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(OVERNIGHT COURIER 11/19/01)

Dockets Management Branch
Food and Drug Administration, HFA-305
Department of Health and Human Services
Room 1061
5630 Fishers Lane
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 the Food and Drug Administration make a determination that an Abbreviated New Drug Application (ANDA) may be submitted for Hydrocodone Bitartrate and Acetaminophen Oral Solution, 10 mg / 300 mg per 15 mL.

A. Action Requested

The petitioner requests that the Commissioner of Food and Drug Administration make a determination that a Hydrocodone Bitartrate and Acetaminophen Oral Solution, 10 mg / 300 mg per 15 mL is suitable for submission as an ANDA. The reference-listed drug product upon which this petition is based is LORTAB® Elixir (Hydrocodone Bitartrate and Acetaminophen Oral Solution, 7.5 mg / 500 mg per 15 mL) manufactured by Mikart, Inc. Therefore, this petition requests a change in the strength of both of the active ingredients: hydrocodone bitartrate from 7.5 mg to 10 mg and acetaminophen from 500 mg to 300 mg per 15 mL. Because this request involves only a change in strength, this petition is not subject to the Pediatric Final Rule.

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 both of the active ingredients, which are found in the reference listed drug, LORTAB® Elixir manufactured by Mikart, Inc. The listing of LORTAB® Elixir Hydrocodone Bitartrate and Acetaminophen Oral Solution, 7.5 mg/500 mg per 15 mL is on page 3-4 of the 21st

01P-0524 CP1

Edition of the Approved Drug Products with Therapeutic Equivalents Evaluation (commonly referred to as "The Orange Book"). (Attachment A).

The recommended maximum daily dosage for Hydrocodone Bitartrate according to the labeling of the reference listed drug product is 45 mg per day. The approved labeling of the listed drug product indicates that the usual dosage is "one tablespoon every four to six hours as needed for pain. The total daily dose should not exceed 6 tablespoonfuls." The approved package insert for LORTAB® Elixir is included in Attachment B. The dosage for the proposed product is "one tablespoon every four to six hours as needed for pain. The total daily dose should not exceed 4 tablespoons.". Acetaminophen is approved at a dose of 300 mg in numerous Acetaminophen and Codeine Phosphate Tablet products. As indicated in the approved labeling of the reference-listed drug, hydrocodone is an analgesic and antitussive with multiple actions qualitatively similar to codeine. Additionally, a 10 mg strength of hydrocodone bitartrate, in combination with acetaminophen, has been determined to be safe and effective as evidenced by the approval of other drug products in tablet and capsule form including ANDA 40-148 for NORCO® (hydrocodone bitartrate and acetaminophen tablets, 10 mg / 325 mg) manufactured by Watson Laboratories.

In summary, the proposed change in strength of the active ingredients from that of the reference-listed drug is consistent with the strengths of these active ingredients approved in other combination drug products. This change does not raise questions of the product's safety or efficacy. The uses, dosage form and route of administration remain unchanged and the proposed dosing is consistent with dosing recommendations in the labeling of the approved reference-listed drug. Therefore, the Agency should conclude that clinical investigations are not necessary to demonstrate the proposed product's safety or effectiveness.

The proposed labeling for Hydrocodone Bitartrate and Acetaminophen Oral Solution, 10 mg / 300 mg per 15 mL is included as Attachment C. Labeling for the proposed product is consistent with the approved labeling for other Hydrocodone Bitartrate and Acetaminophen Oral Solution combination products.

For the aforementioned reasons, the undersigned requests that the Commissioner grant this petition and authorize submission of an ANDA for Hydrocodone Bitartrate and Acetaminophen Oral Solution, 10 mg/300 mg per 15 mL.

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

Robert W. Pollock
Vice President

RWP/mk

Enclosures: Attachment A: Listing of Lortab from Approved Drug Products with Therapeutic Equivalence Evaluations
Attachment B: Lortab Package Insert Labeling
Attachment C: Draft Package Insert Labeling for Proposed Drug Product

cc: Greg Davis, R.Ph., OGD

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