

LACHMAN CONSULTANT SERVICES, INC.
CONSULTANTS TO THE PHARMACEUTICAL AND ALLIED INDUSTRIES

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

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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the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug has been withdrawn for safety or effectiveness reasons, as outlined below.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 Aciphex (rabeprazole sodium) Delayed-release Tablets, 10 mg (NDA 20-973), manufactured by Eisai Inc. has been voluntarily withdrawn or withheld from sale for safety or efficacy reasons.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. Aciphex Delayed-release Tablets, 10 mg were approved by the FDA on May 29, 2002 and were, upon approval, considered to be "listed drug products" in the Orange Book. From its first appearance in the Orange Book (Cumulative Supplement No. 7, July 2002 of the 22nd Edition), this product appeared as a discontinued product. It is not clear from the available data whether 10 mg Aciphex Delayed-release Tablets have ever actually been marketed. 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Under FDA regulations drugs are withdrawn from the list if the Agency withdraws or suspends approval of the drug product's application for reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162). The regulations also provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 CFR 314.161(a)(1)).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 Aciphex 10 mg Delayed-release Tablets. Therefore, because there has been no apparent commercial distribution of this drug product, it is requested that the FDA determine whether the NDA holder's decision not to market Aciphex Delayed-release Tablets, 10 mg was for reasons of safety or effectiveness.

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Should the NDA holder commence marketing of Aciphex Delayed-release Tablets, 10 mg after the submission of this petition and prior to FDA response, and there is evidence that the product is available in the marketplace, Lachman Consultant Services, Inc. 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

RP/bh

cc: Martin Shimer (Office of Generic Drugs)

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