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Dockets Management Branch
Food and Drug Administration (HFA-305)
Room 1-23
12420 Parklawn Drive
Rockville, Maryland 20857

CITIZEN PETITION

Re: Propoxyphene Napsylate and Acetaminophen,
100 mg/325 mg and 100 mg/500 mg Oral Tablets

Ladies/Gentlemen:

The undersigned hereby submits in quadruplicate this Citizen Petition pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(C), and 21 CFR §§ 10.25, 10.30.

A. Action Requested

This petition requests a declaration by the Commissioner of Food and Drugs, head of the Food and Drug Administration ("FDA"), that an Abbreviated New Drug Application ("ANDA") may be submitted for combination propoxyphene napsylate/acetaminophen oral tablet drug products in strengths of 100 mg/325 mg and 100 mg/500 mg.

B. Statement of Grounds

An ANDA may be filed for the approval of a new drug that is the same as a reference listed drug. 21 U.S.C. § 355(j)(2)(A). An ANDA may also be filed for a new drug which differs from a reference listed drug in the strength of an active ingredient, provided that FDA has granted permission to file an ANDA upon the submission and approval of a pertinent citizen petition. 21 U.S.C. § 355(j)(2)(C). FDA is authorized to approve such a petition seeking a change in strength from a reference listed drug. Id.

02P-0422

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This petition seeks FDA's authorization to submit an ANDA for propoxyphene napsylate 100 mg/acetaminophen 325 mg tablets, and for propoxyphene napsylate 100 mg/acetaminophen 500 mg tablets.

The reference listed drug upon which this petition is based is DARVOCET-N 100 (propoxyphene napsylate 100 mg/acetaminophen 650 mg) tablets, indicated for relief of mild to moderate pain (see Attachments 1 and 2 hereto). The NDA for the reference listed drug has been held by Eli Lilly and Company, is currently listed in FDA's Electronic Orange Book as held by AAI Pharma LLC. Id.

The proposed drug products will contain the same active ingredients as the reference listed drug. The products will differ from the reference listed drug only in the strength of one of the active ingredients -- acetaminophen. The amount of acetaminophen will be reduced from 650 mg to 500 mg for one formulation, and from 650 mg to 325 mg for the second formulation. The amount of propoxyphene napsylate will remain the same as the amount of propoxyphene napsylate in the reference listed drug (100 mg).

The availability of propoxyphene napsylate and acetaminophen tablets in 100 mg/325 mg and 100 mg/500 mg strengths will provide physicians with additional dosing titration options, containing less acetaminophen per dose, for patients who may be at risk of potential hepatotoxicity from high levels of acetaminophen. Due to this risk, many physicians prefer to prescribe lower doses of acetaminophen for particular patients than the maximum available strength of this ingredient in particular drug products.

The labeling of the proposed drug products will be the same as the currently approved labeling for the reference listed drug, except for changes which are required because of the differences proposed under this Petition; viz., differences in acetaminophen strength (see Attachment 3).

In light of the above, and since propoxyphene napsylate/acetaminophen oral tablets have been marketed in the United States for many years with an established safety and effectiveness profile, there is no reason to question the safety or effectiveness of the proposed propoxyphene napsylate/acetaminophen formulations for their labeled use. Notably, the strengths of acetaminophen in the proposed drug products (325 mg and 500 mg) are equal to or fall between the strengths of acetaminophen in the approved and marketed combinations of propoxyphene napsylate and acetaminophen, which have strengths of acetaminophen ranging from 325 mg to 650 mg (see Attachments 1 and 4).

C. Environmental Impact

Petitioner claims a categorical exclusion from the requirement of preparing an environmental assessment or environmental impact statement pursuant to 21 C.F.R. § 25.31.

E. Economic Impact

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

F. Certification

The undersigned certifies that, to their best knowledge and belief, this Citizen Petition includes all information and views upon which the Petition relies, and includes representative data and information known to Petitioner which are unfavorable to the petition.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP

By 
Charles J. Raubicheck

Attachments:

1. Approved Drug Products with Therapeutic Equivalence Evaluations ("the Electronic Orange Book", current through June, 2002): DARVOCET-N 100 (propoxyphene napsylate 100 mg/acetaminophen 650 mg) tablets.
2. Package insert for DARVOCET-N 100 (propoxyphene napsylate 100 mg/acetaminophen 650 mg) tablets from Physicians' Desk Reference (56th Edition, 2002).
3. Proposed package insert for propoxyphene napsylate 100 mg/acetaminophen 325 mg tablets, and propoxyphen napsylate 100 mg/acetaminophen 500 mg tablets.
4. Approved Drug Products: Propoxyphene napsylate and acetaminophen oral tablets.