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28 May 2013

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam:

The undersigned submits this petition under Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 314.93 to request the Commissioner of Food and Drugs to permit the filing of an Abbreviated New Drug Application (ANDA) for a drug that has the same active ingredient, route of administration and dosage form as a drug listed in FDA's publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluation" (i.e., the Orange Book), but that differs in dosage strength.

A. Action requested

The petitioner requests that the Commissioner of the Food and Drug Administration make a determination that the drug product, Piroxicam Capsules, 5mg is suitable for evaluation under an ANDA. The petitioner proposes submitting a dose proportional 5mg capsule as a supplemental application to an existing approved ANDA (73-536) for Piroxicam Capsules, 10mg and 20mg, with a request for bioequivalence waiver based on the bioequivalence between the approved Piroxicam 20mg capsule and the Reference Listed Drug's 20mg capsule. The referenced product is Feldene® (piroxicam) Capsules, 10mg and 20mg (NDA 18-147). This petition requests a change in the dosage strength from that of the listed drug product to include a 5mg capsule.

B. *Statement of Grounds*

The Reference Listed Drug (RLD) product upon which this petition is based is currently available in capsules containing 10mg and 20mg of piroxicam. The approved dose of the RLD is "...20mg given orally once per day. If desired, the daily dose may be divided." The proposed product contains the same active ingredient as the RLD, is the same dosage form as the RLD, and is intended for the same route of administration as the RLD. Thus, the proposed product will be labeled with the same dosage recommendations as the RLD and is expected to have the same therapeutic effect when used as indicated in the approved labeling. The proposed drug product represents a capsule that will contain a lower strength of the drug product, 5mg. The 5mg capsule will be of an appropriate smaller size to contain a dose proportional quantity of the same formulation approved in ANDA 73-536, thus providing flexibility in dosing for patients with difficulty swallowing a larger capsule.

In addition, the labeling for the proposed product will be substantially the same as the RLD except for changes necessitated by the fact that the product is manufactured by a different company, the product is referred to by the generic name piroxicam capsules rather than the Feldene® brand name, and the product's appearance and "How Supplied" information are different. Furthermore, the labeling for the proposed product will be identical to the labeling approved under ANDA 73-536, with the exception that the 5mg capsule will be added to the "How Supplied" section. The initial draft labeling and the approved labeling for the RLD are included as Attachments 2 and 3 respectively.

C. *Environment Impact*

The petitioner claims a categorical exclusion under 21 CFR 25.31.

D. *Economic Impact*

Pursuant to 21 CFR 10.30(b), the economic impact information will be submitted 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 petitioner.

Sincerely,

Robert Dettery
Vice President, Regulatory Affairs
Mutual Pharmaceutical Company, Inc.
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Attachments:
1) electronic Orange Book listing
2) draft labeling
3) Feldene® Capsules labeling