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May 25, 2004

OVERNIGHT COURIER 5/25/04

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
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 (21 U.S.C. § 355(j)(2)(C)), and 21 CFR. §§ 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 / 700 mg, 7.5 mg / 700 mg, and 10 mg / 700 mg.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration make a determination that Hydrocodone Bitartrate and Acetaminophen Tablets, 5 mg / 700 mg, 7.5 mg / 700 mg and 10 mg / 700 mg combination drug product are suitable for submission in an ANDA. The reference-listed drug product upon which this petition is based is Hydrocodone Bitartrate and Acetaminophen Tablets, USP, 10 mg / 650 mg, Application 81-223, manufactured by Mikart, Inc. Therefore, this petition requests a change in the strength of one of the active ingredients (acetaminophen) from 650 mg to 700 mg per tablet and to include in combinations with the 700 mg of acetaminophen previously approved strengths of Hydrocodone Bitartrate including 5 mg and 7.5 mg.

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 650 mg per tablet, to 700 mg per tablet. The listing of reference-drug product upon which this petition is based, Hydrocodone Bitartrate and Acetaminophen Tablets, USP, 10 mg / 650 mg, appears on page 3-5 of the 23rd Edition of the Approved Drug Products with Therapeutic Equivalence Evaluations (commonly referred to as "The Orange Book"). See Attachment A.

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According to the approved labeling of the reference-listed drug product, the usual dosage is "one tablet every four to six hours as needed for pain. The total daily dose should not exceed 6 tablets." The approved package insert for Mikart's Hydrocodone Bitartrate and Acetaminophen Tablets 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 should not exceed 5 tablets." This dosage is consistent with that stated in the approved labeling of the reference-listed drug product with the exception of the requirement that no more than 5 tablets of the proposed product may be taken in a 24-hour period. This revision is also consistent with the maximum daily intake of acetaminophen that is permitted (i.e. 700 mg x 5 tablets = 3500 mg, well within the daily maximum of 4000 mg permitted for this ingredient. A dose of 6 tablets of the proposed product would not be appropriate since the total daily intake of acetaminophen would result in a 24-hour dose of 4200 mg, and thus, exceed the maximum daily exposure permitted for this component). Also, acetaminophen has a maximum single approved dose of 1000 mg and FDA has approved other single higher doses of acetaminophen (750 mg) in combination with 10 mg of Hydrocodone Bitartrate as safe and effective. Therefore, the proposed Hydrocodone Bitartrate and Acetaminophen Tablets, USP 10 mg / 700 mg product in which a request for a change of dose of the acetaminophen component from 650 mg to 700 mg would not raise questions of safety or effectiveness.

In summary, the strength change proposed for the non-narcotic component (a change in the level of acetaminophen from 650 mg to 700 mg) with 10 mg of Hydrocodone Bitartrate and a change in strength of the narcotic component to also include a 5 mg and 7.5 mg dose of Hydrocodone with 700 mg of acetaminophen 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 that have been previously approved (there are multiple approved Hydrocodone Bitartrate and acetaminophen product containing 5 mg and 7.5 mg of the narcotic component) or are in the range previously approved by the FDA in other Hydrocodone Bitartrate and acetaminophen 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 recommended dosing for the non-narcotic component for other FDA approved products containing these active 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 / 700 mg, 7.5 mg / 700 mg and 10 mg / 700 mg product is included as Attachment C. Labeling for the proposed product will be consistent with the approved labeling for the RLD Hydrocodone Bitartrate and Acetaminophen Tablets, USP, 10 mg / 650 mg with the exception noted above regarding the total number of tablets permitted per day.

For the reasons mentioned above, the undersigned requests that the Commissioner grant this petition and authorize submission of an ANDA for Hydrocodone Bitartrate and Acetaminophen Tablets, USP 5 mg / 700 mg, 7.5 mg / 700 mg, and 10 mg / 700 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.

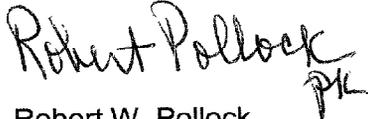
D. Economic Impact Statement

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,



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RWP/pk

Attachments:

- A. Page 3-5 of the 23rd Edition of the Approved Drug Products with Therapeutic Equivalence Evaluations
- B. Approved Package Insert for Mikart's Hydrocodone Bitartrate and Acetaminophen Tablets
- C. Proposed Labeling for Hydrocodone Bitartrate and Acetaminophen Tablets, USP 5 mg / 700 mg, 7.5 mg / 700 mg, and 10 mg / 700 mg product

cc: Emily Thomas (Office of Generic Drugs)

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