



Rec'd 1/4/00 JB

417 Harvester Court
Wheeling, IL 60090
Phone 847.459.9122
Fax 847.459.5602

December 28, 1999

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, Maryland 20857

CITIZEN PETITION

Dear Sir/Madam:

Pentech Pharmaceuticals, Inc. ("Pentech") submits this petition pursuant to 21 C.F.R. " 10.25(a) and 10.30 and in accordance with the regulations at 21 C.F.R. ' 314.122 to request that the Commissioner of the Food and Drug Administration ("Commissioner") make a determination that a drug listed in the Discontinued Drug Products section of the Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") has not been voluntarily withdrawn from marketing for safety or effectiveness reasons as outlined below.

A. Action Requested

The petitioner requests that the Commissioner make a determination that Smithkline Beecham's Paxil oral capsules in the 10, 20, 30, and 40 mg strengths ("Paxil Capsules"), have not been voluntarily withdrawn or withheld from sale for safety or effectiveness reasons and that an Abbreviated New Drug Application ("ANDA") may be submitted and approved pursuant to 21 C.F.R. " 314.122 and 314.161 using Paxil Capsules as the Reference Listed Drug ("RLD").

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B. Statement of Grounds

The Orange Book is a list of all drug products approved by the Food and Drug Administration ("FDA") which are eligible for submission as ANDAs. The August 1999 Supplement to the 1999 Orange Book (19th edition) lists the Paxil Capsules to show their "non-marketed status" (copies of the relevant excerpts are attached). Prior to a 1984 law, FDA did not include in the Orange Book any product not on the market. However, since the enactment of the 1984 law, any approved drug, whether it is on the market or not, is still included in the Orange Book and is still a listed drug. Pursuant to 21 C.F.R. ' 314.161(a)(1), FDA must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA using that listed drug as an RLD may be approved.

Paxil Capsules are currently listed in the Orange Book under Discontinued Drug Products and are not available for sale in the marketplace. Pentech intends to use Paxil Capsules as its RLD in submitting an ANDA for paroxetine. Because there is no current commercial distribution of Paxil Capsules, and as such there is no product in the marketplace against which Pentech may conduct the bioequivalence trial, 21 C.F.R. ' 314.94(a)(7), or any currently approved labeling Pentech may use in a side-by-side comparison, 21 C.F.R. ' 314.94(a)(8), for its proposed ANDA, Pentech requests that FDA determine whether Smithkline Beecham's decision not to market Paxil Capsules is for reasons of safety or effectiveness. As such, Pentech is submitting this petition pursuant to 21 C.F.R. ' 314.161(a)(3). Consistent with 21 C.F.R. ' 314.122(a) and ' 314.161(b), Pentech has no information or evidence available to it concerning the reason that the Paxil Capsules are not available for sale. However, since FDA approved these Paxil Capsules as safe and effective a little more than a year ago, in October 1998, it is unlikely that the reason that Paxil Capsules have never been launched or marketed is due to a safety or effectiveness problem. We submit that the non-marketing of the capsule product may well be strictly an economic/strategic decision by Smithkline Beecham and is totally unrelated to safety or efficacy.

C. Environmental Impact

An environmental assessment on the action requested in this petition qualifies for a categorical exclusion under 21 C.F.R. ' 25.31. Therefore, an environmental assessment is not required for the requested action.

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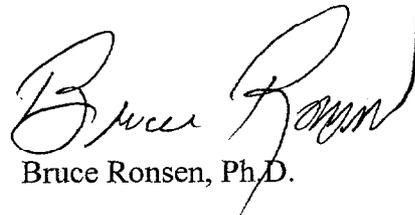
D. Economic Impact

Pursuant to 21 C.F.R. ' 10.30(b), economic impact information is to be submitted only when requested by the Commissioner. Pentech will promptly provide such information if so requested.

E. Certification

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

Respectfully submitted,

A handwritten signature in cursive script that reads "Bruce Ronsen".

Bruce Ronsen, Ph.D.

Pentech Pharmaceuticals, Inc.

1110 Lake-Cook Road

Buffalo Grove, IL 60089

(847)215-0971



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P H A R M A C E U T I C A L S , I N C .

417 Harvester Court
Wheeling, IL 60090

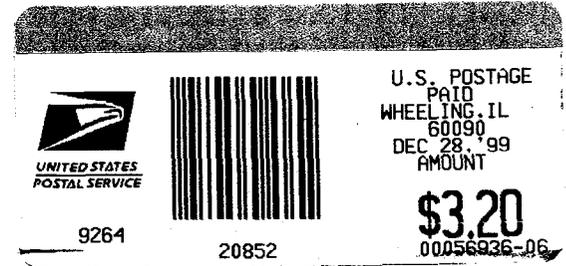
CERTIFIED

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MAIL

**RETURN RECEIPT
REQUESTED**

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Dept. of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD. 20857-
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