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Dockets Management Branch
Food and Drug Administration (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Citizen Petition

Dear Sir or Madam:

The undersigned submits this petition on behalf of a client in quadruplicate pursuant to 21 CFR 10.30 and in accordance with the regulations at 21 CFR 314.161, requesting the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug has been withdrawn for safety or effectiveness reasons as outlined below.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration determine whether Lexapro (escitalopram oxalate) Tablets 5 mg (NDA 21-323, Product 001), manufactured by Forest Laboratories, have been voluntarily withdrawn or withheld from sale for safety or efficacy reasons.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products, which are eligible for submission as abbreviated new drug applications (ANDAs). The List, referred to as the Orange Book, contains all FDA-approved drug products. Lexapro (escitalopram oxalate) Tablets 5 mg were approved by the FDA on August 14, 2002 and were, upon approval, considered to be "listed drug products" in the Orange Book. The approval of the above-referenced drug product appears in the active section of the Orange Book 23rd Edition, however, as of the date of submission of this petition, our client has not been able to obtain the Lexapro (escitalopram oxalate) Tablets 5 mg product upon which to perform the required comparative testing for the submission of an ANDA. Therefore, comparative testing has been conducted on the marketed 10 mg and 20 mg strengths, as well as required dissolution testing on the proposed Escitalopram Oxalate Tablets 5 mg. The FDA has previously determined "for purposes of 21 CFR 314.161 and 314.162 that never marketing an approved product is equivalent to withdrawing the drug from sale". (65 FR 38561)

Under FDA regulations, drugs are withdrawn from the list if the Agency withdraws or suspends approval of the drug product's application for reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162). The regulations also provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or

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effectiveness before an ANDA that refers to that listed drug may be approved (21 CFR 314.161(a)(1)).

As stated above at the time of submission of this petition, there is no evidence that the innovator has commenced marketing of its Lexapro (escitalopram oxalate) Tablets 5 mg product. Therefore, because there has been no commercial distribution of this drug product, it is requested that the FDA determine whether Forest Laboratories' decision not to market Lexapro (escitalopram oxalate) Tablets 5 mg was for reasons of safety or effectiveness.

Should Forest Laboratories commence marketing Lexapro (escitalopram oxalate) Tablets 5 mg after the submission of this petition and prior to FDA response and we have evidence that the product is available in the marketplace, we will consider the petition moot. We will at that time take appropriate action to request withdrawal of the petition.

C. Environmental Impact

A claim for categorical exclusion of the requirement for submission of an environmental assessment is made pursuant to 21 CFR 25.31.

D. Economic Impact

Pursuant to 21 CFR 10.30(b), economic impact information is to be submitted only when requested by the Commissioner. This information will promptly be submitted, if so requested.

E. Certification

The undersigned certifies, that to the best of its knowledge and belief, this petition includes all information and views on which the petitioner relies, and that includes representative data and information known to the petitioner, which are unfavorable to the petition.

Respectfully submitted,

Robert W. Pollock
Vice President

RWP/pk

cc: L. Lachman

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