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CONSULTANTS TO THE PHARMACEUTICAL AND ALLIED INDUSTRIES

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December 8, 2008

OVERNIGHT COURIER 12/8/08

Dockets Management Branch  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**CITIZEN PETITION**

Dear Sir or Madam:

The undersigned, on behalf of a client, submits this petition in quadruplicate under Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act and in accordance with 21 CFR 10.30 to request the Commissioner of the Food and Drug Administration declare that the drug product Sulindac Capsules, 200 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 the drug product Sulindac Capsules, 200 mg is suitable for submission in an ANDA. The reference-listed drug (RLD) product upon which this petition is based is Clinoril<sup>®</sup> (Sulindac Tablets), 200 mg, NDA 17-911, held by Merck & Co., Inc. (see copy of the page from the current Electronic Edition of the *Approved Drug Products with Therapeutic Equivalence Evaluations*, Attachment 3). The petitioner seeks a change in dosage form from (from the approved dosage form of a tablet to a capsule) that of the RLD.

**B. Statement of Grounds**

Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act provides for the submission of an ANDA for a new drug product that differs in dosage form from a listed drug, provided that the FDA has approved a petition seeking permission to file such an application.

According to the approved labeling of the RLD, Clinoril<sup>®</sup> (Sulindac Tablets), 200 mg, this non-steroidal anti-inflammatory drug (NSAID) should be administered orally twice a day with food. The maximum dosage is 400 mg per day. Dosages above 400 mg per day are not recommended.

In osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis, the recommended starting dosage is 150 mg twice a day. The dosage may be lowered or raised depending on the response. A prompt response (within one week) can be expected in about one-half of patients with osteoarthritis, ankylosing spondylitis, and rheumatoid arthritis. Other patients may require longer to respond.

In acute painful shoulder (acute subacromial bursitis/supraspinatus tendonitis) and acute gouty arthritis, the recommended dosage is 200 mg twice a day. After a satisfactory response has been achieved, the dosage may be reduced according to the response. In acute painful shoulder, therapy for 7-14 days is usually adequate. In acute gouty arthritis, therapy for 7 days is usually adequate.

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The proposed package insert for the Sulindac Capsules, 200 mg is consistent with the reference listed drug labeling. This strength is within the treatment ranges described in the reference listed drug labeling. The petitioner is seeking a change in dosage form in an effort to make an alternate dosage form (capsule) available for those individuals who either have difficulty in swallowing a tablet or who prefer a capsule dosage form as an alternative to Clinorik® (Sulindac) Tablets.

There are no proposed changes in the labeling with the exception of the obvious changes in dosage form sought in this petition. The indications, route of administration, warnings and recommendations for use will remain the same as for the RLD. The package insert for the RLD is provided in Attachment 1 of this petition. The draft package insert for the proposed Sulindac Capsules, 200 mg is provided in Attachment 2.

Therefore, the petitioner's request for the Commissioner to find that a change in dosage form from a tablet to a capsule should raise no questions regarding safety and/or effectiveness, and the Agency should approve the petition.

### **Pediatric Waiver Request**

In September 2007, Congress reauthorized the Pediatric Research Equity Act of 2003 (PREA) 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 a pediatric evaluation. The Act also provides for a waiver from such requirement if the drug:

(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients; and

(II) is not likely to be used in a substantial number of pediatric patients.

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

The reference-listed drug product that is the subject of this petition is an immediate release capsule. Sulindac, a product first approved for use in 1978, was not on the list of drug products for which additional pediatric information may produce health benefits in the pediatric population (May 2001) nor is Sulindac on the current list of off-patent drugs for which pediatric studies are needed (<http://bpca.nichd.nih.gov/index.cfm>). Additionally, according to FDA's list of issued written requests, no written requests have been issued by the Agency for pediatric studies for Sulindac.

The introduction of an alternate dosage form that can be used in the exact same manner as the RLD will not represent a meaningful therapeutic benefit over existing therapies for pediatric patients. Based on the nature of the medication and its routine use, it is not likely that the product will be used in a substantial number of pediatric patients for its labeled indications.

### **C. Environmental Impact**

The petitioner claims a categorical exclusion under 21 CFR 25.31.

### **D. Economic Impact Statement**

The petitioner does not believe that it is applicable in this case, but will agree to provide an analysis, upon request 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 *PK*  
Senior Vice President  
Lachman Consultant Services, Inc.

RWP/pk

Attachments:

1. Clinoril® (Sulindac, 200 mg Tablets) Insert Labeling
2. Draft Insert Labeling for Proposed Drug Product
3. Approved Drug Products with Therapeutic Equivalence Evaluations, 28<sup>th</sup> Edition

cc: Craig Kiester (OGD)

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