

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

1600 STEWART AVENUE, WESTBURY, NY 11590
(516) 222-6222 • FAX (516) 683-1887

043 '04 JUL 12 AS:11

July 9, 2004

OVERNIGHT COURIER 7/9/04

Division of Dockets Management
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the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug has been withdrawn for safety or effectiveness reasons as outlined below.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whether Zyvox (linezolid) Tablets 400 mg (NDA 20-130), manufactured by Pharmacia and Upjohn has been voluntarily withdrawn or withheld from sale for safety or efficacy reasons.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 that are eligible for submission as abbreviated new drug applications (ANDAs). The List, referred to as the Orange Book, contains all FDA-approved drug products. Zyvox (linezolid) Tablets 400 mg were approved by the FDA on April 18, 2000 and were, upon approval, considered to be "listed drug products" in the Orange Book. This product appears in the discontinued section of the Orange Book. It is not clear from the available data whether Zyvox (linezolid) Tablets 400 mg 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Under FDA regulations, drugs are withdrawn from the list if the Agency withdraws or suspends approval of the drug product's application for reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162). The regulations also provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 CFR 314.161(a)(1)).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 available evidence to indicate that the innovator has commercially marketed its Zyvox (linezolid) Tablets 400 mg. Therefore, because there has been no apparent commercial distribution of this drug product,

043 '04 JUL 12 AS:11

06

(and regardless of whether the 400 mg tablet has ever been marketed), it is requested that the FDA determine whether the NDA holder's decision not to market and or discontinue marketing of Zyvox (linezolid) Tablets 400 mg was for reasons of safety or effectiveness.

Should the NDA holder commence marketing of Zyvox (linezolid) Tablets 400 mg after the submission of this petition and prior to FDA response and there is evidence that the product is available in the marketplace, LCS 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 *pk*

Vice President
Lachman Consultant Services, Inc.
1600 Stewart Avenue
Westbury, New York 11590

RWP/pk

cc: Martin Shimer (Office of Generic Drugs)

T05P4191