DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-252/S-002

Axcan Scandipharm Inc.
Attention: Becky Prokipcak, Ph.D.
U.S. Regulatory Affairs Agent
22 Inverness Center Parkway
Birmingham, AL 35242

Dear Dr. Prokipcak:

Please refer to your supplemental new drug applications dated April 4, 2003, received April 14, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CANASA™ (mesalamine) Suppository, 500 mg.

We acknowledge receipt of your submission dated June 4, 2003.

This supplemental new drug application provides for a change in the storage recommendations.

We have completed the 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.

The final printed labeling (FPL) must be identical to the submitted draft labeling for the package insert, immediate carton label, and carton label, submitted April 4, 2003.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please mount individually ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled, *Providing Regulatory Submissions in Electronic Format – NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-252/S-002". Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Dr. Betsy Scroggs, Consumer Safety Officer, at (301) 827-1250.

Sincerely,

{See appended electronic signature page}

Robert Justice, M.D., M.S.
Director
Division of Gastrointestinal and
Coagulation Drug 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/

Robert Justice

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