DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-252/S-006

Axcan Scandipharm Inc.
Attention: Becky Prokipcak, Ph.D.
U.S. Regulatory Affairs Agent (CanReg, Inc.)
450 North Lakeshore Drive
Mundelein, IL 60060

Dear Dr. Prokipcak:

Please refer to your supplemental new drug application dated March 22, 2004, received March 24, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for of the Federal Food, Drug, and Cosmetic Act for CANASA® (mesalamine) Suppository, 500 mg.

This "Changes Being Effected in 30 days" supplemental new drug application provides for a revision to the CONTRAINDICATIONS section of the package insert.

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below.

> "CANASA® Suppositories are contraindicated ~~for~~ in patients ~~known to have~~ who have demonstrated hypersensitivity to mesalamine (5-aminosalicylic acid) or to the suppository vehicle [saturated vegetable fatty acid esters (Hard Fat, NF)], or to salicylates (including aspirin)." ~~(b)(6)~~
> **(b)(4)**

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated to the draft paper package insert submitted March 22, 2004, identified as "2006040-02 Date: December 17, 2003.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. 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.

For administrative purposes, these submission should be designated "FPL for approved supplement NDA 21-252/S-006. Approval of these submission by FDA is not required before the labeling is used.

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 Betsy Scroggs, Pharm.D., 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

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

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/s/

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Joyce Korvick

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