DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-252/S-007

Axcan Scandipharm, Inc. c/o CanReg, Inc.
Attention: Irma Monaco
Manager, Regulatory Affairs
450 North Lakeshore Drive
Mundelein, IL 60060

Dear Ms. Monaco:

Please refer to your supplemental new drug application dated December 13, 2005, received December 15, 2005, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Canasa® (mesalamine) Suppository.

We also acknowledge receipt of your amendment dated January 31, 2006.

This "Changes Being Effected" supplemental new drug application provides for the removal of the 500 mg suppository from the Package Insert for Canasa® Suppositories.

We completed our review of this supplemental new drug application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on January 31, 2006.

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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Kristen Everett, R.N., Regulatory Project Manager, at (301) 796-0453.

Sincerely,

{See appended electronic signature page}
Brian E. Harvey, M.D., Ph.D.
Director
Division of Gastroenterology 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/

Brian Harvey
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