DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-252/S-009

Axcan Scandipharma Inc.
Attention: Irma Monaco, Manager, Regulatory Services
450 North Lakeshore Drive
Mundelein, IL 60060

Dear Ms. Monaco:

Please refer to your supplemental new drug application dated November 21, 2007, received November 23, 2007, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for CANASA® (mesalamine) Suppository, 1000 mg.

This supplemental new drug application provides for an additional package size (42 count).

We completed our review of this supplemental new drug application and it is approved.

We note that SPL has not been submitted representing the content of your proposed labeling. By regulation [21 CFR 314.50(1), 314.94(d), and 601.14(b); Guidance for Industry: Providing Regulatory Submissions in Electronic Format - Content of Labeling (April 2005); http://ww.fda.gov/ohrs/dockets/dockets/92s0251/92s-025 1 -m000032-vol1.pdf], you are required to submit to FDA prescribing and product information (i.e., the package insert or label) in SPL format. Please submit PLR compliant SPL identical to the draft labeling submitted in this supplement within 14 days of the date of this letter.

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Teshara G. Bouie, Regulatory Health Project Manager, at (301) 796-1649.

Sincerely,

{See appended electronic signature page}

Hasmukh Patel, Ph.D.
Branch Chief
Branch VIII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
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/

Hasmukh Patel

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