TEDOR
PHARMA INC.

400 HIGHLAND CORPORATE DRIVE
CUMBERLAND, RI 02864

T: 401.658.5219
F: 401.658.5263

TEDOR PHARMA.COM

March 06, 2013

2013 MAR 13 P 12:32

Division of Dockets Management,
Food and Drug Administration,
Department of Health and Human Services (HFA-305)
5630 Fishers Lane, rm. 1061,
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam:

Tedor Pharma Inc (Tedor) hereby submits a Citizen Petition, in quadruplicate, pursuant to 21 CFR §10.20, §10.30 and §314.161, requesting the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug has been voluntarily withdrawn for safety or effectiveness reasons.

A. Action Requested

The petitioner respectfully requests that the Commissioner of the Food and Drug Administration (FDA) to make the determination that Metadate® ER 10 mg (Methylphenidate Hydrochloride) Tablets (ANDA 040-306) by UCB Inc, has been voluntarily withdrawn or withheld from sale for reasons unrelated to safety or efficacy and to allow companies to file Abbreviated New Drug Application ("ANDA") seeking approval to market the generic version of Metadate® ER 10 mg.

B. Statement of Grounds

Metadate® ER 10 mg (Methylphenidate Hydrochloride) Tablet (ANDA 040-306) was approved by the FDA on October 20, 1999, and was considered to be listed drug products in the Approved Drug Product with Therapeutic Equivalence Evaluation ("The Orange Book"). UCB Inc also has Metadate® ER 20 mg (Methylphenidate Hydrochloride) Tablet (ANDA 089-601), approval date June 1, 1988, listed in the current Orange Book and is designated as the Reference Listed Drug.

The current Orange Book does not listed Metadate® ER 10 mg (Methylphenidate Hydrochloride) Tablet in the active section. Rather the 10 mg Metadate® ER is listed in the "Discontinued" section of the Orange Book and is currently not available in market.

According to 21CFR314.161, a determination whether a listed drug product has been voluntarily withdrawn from sale was withdrawn for safety or effectiveness reasons may be made by the agency at any time after the drug has been voluntarily withdrawn from sale. Any person may petition for a determination whether a listed drug has been voluntarily withdrawn for safety or effectiveness reasons. The agency must make a determination when a person petitions for such a determination is submitted.

It is believed that Metadate® ER 10 mg Tablet has been discontinued from the marketing for commercial reasons. It is requested that the agency determines whether UCB Inc discontinued marketing Metadate® ER 10 mg Tablet for safety or effectiveness reasons and allows the filing of abbreviated New Drug Application seeking approval to market the generic version of Metadate® ER 10 mg Tablet.

C. Environmental Impact

Under 21CFR §25.31(a), this petition qualifies for a categorical exemption from the requirements to submit an environmental assessment.

20130827

FDA-2013-P-0303

CP

D. Economic Impact

According to 21 CFR §10.30(b), economic impact information is to be submitted only when requested by the Commissioner following review of the petition.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, 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,

Whe-Yong Lo, Ph.D.
Vice President R & D and Regulatory Affairs
Tedor Pharma Inc.
400 Highland Corporate Drive
Cumberland, Rhode Island 02864
Tel: 401 658-5219 Ext. 30

Attachment: Electronic Edition of the Orange Book
(Discontinued and active sections of Methylphenidate Hydrochloride Extended Release Tablets, ANDA #040306 and ANDA #089601)

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Search results from the "OB_Disc" table for query on "040306."

Active Ingredient:	METHYLPHENIDATE HYDROCHLORIDE
Dosage Form;Route:	TABLET, EXTENDED RELEASE; ORAL
Proprietary Name:	METADATE ER
Applicant:	UCB INC
Strength:	10MG
Application Number:	A040306
Product Number:	001
Approval Date:	Oct 20, 1999
RX/OTC/DISCN:	DISCN

Patent and Exclusivity Info for this product: View

Return to Electronic Orange Book Home Page

FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:
Orange Book Data - **Monthly**
Generic Drug Product Information & Patent Information - **Daily**
Orange Book Data Updated Through January, 2013
Patent and Generic Drug Product Data Last Updated: March 01, 2013

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Search results from the "OB_Rx" table for query on "089601."

Active Ingredient:	METHYLPHENIDATE HYDROCHLORIDE
Dosage Form;Route:	TABLET, EXTENDED RELEASE; ORAL
Proprietary Name:	METADATE ER
Applicant:	UCB INC
Strength:	20MG
Application Number:	A089601
Product Number:	001
Approval Date:	Jun 1, 1988
Reference Listed Drug	Yes
RX/OTC/DISCN:	RX
TE Code:	**AB**
Patent and Exclusivity Info for this product:	View

Return to Electronic Orange Book Home Page

FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:
- Orange Book Data - **Monthly**
- Generic Drug Product Information & Patent Information - **Daily**

Orange Book Data Updated Through January, 2013
Patent and Generic Drug Product Data Last Updated: March 01, 2013

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

CERTIFIED MAIL

7012 1640 0002 4853 3394

UNITED STATES POSTAL SERVICE

1023

20852

U.S. POSTAGE
PAID
WOONSOCKET,RI
02895
MAR 06, 13
AMOUNT
$8.06
00037545-03

From: WHE-YONG Lo
Tedor Pharma Inc
400 Highland Corporate Dr.
Cumberland RI 02864

[redacted]

MAR 12 2013

Mail Screening Facility

To: Division of Dockets Management
FDA / HHS. HFA-305
5630 Fishers Lane, Rm 1061
Rockville, MD 20852