NDA 20-675/S-006
NDA 20-675/S-007

Axcan Scandipharm, Inc. 8 MAR 2001
Attention: Anne M. Tomalin, President
Greater Hamilton Technology Enterprise Centre
7 Innovation Drive
Flamborough, Ontario L9H 7H9

Dear Ms. Tomalin:

Please refer to your supplemental new drug applications dated July 21, 2000, received July 24, 2000 (S-006), and dated September 18, 2000, received September 19, 2000 (S-007) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Urso® (ursodiol) Tablets.

We acknowledge receipt of your submissions to S-006 dated February 1, and February 9, 2001. Your submission of February 1, 2001 constituted a complete response to our January 24, 2001 action letter.

S-006 provides for the addition of Schwarz Pharma Manufacturing Inc. as an additional site for tablet manufacture, with storage of bulk tablets up to three months; packaging as bottles of 100 tablets; release and stability testing; and revised packaging components and packaging component suppliers for the 100 tablet package.

S-007 provides for a new tradename, URSO®250.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective

for use as recommended in the agreed upon labeling text and with the revision listed below. Accordingly, these supplemental applications are approved effective on the date of this letter.

Replace the currently approved tradename, URSO®, with the tradename, URSO®250, in the submitted draft labeling (package insert, and immediate container label submitted February 9, 2001).

The final printed labeling (FPL) must be identical, and include the revisions indicated, to the submitted draft labeling (package insert and immediate container labels submitted February 9, 2001). This revision is a term of approval of these supplemental applications.

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 20-675/S-006, 20-675/S-007." Approval of these submissions by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2

FDA

5600 Fishers Lane

Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Brian Strongin, Project Manager, at (301) 827-7310.

Sincerely,

Lilia Talarico, M.D.
Director
Division of Gastrointestinal and
Coagulation Drug Products, (HFD-180)
Center for Drug Evaluation and Research