DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-786

Axcan Scandipharm, Inc.
c/o CanReg, Inc.
Attn: Ms. Irma Monaco
Manager, Regulatory Affairs (CMC)
450 North Lakeshore Drive
Mundelein, IL 60060

Dear Ms. Monaco:

Please refer to your new drug application (NDA) dated September 28, 2001, received October 2, 2001, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Pylera™ (biskalcitrate, metronidazole, and tetracycline hydrochloride) Capsules, 140 mg/125 mg/125 mg.

This application is subject to the exemption provisions in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submissions dated:

October 1, 2003
October 8, 2003
October 31, 2003
March 27, 2006
April 13, 2006
May 10, 2006
June 26, 2006
August 14, 2006
September 12, 2006
September 21, 2006
September 27, 2006 (2)

The March 27, 2006 submission constituted a complete response to our October 2, 2003 action letter.

This new drug application provides for the use of Pylera™ (biskalcitrate, metronidazole, and tetracycline hydrochloride) Capsules, in combination with omeprazole, for the treatment of patients with *Helicobacter pylori* infection and duodenal ulcer disease (active or history of within the past 5 years) to eradicate *H. pylori*.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

Submit revised content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

We note that a USAN name has not been established for biskalcitrate although you have applied for one. Please provide us with the outcome of the decision by USAN immediately after you are notified of their decision.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for ages 0 to 2 years, and deferring pediatric studies for ages >2 to 16 years for this application.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of this postmarketing study shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

1. Deferred pediatric study under PREA for the treatment of patients with *H. pylori* infection and duodenal ulcer disease (active or history of within the past 5 years) to eradicate *H. pylori* in pediatric patients ages >2 to 16 when used in combination with omeprazole.

   Final Report Submission: September 30, 2011

Submit final study reports to this NDA. For administrative purposes, all submissions related to this pediatric postmarketing study commitment must be clearly designated "**Required Pediatric Study Commitment**."

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Special Pathogen and Transplant Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

Please submit one market package of the drug product when it is available.

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

The MedWatch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biologics qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for this product. To participate in the program, please see the enrollment instructions and program description details at www.fda.gov/medwatch/report/mmp.htm.

If you have any questions, call Rebecca Saville, Pharm.D., Regulatory Project Manager at (301) 796-1600.

Sincerely,

{See appended electronic signature page}

Edward Cox, M.D., M.P.H.
Acting Director
Office of Antimicrobial Products
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/

Edward Cox

9/28/2006 05:30:27 PM