LACHMAN CONSULTANT SERVICES, INC.
CONSULTANTS TO THE PHARMACEUTICAL AND ALLIED INDUSTRIES

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December 7, 2006

OVERNIGHT COURIER 12/7/06

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 in accordance with 21 CFR 10.30 on behalf of a client requesting the Commissioner of the Food and Drug Administration to declare that the drug product, Ursodiol Capsules, USP 100 mg, 200 mg, and 400 mg, are 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 Ursodiol Capsules USP, 100 mg, 200 mg, and 400 mg, are suitable for submission as an ANDA. The listed reference drug product (RLD), upon which this petition is based, is Actigall® (ursodiol) Capsules, 300 mg, NDA 19-594 held by Watson Pharmaceuticals, Inc. The petitioner also references Actigall® Capsules, 150 mg, in support of this petition. Therefore, the petitioner seeks a change in strength (from 300 mg to 100 mg, 200 mg and 400 mg) from that of the listed drug product.

B. Statement of Grounds

The Federal Food, Drug and Cosmetic Act provides for the submission of an Abbreviated New Drug Application for a drug product that differs in dosage strength from that of the listed drug provided the FDA has approved a petition that proposed filing such an application.

The RLD, Actigall® Capsules by Watson Pharmaceuticals, Inc. is a capsule product containing 300 mg of Ursodiol. See copy of the page from the current Electronic Edition of the *Approved Drug Products with Therapeutic Equivalence Evaluations* (Attachment 1). The proposed drug product also represents a capsule dosage form, but containing 100 mg, 200 mg or 400 mg of Ursodiol. The petition is thus seeking a change in strength (from 300 mg to 100 mg, 200 mg and 400 mg) from that of the RLD. Please note that the proposed changes in strength represent a dosage strength that is contemplated in the approved labeling for the RLD.

The current dosing instructions in the approved labeling of the RLD are as follows:

> Gallstone Dissolution – "The recommended dose for Actigall treatment of radiolucent gallbladder stones is 8-10 mg/kg/day given in 2 or 3 divided doses."

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Gallstone Prevention – "The recommended dosage of Actigall for gallstone prevention in patients undergoing rapid weight loss is 600 mg/day (300 mg b.i.d.)."

The 100 mg, 200 mg and 400 mg capsules would permit flexibility in administration of the dose for the dissolution of gallstones for those patients that may require an alternative dose due to varying weight. Based on a range of adult weights from 45 kg to 100 kg, the approved dosing regimen of 8-10 mg/kg/day in 2 to 3 divided doses allows for a dose of 360 mg to 1000 mg per day in divided doses. The proposed strengths of 100 mg, 200 mg and 400 mg, would allow flexibility in dosing for these individuals with varying weights. Additionally, Actigall® Capsules were also approved in a 150 mg dosage strength (see copy of the page from the current Discontinued Drug Products section of the Electronic Edition of the *Approved Drug Products with Therapeutic Equivalence Evaluations* (Attachment 2). The Actigall® 150 mg capsule is no longer commercially available limiting the healthcare practitioner's ability to titrate to the recommended doses. The additional strengths of 100 mg, 200 mg and 400 mg will increase the healthcare practitioner's ability to titrate to the recommended doses while limiting the potential of adverse effects.

There are no proposed changes in labeling with the exception of the obvious changes in strength sought in this petition. The uses, indications, warnings and directions for use will remain the same as that of the RLD. Draft labeling for the proposed products is included in Attachment 3, and the RLD's approved labeling is provided in Attachment 4.

Therefore, the petitioner's request for the Commissioner to find that a change in strength from 300 mg to 100 mg, 200 mg, and 400 mg, for Ursodiol Capsules, USP should raise no questions of safety or effectiveness, and the Agency should approve the petition.

C. Environmental Impact

The petitioner claims a categorical exclusion under 21 CFR 25.31.

D. Economic Impact

The petitioner does not believe that this is applicable in this case, but will agree to provide such an analysis 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 petition.

Respectfully submitted,

Robert Pollock

Robert W. Pollock
Senior Vice President

RWP/pk

Attachments:
1. Approved Drug Products with Therapeutic Equivalence Evaluations, accessed December 4, 2006
2. Approved Drug Products with Therapeutic Equivalence Evaluations, accessed December 4, 2006, Discontinued Drug Products section

3. Draft Insert Labeling Proposed for Ursodiol Capsules
4. Labeling for Actigall® Capsules

cc: Craig Kiester (OGD)

Actigall® is registered trademark of Watson Pharmaceuticals, Inc.

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