

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

284 1600 STEWART AVENUE
WESTBURY, NY 11590
(516) 222-6222 • FAX (516) 683-1887

September 18, 2001

OVERNIGHT COURIER 9/18/01

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the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug has been withdrawn for safety or effectiveness reasons as outlined below.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 Oxycontin (Oxycodone Hydrochloride) Extended-Release Tablets 160 mg (NDA 20-553) manufactured by Purdue Fredrick, Inc., have been voluntarily withdrawn, discontinued from marketing, or withheld from sale for safety or efficacy reasons.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. Oxycontin Tablets, 160 mg was approved by the FDA on March 15, 2001, and upon approval, is considered to be a "listed drug product" in the Orange Book. The approval of Oxycontin is documented in the Orange Book. It has, however, been brought to our attention by the Office of Generic Drugs, that the NDA holder has discontinued the marketing of its 160 mg Oxycontin drug product

Under FDA regulations, drugs are withdrawn from the list if the Agency withdraws or suspends approval of the drug product's application for reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn, discontinued from marketing or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162). The regulations also provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 CFR 314.161(a)(1)).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, the FDA has advised our client that the innovator has discontinued marketing of its Oxycontin Extended-Release Tablet, 160 mg product. Therefore, because the NDA holder has

discontinued marketing of this drug product, it is requested that the FDA determine whether Purdue Fredrick's decision to discontinue marketing the 160 mg product was for reasons of safety or effectiveness.

Should Purdue Fredrick recommence marketing Oxycontin Tablets 160 mg after the submission of this petition and prior to FDA response and we will consider this 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.

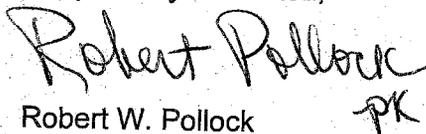
D. Economic Impact

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 it includes representative data and information known to the petitioner that are unfavorable to the petition.

Respectfully submitted,

 Robert W. Pollock
pk

Robert W. Pollock
Vice President

RWP/pk

cc: P. Patel (Office Of Generic Drugs)
L. Lachman

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