actavis
creating value in pharmaceuticals

October 30, 2006

Division of Dockets Management
Food and Drug Administration
Room 1061 (HFA-305)
5600 Fishers Lane
Rockville, Maryland 20852

Suitability Petition

Pursuant to 21 CFR 10.20 and 10.30, Actavis Totowa, LLC is submitting this petition under Section 505 (j)(2)(C) of the Federal Food Drug and Cosmetic Act to request that the Commissioner of the Food and Drug Administration make a determination and declare that a Abbreviated New Drug Application (ANDA) is suitable for filing of Oxycodone Hydrochloride Capsules, 5mg.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration declare that Oxycodone Hydrochloride Capsules, 5mg be determined suitable for submission of an ANDA. The referenced listed drug product (RLD), upon which this petition is based is Oxycodone Hydrochloride Tablets, 5mg USP. The petitioner also refers to the approved Oxycodone Hydrochloride, oral 5mg tablet, USP, as the referenced listed drug product in the Orange Book in support of this suitability petition. Thus, the petitioner seeks listing of Oxycodone Hydrochloride 5mg, oral capsule drug product which is a change in dosage form from the RLD Oxycodone Hydrochloride, 5mg, USP oral tablet dosage form.

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Actavis Totowa LLC | 101 East Main Street Little Falls, NJ 07424 USA | t 973 890 1440 f 973 890 7980 | w www.actavis.

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B. Statement of Grounds

The Federal Food, Drug and Cosmetic Act Section 505 (j)(2)(C) provides for the submission of an Abbreviated New Drug Application for a drug product that has a different dosage form of the referenced listed drug product provided that the FDA has approved a suitability petition proposing such an application.

The referenced listed product (RLD), Oxycodone Hydrochloride Tablets, 5mg, USP, is marketed by KV Pharmaceuticals under ANDA 77290 for oral administration as a narcotic analgesic for the treatment of moderate to severe pain. In support of this drug product a copy is provided of the applicable page from the FDA's electronic **Approved Drug Products with Therapeutic Equivalent Evaluations**, also know as the Orange Book (Attachment 1). The proposed drug product in this petition is Oxycodone Hydrochloride Tablets, USP, which is an old drug and currently being marketed as an oral active single ingredient drug product tablet as well as a combination capsule containing acetaminophen 500mg and oxycodone hydrochloride 5mg. Thus, a combination in a capsule dosage form has been previously approved by FDA. The single active ingredient Oxycodone Hydrochloride 5mg capsule will be bioequivalent to the RLD drug product Oxycodone Tablets, 5mg, USP.

Oxycodone Hydochloride active drug substance and Oxycodone Hydrochloride single active ingredient tablets are currently listed in The United States Pharmacopeia as official product monographs for both the bulk drug substance and the finished drug product (Attachment 2). The 5mg tablet and 5mg capsule drug products have the same drug active ingredient and only differ in their dosage form, tablet vs capsule. Both drug products are immediate release oral dosage forms. Oxycodone hydrochloride after oral administration has high oral bioavailability when compared to other orally administered narcotic drug products (Attachment 3).

The active ingredient, oxycodone hydrochloride is a semi-synthetic narcotic with multiple actions qualitatively similar to those of morphine for the treatment of moderate to severe pain. The capsule will provide the prescribing physician an alternate dosage form for those patients who have difficulty in swallowing tablets. In addition, the low strength capsule like the tablet will provide for individual low dose titration as needed to adjust treatment of moderate to severe pain symptoms.

The proposed drug product is to meet current bioavailability requirements under Section 505(j)(2)(A)(iv) of the Act and have the same therapeutic effect as the listed drug product when administered for use as indicated in the approved product labeling. The labeling of the proposed drug product will be identical to the referenced listed drug product with the exception of company name, product description and how supplied information. A package insert for the approved drug product is included in (Attachment 3).

C. Pediatric Use Information

We request a waiver from the Pediatric Research Equity Act of 2003 (PREA) for this new capsule dosage form of Oxycodone Hydrochloride 5mg because it does not change the assessment of safety or effectiveness of the drug for the claimed indications. The drug product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients. Also, it is not likely to be used in a substantial number of pediatric patients.

Therefore, the petitioner's request for the Commissioner to find that a change in dosage form of the RLD Oxycodone Hydrochloride Tablet, 5mg to Oxycodone Hydrochoride Capsule, 5mg, with no change in route of administration, should raise no questions with regard to safety or efficacy and the FDA should approve this Suitability Petition.

D. Environmental Impact

An environmental assessment report on the action requested is not required and the petitioner claims a categorical exclusion under 21 CFR 25.31.

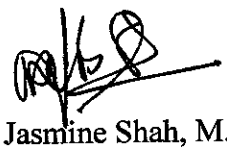
E. Economic Impact

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

F. Certification

The undersigned certifies, that to the best of its knowledge and belief, this petition includes all the information and views on which the petition relies, and that it included representative data and information to the petitioner, which are unfavorable to the petition.

Sincerely,



Jasmine Shah, M.S., R.Ph.
US Vice President Regulatory and Medical Affairs

Attachments:

1. Applicable page FDA's Electronic Orange Book,
2. Monographs for Products Current USP/NF,
3. Drug Product Labeling.