JRRapoza Associates, Inc.

508 Elm Avenue • Moorestown • NJ 08057
Telephone (856) 727-1712 • Fax (215) 689-2109
E-Mail: rapozassociates@aol.com

ORIGINAL

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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, JRRapoza Associates, Inc. a New Jersey, Corporation, is submitting this petition in quadruplicate 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 Ciprofloxacin Hydrochloride Capsules, 100mg, 250mg, 500mg, and 750mg equivalent to Ciprofloxacin Base.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration declare that Ciprofloxacin Hydrochloride Capsules, be determined suitable for submission of an ANDA. The referenced listed drug product (RLD), upon which this petition is based is Ciprofloxacin Hydrochloride Tablets, 100mg, 250mg, 500mg and 750mg equivalent to ciprofloxacin base. The petitioner also refers to the approved drug product Ciprofloxacin Hydrochloride oral tablets as listed in the Orange Book in support of this suitability petition. Thus, the petitioner seeks listing of Ciprofloxacin Hydrochloride oral capsule drug product which is a change in dosage form from the RLD Ciprofloxacin Hydrochloride, oral tablet dosage form.

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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), Ciprofloxacin Hydrochloride, 100mg, 250mg, 500mg and 750mg oral tablets, USP, are marketed by Schering Corporation under a Bayer Pharmaceuticals NDA 19375 for the treatment of clinical infections caused by susceptible strains of designated microorganisms. 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 active ingredient Ciprofloxacin Hydrochloride capsules will be bioequivalent to the RLD drug product Ciprofloxacin Tablets.

Ciprofloxacin Hydrochloride active drug substance and Ciprofloxacin 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. The tablet and capsule drug products have the same drug active ingredient and only differ in inactive ingredients and their dosage form, tablet compared to capsule. Both drug products are immediate release solid oral dosage forms.

The capsule which has a patent pending formulation will provide the prescribing physician an alternate dosage form for those patients who have difficulty in swallowing tablets. In addition, the capsule unlike the tablet will provide the convenience of removal of capsule contents for those patients who have difficulty even in swallowing any solid dosage form.

The proposed capsule 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 Ciprofloxacin Hydrochloride and strengths, because it does not change the assessment of safety or effectiveness of the drug for the claimed indications. The reference listed drug product is approved and indicated for use in the pediatric patient population.

Therefore, the petitioner's request for the Commissioner to find that a change in dosage form of the RLD Ciprofloxacin Hydrochloride, 100mg, 250mg, 500mg, and 750mg tablets to Ciprofloxacin Hydrochloride Capsules, 100mg, 250mg, 500mg and 750mg 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.

Sincerely,

John R. Rapoza, M.S., R.Ph.
President
JRRapoza Associates, Inc.

Attachments:

1. Applicable page FDA's Electronic Orange Book,
2. Drug Product Labeling.