DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-675/S-011

Axcan Scandipharm, Inc.
Attention: Irma Monaco
Manager, U.S. Regulatory Affairs
22 Inverness Parkway, Suite 310
Birmingham AL 35242

Dear Ms. Monaco:

Please refer to your supplemental new drug application dated July 23, 2004, received July 26, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for URSO 250™ (ursodiol) 250 mg Tablets and ursodiol 500 mg Tablets.

This supplemental new drug application provides for the addition of a tradename for the 500 mg Tablet.

The review of the proposed proprietary name, (b)(4) and URSO Forte™ is complete. We find the proposed name (b)(4) unacceptable for the following reasons.

1. We do not recommend the use of the proprietary name (b)(4) . In reviewing the proprietary name, the primary concerns related to look-alike and/or sound-alike confusion with Urimax and Trimox and dosing/strength confusion with the suffix or modifier of "max."

2. As URSO is a currently marketed product, the addition of a modifier could be interpreted as a pharmacokinetic difference (e.g. delivery difference). The addition of this modifier implies the maximum dose of ursodiol; when in actuality, this only represents highest strength of URSO currently marketed. As this is merely a new strength added to an existing product line, a new name or modifier is not justified with the potential for misinterpretation and dosing confusion.

We find the proposed name URSO Forte™ acceptable and have the following recommendations:

1. Please remove or decrease the (b)(4) (b)(4) . It is distracting from the proprietary and established name.

2. Currently, the established name is listed (b)(4) on the label. Please delete one reference and adjust to comply with 21 CFR 201.10 (g) (2) in regard to size and placement.

We completed our review of this application. This application is approved with the proprietary name of URSO Forte™, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the labeling approved under NDA 20-675/S-009, dated September 17, 2003, received September 22, 2003, and approved July 21, 2004.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-675/S-011." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Gastrointestinal and Coagulation Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Monika Houstoun, Regulatory Project Manager, at (301) 827-9333.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Acting Director
Division of Gastrointestinal and
Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Joyce Korvick
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