



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 21-252/S-005

Axcan Scandipharm Inc.  
Attention: Becky Prokipcak, Ph.D., CanReg Inc.  
U.S. Regulatory Affairs Agent  
22 Inverness Center Parkway, Suite 310  
Birmingham, AL 35242

Dear Dr. Prokipcak:

Please refer to your supplemental new drug application dated December 31, 2003, received January 6, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Canasa<sup>®</sup> (Mesalamine, USP) Rectal Suppositories.

We acknowledge receipt of your submissions dated February 6, February 20, March 2, March 22, June 1, June 7, July 9, July 26, September 21, September 24, September 27, November 1, and November 4, 2004.

This supplemental new drug application provides for the addition of a new strength (1000 mg suppository).

We completed our review of this application, as amended. This application is approved, 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 enclosed labeling text for the package insert with attached patient package insert submitted November 4, 2004 and container label submitted November 1, 2004.

Additionally, we refer to our October 28, 2004 teleconference in which you requested to be able to use your commercial validation lots using the previously proposed "CANASA<sup>(b)</sup><sub>(4)</sub>" rotoplast labeling along with the corrected labeling for the PI/PPI and container labeling based on your response to questions regarding the number of suppositories this would represent as well as weeks of patient supply. We have reviewed your request and it is granted. We remind you that once this supply is exhausted, the rotoplast labeling will reflect the approved tradename. FPL will be submitted.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). The guidances specify that labeling is to be submitted in pdf format. To assist in our review, we request that labeling also be submitted in MS Word format. If formatted copies of all labeling pieces (i.e., package insert, patient package insert,

container labels, and carton labels) are submitted electronically, labeling does not need to be submitted in paper.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

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 this division 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 Dr. Betsy Scroggs, Consumer Safety Officer at (301) 827-1250.

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

Enclosure:

-----  
**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  
11/5/04 03:49:06 PM