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CONSULTANTS TO THE PHARMACEUTICAL AND ALLIED INDUSTRIES

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March 12, 2002

**OVERNIGHT DOCUMENT 3/12/02**

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

Dear Sir/Madam:

**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 in the following strengths, 5 mg / 300 mg; 7.5 mg / 300 mg, and 10 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 three strengths of 5 mg / 300 mg, 7.5 mg / 300 mg and 10 mg / 300 mg, 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, ANDA 85-106, 325 mg / 5 mg). Reference is also made to other PERCOCET® Tablet product strengths also designated as reference-listed drugs in approved ANDA 40-434 (325 mg / 7.5 mg and 325 mg / 10 mg). The PERCOCET® applications are held by Endo Pharmaceuticals. This petition, therefore, requests a change in the strength of the non-narcotic active ingredient, Acetaminophen, from 325 mg to 300 mg per tablet. Because this request involves a change in strength, the provisions of the Pediatric 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 found in combination with respective strengths of 5 mg, 7.5 mg, or 10 mg of the narcotic component of the listed drug product, PERCOCET®, (Endo Pharmaceuticals), to 300 mg per tablet with the same respective strengths of the narcotic component.

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The listing of PERCO CET<sup>®</sup> (Oxycodone Hydrochloride and Acetaminophen Tablets, 5 mg / 325 mg) can be found on page 3-6 of the 21<sup>st</sup> Edition of the Approved Drug Products with Therapeutic Equivalents Evaluation (commonly referred to as "The Orange Book"). The listing of PERCO CET<sup>®</sup> (Oxycodone Hydrochloride and Acetaminophen Tablets, 7.5 mg / 325 mg and 10 mg / 325 mg) can be found on page 1-2 of Cumulative Supplement 11 of the 21<sup>st</sup> Edition. (See Attachment A)

According to the approved labeling of the reference-listed drug product, PERCO CET<sup>®</sup> (Oxycodone Hydrochloride and Acetaminophen Tablets, 5 mg / 325 mg), the usual dosage is "one tablet every four to six hours as needed for pain. The total daily dose of Acetaminophen should not exceed 4 grams". The approved package insert for PERCO CET<sup>®</sup> Tablets (Oxycodone Hydrochloride and Acetaminophen Tablets, 5 mg / 325 mg) is included in Attachment B. The dosage for the proposed product is "one tablet every four to six hours as needed for pain. The total daily dose of Acetaminophen should not exceed 4 grams". This dosage is consistent with the dosage approved in the reference-listed drug product's labeling. Also, Acetaminophen 300 mg has been approved by the FDA as a safe and effective dose in other combination products, such as Acetaminophen and Codeine Phosphate. Please see Attachment C.

In summary, the proposed change in strength 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 5 mg / 300 mg, 7.5 mg / 300 mg, and 10 mg / 300 mg is included as Attachment D. Labeling for the proposed product will be consistent with the approved labeling for the reference listed Oxycodone and Acetaminophen Tablet USP combination product upon which this petition is based and other approved Oxycodone and Acetaminophen Tablet USP combination drug products.

For the aforementioned reasons, the undersigned requests that the Commissioner approve this petition and find that an application for Oxycodone and Acetaminophen Tablets, USP, 5 mg / 300 mg, 7.5 mg / 300 mg, and 10 mg / 300 mg is suitable for submission as an ANDA.

### ***C. Environmental Impact***

The petitioner claims a categorical exclusion under 21 CFR 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,



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RWP/pk

Attachments:

- A. Page 3-6, Approved Drug Products with Therapeutic Equivalence Evaluations, 21<sup>st</sup> Edition  
Page 1-2, Approved Drug Products with Therapeutic Equivalence Evaluations, 21<sup>st</sup> Edition Cumulative Supplement 11
- B. PERCOCET<sup>®</sup> (Oxycodone Hydrochloride and Acetaminophen Tablets, 5 mg / 325 mg) Insert Labeling
- C. Page 3-3, Approved Drug Products with Therapeutic Equivalence Evaluations, 21<sup>st</sup> Edition
- D. Draft Insert Labeling for Proposed Drug Product

cc: G. Davis, FDA  
L. Lachman

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