DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-183/S-009

Axcan Scandipharm, Inc.
Attention: Irma Monaco
Manager, U.S. Regulatory Affairs
450 Lakeshore Drive
Mundelein, IL 60060

Dear Ms. Monaco:

Please refer to your supplemental new drug application dated August 10, 2005, received August 11, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Carafate® (sucralfate) Suspension.

We acknowledge receipt of your submissions dated August 25 and September 26, 2005.

This supplemental new drug application provides for the addition of Carafate® (sucralfate) Suspension unit dose sample trays of 10 mL x 6.

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 submitted labeling.

The final printed labeling (FPL) must be identical to the submitted labeling (submitted August 10, 2005).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 19-183/S-009**." Approval of this 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
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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Ryan Barraco, Regulatory Project Manager, at (301) 796-0846.

Sincerely,

{See appended electronic signature page}

Hasmukh Patel, Ph.D.
Branch Chief
Branch 8, 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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