CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: 020675

Trade Name: URSO TABLETS

Generic Name: URSODIOL

Sponsor: AXCAN PHARMA U.S. INCORPORATED

Approval Date: 12/10/97

INDICATION(s): TREATMENT OF PRIMARY BILIARY CIRRHOSIS

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION: 020675

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	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
Tenative Approval Letter				X
Approvable Letter				X
Final Printed Labeling			X	
Medical Review(s)	X			
Chemistry Review(s)	X			
EA/FONSI				X
Pharmacology Review(s)	X			
Statistical Review(s)	X			
Microbiology Review(s)				X
Clinical Pharmacology Biopharmaceutics Review(s)	X			
Bioequivalence Review(s)				X
Administrative/ Correspondence Document(s)	X			

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Application Number: 020675

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NDA 20-675

Food and Drug Administration
Rockville MD 20857

Axcan Pharma U.S., Incorporated
Attention: Leon Gosselin
25 - 27 Margaret Street
Plattsburgh, New York 12901

DEC 10 1997

Dear Mr. Gosselin:

Please refer to your new drug application dated March 22, 1996, received March 26, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Urso (ursodiol) Tablets.

We acknowledge receipt of your submissions dated March 13, June 30, July 30, October 7, November 14, and December 2, 1997. The User Fee goal date for this application is December 30, 1997.

This new drug application provides for the treatment of primary biliary cirrhosis.

We have completed the review of this application and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the final printed labeling submitted on December 2, 1997. Accordingly, the application is approved effective on the date of this letter.

In addition, please submit three copies of the introductory promotional material that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising and Communications, HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

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, please contact Brian Strongin, Project Manager, at (301) 443-0483.

Sincerely yours,

/S/ [redacted]

Lilia Talarico, M.D.
Director
Division of Gastrointestinal and Coagulation
Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

APPEARS THIS WAY ON ORIGINAL