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CONSULTANTS TO THE PHARMACEUTICAL AND ALLIED INDUSTRIES

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March 26, 2007

OVERNIGHT COURIER 3/26/07

Division of Dockets Management
Food and Drug Administration (HFA-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam:

The undersigned submits this petition, in quadruplicate, pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act, and in accordance with 21 CFR 10.30 on behalf of a client requesting the Commissioner of the Food and Drug Administration to declare that the drug product, Hydrocodone Bitartrate and Homatropine Methylbromide Tablets, 2.5 mg / 0.75 mg, is suitable for consideration in an abbreviated new drug application (ANDA).

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration declare that Hydrocodone Bitartrate and Homatropine Methylbromide Tablets, 2.5 mg / 0.75 mg, is suitable for submission as an ANDA. The listed reference drug product (RLD), upon which this petition is based, is Hycodan[®] (Hydrocodone Bitartrate and Homatropine Methylbromide Tablets) 5 mg / 1.5 mg, NDA 05-213 currently held by Endo Pharmaceuticals as designated in the Orange Book (See copy of the page from the current Electronic Edition of the Approved Drug Products with Therapeutic Equivalence Evaluations [Attachment 1]).

B. Statement of Grounds

The Federal Food, Drug, and Cosmetic Act provides for the submission of an Abbreviated New Drug Application for a drug product that differs in dosage strength from that of the listed drug provided the FDA has approved a petition that proposed filing such an application.

The RLD, Hycodan[®] Tablets by Endo Pharmaceuticals is a tablet product containing 5 mg of Hydrocodone Bitartrate and 1.5 mg of Homatropine Methylbromide. The proposed drug product also represents a tablet dosage form, but containing 2.5 mg of Hydrocodone Bitartrate in combination with 0.75 mg of Homatropine Methylbromide. This petition is thus seeking a change in strength of the Hydrocodone Bitartrate component (from 5 mg to 2.5 mg per tablet) and in the Homatropine Methylbromide component (from 1.5 mg to 0.75 mg per tablet) from that of the RLD, i.e., both ingredients are proposed at half the strength of the RLD. Please note that the proposed change in strength represents a dosage strength that is consistent with the dosing recommendations of the RLD's approved labeling.

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The current dosing instructions in the approved labeling of the RLD are as follows:

“Adults

One (1) tablet or one (1) teaspoonful (5 mL) of the syrup every 4 to 6 hours as needed; do not exceed six (6) tablets or six (6) teaspoonfuls in 24 hours.

Children 6 to 12 Years of Age

One-half (1/2) tablet or one-half (1/2) teaspoonful (2.5 mL) of the syrup every 4 to 6 hours as needed; do not exceed three (3) tablets or three (3) teaspoonfuls in 24 hours.”

The approved labeling clearly contemplates the use of the proposed lower strength, 2.5 mg / 0.75 mg of hydrocodone bitartrate / homatropine methylbromide tablet as a ½ tablet dose (½ of the 5 mg / 1.5 mg tablet) for children. The availability of the additional lower strength of hydrocodone bitartrate / homatropine methylbromide, 2.5 mg / 0.75 mg, would provide a more convenient dosage form (i.e., the tablet does not need to be cut in half for pediatric patients) potentially improving patient compliance and making it easier for care givers that may not be able to break tablets to achieve the desired dose. Because this drug product is not without the potential for significant adverse reactions, the proposed new strength of the product would give the healthcare practitioner greater flexibility in selecting the most appropriate dosage strength for the patient while minimizing the potential for medication errors and adverse events.

There are no proposed changes in labeling with the exception of the obvious changes in strength sought in this petition. The uses, indications, warnings and directions for use will remain the same as that of the RLD. Draft labeling for the proposed product is included in Attachment 2, and the RLD's approved labeling is provided in Attachment 3.

Therefore, the petitioner's request for the Commissioner to find that a change in strength from 5 mg of hydrocodone bitartrate to 2.5 mg and from 1.5 mg of homatropine methylbromide to 0.75 mg should raise no questions of safety or effectiveness, and the Agency should approve the petition.

C. Environmental Impact

The petitioner claims a categorical exclusion under 21 CFR 25.31.

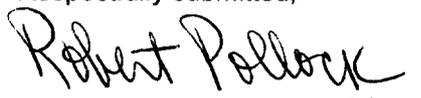
D. Economic Impact

The petitioner does not believe that this is applicable in this case, but will agree to provide such an analysis, if requested by the Agency.

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,


Robert W. Pollock
Senior Vice President 

RWP/pk

- Attachments:
1. Approved Drug Products with Therapeutic Equivalence Evaluations, Electronic Orange Book listing, accessed 3/15/2007
 2. Draft insert labeling for proposed Hydrocodone Bitartrate and Homatropine Methylbromide Tablets, 2.5 mg / 0.75 mg
 3. Approved labeling for reference listed drug, Hycodan® Tablets

cc: Craig Kiester (OGD)

Hycodan® is a registered trademark of Endo Pharmaceuticals.

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