DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-786/S-001

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 supplemental new drug application dated November 27, 2006, received November 30, 2006, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Pylera™ (bismuth subcitrate potasium, 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 December 8, 2006 and March 22, 2007.

This "Changes Being Effected in 30 days" supplemental new drug application provides for a change in the capsule color of Pylera™ and a change to the capliner in the container closure system. In addition, revisions were proposed in the labeling to reflect the product components listing as well as to change the product established name to the adopted USAN name, bismuth subcitrate potassium.

The following revisions (~~strikethrough~~ = deleted and double-underlined = added) to the text for the labeling for Pylera™ were proposed in this supplemental application:

1. Throughout the labeling, ~~biskalcitrate~~ has been changed to bismuth subcitrate potassium.

2. In the **DESCRIPTION** section, the last paragraph was revised as follows:

   Each PYLERA™ Capsule contains the following inactive ingredients: Magnesium Stearate NF, Lactose Monohydrate NF~~, and~~ Talc USP, Gelatin USP, and Titanium Dioxide NF. Printed with red ink.

3. In the **HOW SUPPLIED** section, the paragraph was revised as follows:

   PYLERA™ is supplied as a ~~red~~white opaque capsule containing 140 mg ~~biskalcitrate~~bismuth subcitrate potassium, 125 mg metronidazole, and 125 mg tetracycline hydrochloride, with Axcan Pharma logo printed on body and ~~HP< diagram of stomach and~~ BMT printed on cap. PYLERA™ is supplied in bottles of 120 capsules.

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.

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 Rebecca Saville, Pharm.D., Regulatory Project Manager at (301) 796-1600.

Sincerely,

{See appended electronic signature page}

Eric Duffy, Ph.D.
Director
Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
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/

Eric Duffy

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