Lupin Pharmaceuticals, Inc.

1976 13 MAY 10 A9:52

May 9, 2013

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

Citizen Petition

This petition is submitted pursuant to 21 CFR 10.25 and 10.30, and in accordance with the regulations of 21 CFR 314.161 to request the Commissioner of the Food and Drug Administration to determine whether BANZEL® (rufinamide) Tablets, 100 mg was voluntarily withdrawn or discontinued from marketing for safety or effectiveness reasons as outlined below.

A. Action Requested

The petitioner, Lupin Pharmaceuticals, Inc. ("Lupin") on behalf of Lupin Limited requests that FDA determine whether EISAI INC.'s BANZEL® (rufinamide) Tablets, 100 mg (NDA #N021911, Product No. 001) has been voluntarily withdrawn, discontinued or withheld from sale for safety or efficacy reasons. Specifically, the petitioner requests that FDA:

1. Find that EISAI INC. discontinued its BANZEL® (rufinamide) Tablets, 100 mg for reasons unrelated to safety and efficacy; and
2. Determine that Abbreviated New Drug Applications ("ANDAs") for BANZEL® (rufinamide) Tablets, 100 mg are eligible for approval if all other legal and regulatory requirements are met.

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, in the Approved Drug Product with Therapeutic Equivalence Evaluations (commonly referred to as the "Orange Book") that is separated in to three sections:

HARBORPLACE TOWER, 111 SOUTH CALVERT STREET, 21ST FLOOR, BALTIMORE, MD 21202. TEL: 410-576-2000 FAX: 410-576-2221
www.lupinpharmaceuticals.com

FDA-2013-P-0573 2013-3471 CP

i) Approved Prescription Drug Products

ii) Approved Over The Counter (OTC) Drug Products

iii) Discontinued Drug Products

BANZEL® (rufinamide) Tablets, 100 mg (NDA #N021911) was approved by the FDA on November 14, 2008 and upon approval, was considered to be the "Listed Drug Product" and listed in the Orange Book accordingly. However, the Orange Book now displays BANZEL® (rufinamide) Tablets, 100 mg in its Discontinued Drug Products Section. Lupin is unaware of the precise date that BANZEL® (rufinamide) Tablets, 100 mg was removed from the Approved Prescription Drug Product Section and placed in the Discontinued Product Section of the Orange Book. However, this was noted at the time of our ANDA #204964 submission (and also mentioned in our cover letter). This was also noted in the annual edition of Approved Drug Products List, 33rd Edition, 2013 (Relevant Pages of 33rd Edition are attached). The petitioner believes that this product has been discontinued from the market place for commercial reasons as BANZEL® (rufinamide) Oral Suspension, 40 mg/mL (i.e. lower strength of subject product in Suspension dosage form) is available in Electronic Orange Book and RLD Labeling.

Under FDA regulations, drugs are removed from the approved drug product sections of the Orange Book 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(a)). 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 EISAI INC. is marketing BANZEL® (rufinamide) Tablets, 100 mg. Accordingly, Lupin respectfully requests that FDA determine whether EISAI INC.'s decision to discontinue marketing of its BANZEL® (rufinamide) Tablets, 100 mg strength for reasons of safety or effectiveness.

Should the NDA holder recommence marketing of its BANZEL® (rufinamide) Tablets, 100 mg strength after the submission of this petition and prior to FDA response, and there is evidence that the product is available in the marketplace, Lupin will consider the petition moot. Lupin will at that time take appropriate action to request withdrawal of the petition.

HARBORPLACE TOWER, 111 SOUTH CALVERT STREET, 21ST FLOOR, BALTIMORE, MD 21202. TEL: 410-576-2000 FAX: 410-576-2221
www.lupinpharmaceuticals.com

C. Environmental Impact

A claim for categorical exclusion of the requirements for an environmental assessment is made pursuant to 21 CFR 25.31.

D. Economic Impact

The petitioner does not believe that this is applicable in this case. However, pursuant to 21 CFR 10.30(b) economic impact information will be provided, if requested by the agency.

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 unfavourable to the petition.

Sincerely,

LESLIE SANDS
Director – Regulatory Affairs (USA)
LUPIN PHARMACEUTICALS, INC.
Harborplace Tower,
111 South Calvert Street, 21st Floor,
Baltimore, Maryland 21202

TEL: 410 576 2000
FAX: 410 576 2221

Enclosures: Relevant Pages of Approved Drug Products List, 33rd Edition, 2013 of Orange Book.

Cc: Ms. Linh Vo, Office of Generic Drugs
Mr. Martin Shimer, Office of Generic Drugs

HARBORPLACE TOWER, 111 SOUTH CALVERT STREET, 21ST FLOOR, BALTIMORE, MD 21202. TEL: 410-576-2000 FAX: 410-576-2221
www.lupinpharmaceuticals.com

From: (410) 576-2000
Debashis Mohanty
Lupin Pharmaceuticals, Inc.
111 S. Calvert Street
Suite 2150
Baltimore, MD 21202

Origin ID: ODMA

FedEx Express

J1311302120326

Ship Date: 09MAY13
ActWgt: 0.2 LB
CAD: 1166005/INET3370

Delivery Address Bar Code

Ref #
Invoice #
PO #
Dept #

SHIP TO: (301) 827-6860 BILL SENDER

Division of Dockets Management
Food and Drug Administration
5630 FISHERS LN RM 1061
DEPT. OF HEALTH AND HUMAN SERVICES
ROCKVILLE, MD 20857

FRI - 10 MAY 10:30A
PRIORITY OVERNIGHT

TRK# 0201 7997 2659 3829

20857
MD-US

19 NSFA

IAD

518G1A9983483AB

After printing this label:
1. Use the 'Print' button on this page to print your label to your laser or inkjet printer.
2. Fold the printed page along the horizontal line.
3. Place label in shipping pouch and affix it to your shipment so that the barcode portion of the label can be read and scanned.

Warning: Use only the printed original label for shipping. Using a photocopy of this label for shipping purposes is fraudulent and could result in additional billing charges, along with the cancellation of your FedEx account number.
Use of this system constitutes your agreement to the service conditions in the current FedEx Service Guide, available on fedex.com.FedEx will not be responsible for any claim in excess of $100 per package, whether the result of loss, damage, delay, non-delivery,misdelivery,or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim.Limitations found in the current FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental,consequential, or special is limited to the greater of $100 or the authorized declared value. Recovery cannot exceed actual documented loss.Maximum for items of extraordinary value is $1,000, e.g. jewelry, precious metals, negotiable instruments and other items listed in our ServiceGuide. Written claims must be filed within strict time limits, see current FedEx Service Guide.