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Dockets Management Branch, HFA-305
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Citizen Petition

The undersigned submits this petition in quadruplicate pursuant to 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act and 21 CFR 10.20 and 10.30 to request the Commissioner of the Food and Drug Administration to make a determination that an Abbreviated New Drug Application (ANDA) may be submitted for Ursodiol Oral Suspension, 20 mg/mL in a ready-to-use form for oral administration.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration make a determination that the drug product, Ursodiol Oral Suspension, 20 mg/mL, is suitable for evaluation under an ANDA. The referenced product is URSO® (Ursodiol) Tablets, 250 mg, (NDA 20-675). This Petition requests a change in dosage form from that of the approved tablet to liquid form.

B. Statement of Grounds

The Federal Food, Drug and Cosmetic Act provides for the submission of an ANDA for a drug that differs in dosage form from a listed drug, provided the FDA has approved a petition that proposed filing of such an application. This petition involves a change in dosage form from that of the listed drug. The proposed drug product is equivalent in use, dosage and route of administration to the listed drug, URSO® (Ursodiol) Tablets, 250 mg). This petition proposes to market an oral suspension as an alternative dosage form providing for greater compliance for patients who have difficulty swallowing, or cannot swallow tablets, and for ease of titration while seeking the effective dose level. Dosing of Ursodiol in the treatment of primary biliary cirrhosis is 13-15 mg/kg/day administered in two to four divided doses with food. A suspension dosage form will allow for optimal dosage titration for each patient for the treatment of primary biliary cirrhosis.

CanReg® Inc.

2005P-0315

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A suspension dosage will also allow practitioners to titrate to the lowest effective dose, which may decrease adverse reactions commonly experienced with the tablet dosage form.

Finally, the labeling for the proposed product is the same as the reference-listed drug, except for the change in strength and dosage form reflected in this petition. The draft labeling for Ursodiol Oral Suspension and approved labeling for the reference-listed drug are attached.

**C. Environmental Impact**

An environmental assessment on the action requested in this petition qualifies for a categorical exclusion from the requirements of an environmental assessment or impact statement under 21 CFR 25.31(a).

**D. Economic Impact**

Pursuant to 21 CFR 10.30(b), economic impact information is to be submitted when requested by the Commissioner. Information will be promptly submitted, if requested.

**E. Certification**

CanReg Inc. 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.

Yours sincerely,

(*Irma Monaco*)

Anne M. Tomalin  
President, CanReg Inc.

Attachments: 1) Ursodiol Oral Suspension Draft Package Insert  
2) URSO 250<sup>®</sup> & URSO Forte<sup>™</sup> Approved Package Insert.