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OVERNIGHT COURIER 9/3/03

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 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 Hydrocodone Bitartrate and Acetaminophen Tablets, USP 5 mg / 300 mg.

A. Action Requested

The petitioner requests that the Commissioner of Food and Drugs make a determination that a Hydrocodone Bitartrate and Acetaminophen Tablet, USP 5 mg / 300 mg combination drug product is suitable for submission as an ANDA. The reference-listed drug product upon which this petition is based is NORCO® (Hydrocodone Bitartrate and Acetaminophen Tablets, USP) 5 mg / 325 mg, Application 40-099, manufactured by Watson Laboratories. Therefore, this petition requests a change in the strength of one of the active ingredients (acetaminophen) from 325 mg to 300 mg per tablet.

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 one of the active ingredients, acetaminophen, from 325 mg per tablet, to 300 mg per tablet. The listing of reference drug product upon which this petition is based, NORCO® (Hydrocodone Bitartrate and Acetaminophen Tablets, USP) 5 mg / 325 mg, appears on page 3-6 of the 23rd Edition of the Approved Drug Products with Therapeutic Equivalence Evaluations (commonly referred to as "The Orange Book"). See Attachment A.

According to the approved labeling of the reference-listed drug product, the usual dosage of NORCO® is "one or two tablets every four to six hours as needed for pain". The approved package insert for NORCO® Tablets, is included in Attachment B. The dosage for the proposed product is "one or two tablets every four to six hours as needed for pain". This dosage is consistent with that stated in the approved labeling of the reference-listed drug product. Also, acetaminophen 300 mg has been approved by the FDA as a safe and effective dose of that component in other combination products, such as Acetaminophen and Codeine Phosphate. Additionally on December 20, 2001, the FDA has approved a Citizen Petition, 01P-0441/CP1, for Hydrocodone Bitartrate and Acetaminophen Tablets, USP 10 mg / 300 mg confirming that the requested change from a dose of acetaminophen of 325 mg to 300 mg did not raise questions of safety or effectiveness. See Attachment C.

In summary, the strength change proposed for the non-narcotic component (a change in the acetaminophen from 325 mg to 300 mg) from that of the reference-listed drug is consistent with, and provides for a product with a safe and effective dose of each of the proposed components, which have been previously approved by the FDA in other combination drug products. The proposed change in strength, therefore, should not raise questions of safety or efficacy of the proposed product. The indication and use remain unchanged, and the proposed dosing is consistent with dosing recommendations in the labeling of the approved reference-listed drug product and the dosing for the non-narcotic component for other FDA approved products containing these ingredients. Therefore, the Agency should conclude that clinical investigations are not necessary to support the proposed change in strength.

The proposed labeling for Hydrocodone Bitartrate and Acetaminophen Tablets, USP 5 mg / 300 mg is included as Attachment D. Labeling for the proposed product will be consistent with the labeling for the approved reference-listed drug product, NORCO® (Hydrocodone Bitartrate and Acetaminophen Tablets, USP) 5 mg / 325 mg.

For the aforementioned reasons, the undersigned requests that the Commissioner grant this petition and authorize submission of an ANDA for Hydrocodone Bitartrate and Acetaminophen Tablets, USP 5 mg/300 mg.

C. Environmental Impact

According to 21 C.F.R. § 25.31(a), this petition qualifies for a categorical exemption from the requirement to submit an environmental assessment.

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 that are unfavorable to the petition.

Respectfully submitted,

Robert Pollock PK

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RWP/pk

Attachments:
A. Page 3-6 of the 23rd Edition of the Orange Book
B. Labeling of NORCO® (Approved Reference-Listed Drug)
C. Petition Approval Letter for Docket 01P-0441/CP1, page 3-3 of the 23rd Edition of the Approved Drug Products with Therapeutic Equivalence Evaluations
D. Draft Proposed Labeling

cc: Martin Shimer (Office of Generic Drugs)

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