

2249 5 NOV 23 110:29

November 22, 2005

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 21 CFR § 314.93, on behalf of a client, to request that the Commissioner of Food and Drugs permit the filing of an Abbreviated New Drug Application (ANDA) for a drug that has the same strengths as a drug listed in FDA's publication entitled: "Approved Drug Products with Therapeutic Equivalence Evaluations," but differs in dosage form.

A. Action Requested

By this petition, the Commissioner of the Food and Drug Administration (FDA) is hereby requested to declare that Meloxicam, Orally Disintegrating Tablets, 7.5 mg and 15 mg is suitable for submission as an ANDA. The reference product upon which this petition is based is Mobic® (Meloxicam Tablets, 7.5 mg and 15 mg). Therefore, the petitioner requests a change from the reference product, Mobic® (Meloxicam Tablets, 7.5 mg and 15 mg), only in its dosage form from tablets to orally disintegrating tablets.

B. Statement of Grounds

The Federal Food, Drug and Cosmetic Act provides for the submission of an ANDA for a drug product that differs in dosage form from that of the reference listed drug provided the FDA has approved a petition that proposed filing such an application. A copy of the most recent internet listing of the "Approved Drug Products with Therapeutic Equivalence Evaluations" (Orange Book), included in Attachment 1, lists the reference product, Mobic® (Meloxicam Tablets, 7.5 mg and 15 mg).

This petition requests a change from the reference listed drug in dosage form only: i.e., change from tablets to orally disintegrating tablets. The proposed drug products would contain the same active ingredients, comprise the same dosage strengths and be intended for the same route of administration. The change in dosage form would not affect the site of absorption, but rather would simply provide a dosage form that is more convenient for some patients, i.e., the tablet dissolves in the mouth after being placed on the tongue, allowing its contents to be swallowed.

The proposed product would also bear the same labeling (except for permitted differences) as the reference product. A copy of the RLD labeling is included in Attachment 2. The labeling of the proposed product is expected to be the same as that for the reference product with the exception of the Description section, the Dosage and Administration section, which instructs the user to place the orally disintegrating tablet on the tongue, allowing it to rapidly disintegrate prior to swallowing, and the How Supplied section. Additionally, since the RLD labeling integrates meloxicam tablets and meloxicam oral suspension using the proprietary name, the proposed draft labeling references the oral suspension using the established name. A copy of the draft proposed package insert is provided in Attachment 3.

In support of the change in dosage form requested in this petition, the petitioner would like to point out that the Agency has previously approved a number of ANDA suitability petitions seeking comparable dosage form change from tablet to orally disintegrating tablet. The FDA approved a petition to file an ANDA for hydrocodone bitartrate and acetaminophen orally disintegrating tablets, 5 mg/500 mg; the reference listed drug was Vicodin® (hydrocodone bitartrate and acetaminophen) Tablets, USP, 5 mg/500 mg (ANDA 88-058). *See* Docket No. 02P-0233/CP-1 and PAV-1; *see also* Docket No. 02P-0078 (approval of petition to submit ANDA baclofen orally disintegrating tablets 10 mg and 20 mg), Docket No. 02P-0033 (approval of petition to submit ANDA for carbidopa and levodopa orally disintegrating tablets 10/100 mg, 25/100 mg, and 25/250 mg), and Docket No. 00P-1422 (approval of petition to submit ANDA for famotidine orally disintegrating tablets 10 mg).

C. Pediatric Waiver Request

In December of 2003, Congress passed the Pediatric Research Equity Act of 2003 that amended the Federal Food, Drug and Cosmetic Act to provide the Agency authority to require drug firms to study drugs in pediatric patients, if the Agency concludes that such study would provide beneficial health data for that patient population. The Act specifically requires that a request for a new dosage form is subject to pediatric evaluation.

The petitioner notes that in response to a Pediatric Written Request from the Agency dated November 22, 2004, the NDA holder (Boehringer Ingelheim Pharmaceuticals, Inc.) of the reference listed drug submitted a supplemental NDA. The studies in the pediatric program submitted in this supplemental NDA were performed in response to and in accordance with the Pediatric Written Request. Subsequently, FDA correspondence dated August 11, 2005, informed the NDA holder that supplements S-013 (NDA 20-938) and S-001 (NDA 21-530) provide for the use of Mobic® (meloxicam) Tablets and Mobic Oral Suspension for relief of the signs and symptoms of pauciarticular or polyarticular course Juvenile Rheumatoid Arthritis in patients 2 years of age or older. As noted in the FDA approval letter, the Sponsor "...has fulfilled the pediatric study requirement for this application" (Attachment 4). In that regard, because the requirements for the conduct of pediatric studies were satisfied by the studies submitted by the innovator, there should be no need to repeat such studies or engage in additional studies for the



product proposed by this petition seeking the same condition of use as that of the RLD product upon which this petition is based.

The petitioner hereby requests that a waiver from the conduct of pediatric studies be granted for the approval of this petition to permit an ANDA filing.

D. Environmental Impact

In accordance with 21 CFR § 25.31, neither an environmental assessment nor an environmental impact statement is required in support of this petition.

E. Economic Impact

In accordance with 21 CFR § 10.30 (b), economic impact information will not be submitted unless requested by the Commissioner following review of this petition.

F. 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 be unfavorable to the petition.

Respectfully submitted,

A handwritten signature in black ink that reads "Ruth E. Stevens". The signature is written in a cursive style with a prominent initial "R".

Ruth E. Stevens, Ph.D.
Vice President, Scientific and Medical Affairs
Camargo Pharmaceutical Services, LLC
9825 Kenwood Road, Suite 102
Cincinnati, OH 45242

Suitability Petition for Meloxicam Orally Disintegrating Tablets, 7.5 mg and 15 mg

Table of Contents

Citizen's Petition	1
Action requested.....	1
Statement of grounds.....	1
Pediatric Waiver Request.....	2
Environmental impact.....	3
Economic impact.....	3
Certification.....	3
Attachment 1: Orange Book Listings.....	5
Attachment 2: Reference Listed Drug Labeling.....	7
Attachment 3: Proposed Labeling.....	35
Attachment 4: FDA Letters of Approval.....	88