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CONSULTANTS TO THE PHARMACEUTICAL AND ALLIED INDUSTRIES

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OVERNIGHT COURIER 10/17/02

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

CITIZEN PETITION

The undersigned, on behalf of a client, submits this petition in quadruplicate under Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act ("the FDC Act"), 21 U.S.C. § 355(j)(2)(C), and 21 C.F.R. §§ 10.20, 10.30, and 314.93 to request that the Commissioner of Food and Drugs make a determination that an Abbreviated New Drug Application (ANDA) may be submitted for Oxycodone and Acetaminophen Tablets, USP 2.5 mg / 300 mg.

A. Action Requested

The petitioner requests that the Commissioner of Food and Drugs make a determination that an Oxycodone and Acetaminophen Tablet combination drug product, in a 2.5 mg / 300 mg strength, is suitable for submission as an ANDA. The reference-listed drug product upon which this petition is based is PERCOCET[®] (Oxycodone Hydrochloride and Acetaminophen Tablets, NDA number 40-330 (2.5 mg / 325 mg)). PERCOCET[®] is held by Endo Pharmaceuticals. Therefore, this petition requests a change in the strength of one of the active ingredients (Acetaminophen) from 325 mg to 300 mg per tablet. Because this request involves a change in strength, the provisions of the Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients; Final Rule are not applicable to the evaluation of this petition.

B. Statement of Grounds

Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act provides for the submission of an ANDA for a new drug that differs in strength from a listed drug, provided that the FDA has approved a petition seeking permission to file such an application. This petition requests a change in the strength of the non-narcotic active

ingredient, acetaminophen, from 325 mg per tablet which is found in the reference listed drug, PERCO CET[®] to 300 mg per tablet. The same strength of the narcotic component, 2.5 mg, is proposed.

The listing of PERCO CET[®] (Oxycodone Hydrochloride and Acetaminophen Tablets, 2.5 mg / 325 mg) can be found on page 3-6 of the 22nd Edition of the Approved Drug Products with Therapeutic Equivalence Evaluations (commonly referred to as "The Orange Book"). Please see Attachment A.

According to the approved labeling of the reference listed drug product, PERCO CET[®] (Oxycodone Hydrochloride and Acetaminophen Tablets, 2.5 mg / 325 mg), the usual adult dosage is "one or two tablets every six hours. The total daily dose of acetaminophen should not exceed 4 grams." The approved package insert for PERCO CET[®] Tablets (Oxycodone Hydrochloride and Acetaminophen Tablets, 2.5 mg / 325 mg) is included in Attachment B. The dosage for the proposed product is consistent with the dosage approved in the reference-listed drug product's labeling. Also numerous combination products containing 300 mg of acetaminophen have been approved by the FDA as a safe and effective dose (e.g., Acetaminophen and Codeine Phosphate products). Please see Attachment C.

In summary, the proposed strength change of the non-narcotic component from that of the reference-listed drug (i.e., a change of acetaminophen from 325 mg to 300 mg) will not raise questions of the safety or efficacy of the proposed product. The indication remains unchanged and the proposed dosing is consistent with that recommended in the labeling of the approved reference listed drug product. The efficacy of a 300 mg dose of acetaminophen, in combination with equivalent doses of a narcotic analgesic, is supported by other FDA approved products containing that same proposed dose. Therefore, the Agency should conclude that clinical investigations are not necessary to demonstrate the proposed product's safety or effectiveness.

The proposed labeling for Oxycodone and Acetaminophen Tablets, USP 2.5 mg / 300 mg is included as Attachment D. Labeling for the proposed product will be consistent with the approved labeling for the reference listed drug, Percocet Tablets (Oxycodone and Acetaminophen Tablets, USP), the combination product upon which this petition is based. This proposed labeling includes three additional strengths of Oxycodone and Acetaminophen Tablets, USP: 5 mg / 300 mg; 7.5 mg / 300 mg and 10 mg / 300 mg. The Agency previously approved ANDA submission for these strengths on August 6, 2002 in response to a prior Citizen Petition, Docket No. 02P-0105/CP1. A copy of the petition approval letter, Docket No. 02P-0105/CP1, is included in Attachment E.

For the aforementioned reasons, the undersigned requests that the Commissioner approve this petition and find that an application for Oxycodone and Acetaminophen tablets, USP, 2.5 mg / 300 mg is suitable for submission as an ANDA.

C. Environmental Impact

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

D. Economic Impact Statement

According to 21 C.F.R. § 10.30(b), petitioner will, upon request by the Commissioner, submit economic impact information.

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,

Robert W. Pollock Aw

Robert W. Pollock
Vice President

RWP/aw/m

cc: G. Davis

Attachments:

- A. Page 3-6, Approved Drug Products with Therapeutic Equivalence Evaluations, 22nd Edition.
- B. PERCOCET® (Oxycodone Hydrochloride and Acetaminophen Tablets, 2.5 mg / 325 mg) Insert Labeling.
- C. Page 3-3, Approved Drug Products with Therapeutic Equivalence Evaluations, 22nd Edition.
- D. Draft Insert Labeling for Proposed Drug Product.
- E. Approval Letter for Citizen Petition Docket No. 02P-0105/CP1.

M24P2290