DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-333/S-032

Axcan Scandipharm Inc.
through CANREG INC
Attention: Irma Monaco
450 North Lakeshore Dr.
Mundelein, IL 60060

Dear Ms.Monaco:

Please refer to your supplemental new drug application dated October 24, 2006, received October 26, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Carafate (sucralfate) Tablets.

We acknowledge receipt of your submissions dated October 24 and October 30, 2006, and March 22, 2007.

This "Changes Being Effected" supplemental new drug application provides for geriatric labeling submitted under 201.57(f)(10)(ii)(A) (i.e. where insufficient data exist to determine whether the responses of geriatric patients to a drug are different from responses of younger patients).

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 and with the minor editorial revisions listed below. Please add these changes to the Package Insert at the next printing and include in your next annual report.

1. Under Study 2 in the Clinical Studies Section, the change from "international" to" internation" in the second sentence is a typographical error which should be corrected.
2. In the How Supplied section, the Prescribing Information date should read the date that the changes were effected, not April 2004.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Thomas Moreno, Regulatory Project Manager, at (301) 796-2247.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director
Division of Gastroenterology 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

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