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August 7, 2013

Division of Dockets Management
Food and Drug Administration
Room 1061, HFA-305
5630 Fishers Lane
Rockville, MD 20852

2013 AUG -8 P 1:09

Re: ANDA Suitability Petition for Valproic Acid Delayed Release Capsules, 125 mg, 250 mg and 500 mg

CITIZEN'S PETITION

Dear Sir or Madam:

Pharmaceutics International, Inc. (Pii) submits this Citizen's Petition ("Petition") in quadruplicate pursuant to Section 505(j) (2) (C) of the Federal Food, Drug and Cosmetic Act and in accordance with the U.S. Food and Drug Administration (FDA) regulations 21 C.F.R. § 10.20, 10.30, and 314.122.

A. Action Requested

The petitioner requests the Commissioner of Food and Drug Administration (FDA) to issue a determination that Banner Pharmacaps discontinued its previously approved formulation of the Reference Listed Drug (RLD) STAVZOR® (valproic acid delayed release capsules) (Application Number 022152),for reasons unrelated to safety and effectiveness.

The petitioner requests that FDA, pursuant to the determination requested in this Citizen's petition accept Abbreviated New Drug Application (ANDA) for Valproic Acid Delayed Release Capsules, 125 mg, 250 mg and 500 mg.

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B. Statement of Grounds

Banner Pharmacaps first obtained approval of a new drug application (NDA) for STAVZOR® on July 29, 2008 (NDA 022152) for the following strengths 125 mg, 250 mg and 500 mg. Banner Pharmacaps withdrew the previously approved formulation of STAVZOR®, for the following strengths 125 mg, 250 mg and 500 mg from the market for reasons other than safety and efficacy. This citizen's petition also requests that FDA accept the ANDA for the previously approved version of STAVZOR® in the strengths cited in this petition.

Under Section 505 (j) (2) (C) of the Federal Food, Drug, and Cosmetic Act and pursuant to 21 C.F.R. § 314.122 provides for the submission of an ANDA for a drug product that is discontinued provided FDA has approved a petition that proposed the filing of such an application. The subject of this petition for STAVZOR® (valproic acid delayed release capsules) is to permit a generic version of Valproic Acid Delayed Release Capsules, 125 mg, 250 mg and 500 mg (for oral use) for the same strength of an approved drug product.

The proposed drug product is intended for oral use only as described in the "Indications" and "Dosage and Administration" sections of the currently approved labeling for the RLD. The labeling for the proposed drug product is essentially identical to that of the current proposed RLD. The package insert for the latest RLD is included in Attachment 1.

The Reference Listed Drug (RLD) was STAVZOR® (valproic acid delayed release capsules) manufactured by Banner Pharmacaps Inc., approved under the NDA # 022152 on June 29th, 2008 and was discontinued.

For the reason stated above, the undersigned requests that the Commissioner approves this petition and finds if an ANDA is suitable for submission.

C. Environmental Impact

The petitioner claims a categorical exclusion under 21 C.F.R. § 25.31.

D. Economic Impact Statement

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 knowledge and belief, this Petition includes all information and views that the Petition relies on, and it includes representative data and information known to the Petitioner, which are unfavorable to the petition.

Please do not hesitate to contact me if you have any questions or need any additional information.

Sincerely yours,

Samit Deb
Sr. Director -Technical Operations
Pharmaceutics International, Inc. (Pii)
103 Beaver Ct. Cockeysville, MD 21030
Telephone # (410)584-0001 (Extn: 3044)

Attachments

Attachment 1. STAVZOR® (valproic acid delayed release capsules) Package Insert (RLD Labeling)