. Talbott  
From: Ms. I. M. Brandt

Re: FDA and Fluoxetine NDA

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Tony DeCiccio, FDA Consumer Safety Officer, called today, giving the status of the fluoxetine NDA and requesting Lilly do two things; also that this information be passed along to Max Talbott, all of which I said would be done.

Status of Fluoxetine NDA

FDA Medical Reviewer, Rich Kapit, finished his review of the safety update and gave the document last Friday, October 17, to his medical supervisor, Dr. Laughren. Dr. Laughren has not yet looked at the review.

Two Requests

According to Tony DeCiccio, Dr. Laughren asked if Lilly would provide two things:

1. The proposed labeling on a Wang compatible diskette
2. A summary basis of approval on a Wang diskette. The Division supposedly had a task force working on a new kind of summary basis of approval but, so far, nothing has been done, so Lilly should develop a summary basis of approval based on the old format, for example, the Wellbutran summary basis of approval.

Discussion

Tony DeCiccio stated that Dr. Laughren said "the firm has a friend in Dr. Temple who wants an action letter by the end of this year." Tony DeCiccio at an earlier point in our phone conversation had stated his opinion is an approval letter by the end of the year and January or February for the final.

Division Director, Dr. Leber has been looking at a couple NDA's lately, one older than fluoxetine, diazepam by Marion Labs which is going to be non-approvable. The Division has also been busy answering letters from congressmen, physicians, etc. on Wellbutran.

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*Handwritten initials*

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