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OVERNIGHT COURIER 7/22/03

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 USC § 355(j)(2)(C), and 21 CFR §§ 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 Ibuprofen Tablets, in three strengths of 5 mg / 400 mg; 7.5 mg / 400 mg and 10 mg / 400 mg.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration make a determination that Hydrocodone Bitartrate and Ibuprofen Tablet combination drug products, in three strengths of: 5 mg / 400 mg; 7.5 mg / 400 mg and 10 mg / 400 mg, are suitable for submission in an ANDA. The reference-listed drug product upon which this petition is based is Vicoprofen® (Hydrocodone Bitartrate and Ibuprofen) Tablets, NDA No. 20-716 (7.5 mg / 200 mg) manufactured by Abbott Laboratories Pharmaceutical Products. Therefore, this petition requests a change in the strength from that of the reference-listed drug product from 7.5 mg / 200 mg of Hydrocodone Bitartrate and Ibuprofen to include strengths of 5 mg / 400 mg; 7.5 mg / 400 mg; and 10 mg / 400 mg of Hydrocodone Bitartrate and Ibuprofen 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 from that of the reference-listed drug product from 7.5 mg / 200 mg of Hydrocodone Bitartrate and Ibuprofen per tablet, to include strengths of 5 mg / 400 mg; 7.5 mg / 400 mg; and 10 mg / 400 mg of Hydrocodone Bitartrate and Ibuprofen per tablet. The listing of reference drug product upon which this petition is based, Vicoprofen® (Hydrocodone Bitartrate and Ibuprofen Tablet, 7.5 mg / 200 mg), appears on Page 3-189 of the 23rd Edition of the

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Approved Drug Products with Therapeutic Equivalence Evaluations (commonly referred to as "The Orange Book"). (See Attachment A)

According to the approved labeling of the referenced-listed drug product, the usual dosage of Vicoprofen® is "one tablet every four to six hours, as needed for pain. The total daily dose should not exceed five tablets". The approved package insert for Vicoprofen® 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 five tablets". This dosage is consistent with that stated in the approved labeling of the reference-listed drug product.

In addition, the Agency has approved an ANDA suitability petition (Docket No. 01P-0442/CP1) that requested a change in strength of the narcotic component of the Vicoprofen® product from 7.5 mg to 10 mg, thus supporting this request to include a Hydrocodone Bitartrate and Ibuprofen product containing 10 mg of the narcotic component. (See Attachment C.) Also the FDA has approved numerous combination products containing either 5 mg or 10 mg of Hydrocodone Bitartrate, further attesting to the fact that the proposed product will contain a safe and effective dose of the designated narcotic component. (See Attachment D.) Labeling for such products include a maximum dose of Hydrocodone Bitartrate of up to 60 mg per day. The labeling of the proposed drug product, as stated above, will be consistent with the labeling of the reference-listed drug product and will propose a maximum of five tablets per day, which would provide Hydrocodone Bitartrate at total daily dose within that recommended for other FDA-approved products containing this component.

Labeling for approved products containing Ibuprofen (e.g., Motrin® Tablets, 400 mg) as a single ingredient provides for a maximum total daily dose for this ingredient of up to 3200 mg. Therefore, the labeling of the proposed product will provide for a safe and effective dose of Ibuprofen that is consistent with the FDA-approved single and total daily dosing recommendations for this ingredient, while being consistent with the total number of doses (five per day) that is recommended in the reference-listed drug product's labeling.

In summary, the strength changes proposed for the components (Hydrocodone Bitartrate and/or Ibuprofen) from that of the reference-listed drug are consistent with, and provide a safe and effective dose of each of the proposed components approved by the FDA in other drug products. The proposed changes in strength, therefore, should not affect the safety or efficacy of the proposed product. The indication and uses 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 narcotic and non-narcotic components for other FDA-approved products containing these ingredients. 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 Ibuprofen Tablets, 5 mg / 400 mg; 7.5 mg / 400 mg; and 10 mg / 400 mg per tablet is included as Attachment E. Labeling for the proposed product will be consistent with the approved labeling for Vicoprofen®, Hydrocodone Bitartrate and Ibuprofen Tablets, 7.5 mg / 200 mg.

For the aforementioned reasons, the undersigned requests that the Commissioner grant this petition and authorize submission of an ANDA for Hydrocodone Bitartrate and Ibuprofen Tablets, 5 mg/ 400 mg; 7.5 mg/ 400 mg; and 10 mg / 400 mg.

C. Environmental Impact

According to 21 CFR § 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 CFR § 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 W. Pollock (3H)

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Attachments:
A) Page 3-189 of the 23rd Edition of the Orange Book
B) Vicoprofen Labeling
C) Petition Approval Letter for the 10 mg / 200 mg Suitability Petition
D) Page 3-5 of the 23rd Edition of the Orange Book
E) Proposed PI for the Product

cc: M. Shimer (Office of Generic Drugs)

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