



**DEPARTMENT OF HEALTH & HUMAN
SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-525
NDA 20-451/S-012

Axcan Scandipharm, Inc.
Attention: Debbie O. Co, Ph.D.
4 Innovation Drive
Dundas, Ontario L9H 7P3
Canada

Dear Dr Co:

Please refer to your new drug application (NDA) dated May 24, 2002, received May 31, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PHOTOFRIN® (porfimer sodium) for Injection.

We acknowledge receipt of your submissions dated September 26, October 23, and November 4, 2002 and January 28, February 18, April 4, May 13, June 3, July 29 and July 30, 2003.

Your submission dated January 28, 2003 was a complete response to our action letter dated November 29, 2002.

Please also refer to the April 6, 2003 supplemental new drug application NDA 20-451/S-012.

These new drug applications provide for the use of PHOTOFRIN® (porfimer sodium) for Injection for the ablation of high-grade dysplasia in Barrett's esophagus patients who do not undergo esophagectomy.

We completed our review of these applications, as amended. They are 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 enclosed labeling (text for the package insert). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 NDA 21-525.**” Approval of this submission by FDA is not required before the labeling is used.

We remind you of your postmarketing study commitment in your submission dated July 29, 2003. This commitment is listed below.

1. You commit to completing the ongoing clinical study (PHO BAR 02) entitled, “A multicenter, partially blinded, randomized Phase III study of the efficacy and safety of photodynamic therapy (PDT) using PHOTOFRIN® (porfimer sodium) for Injection for the ablation of high-grade dysplasia (HGD) in Barrett’s esophagus (BE): A 5-year follow-up”.

Final Report Submission: Within 24 months of the date of this letter

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to NDA 20-451. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled “**Postmarketing Study Protocol**”, “**Postmarketing Study Final Report**”, or “**Postmarketing Study Correspondence.**”

Pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act may result in additional marketing exclusivity for certain products. You should refer to the Guidance for Industry on Qualifying for Pediatric Exclusivity (available on our web site at www.fda.gov/cder/pediatric) for details. If you wish to qualify for pediatric exclusivity you should submit a "Proposed Pediatric Study Request". FDA generally does not consider studies submitted to an NDA before issuance of a Written Request as responsive to the Written Request. Applicants should obtain a Written Request before submitting pediatric studies to an NDA.

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 this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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

All 15-day alert reports, periodic (including quarterly) adverse drug experience reports, field alerts, annual reports, supplements, and other submissions should be addressed to the original NDA (NDA 20-451) for this drug product, not to this NDA. In the future, do not make submissions to this NDA except for the final printed labeling requested above.

If you have any questions, call Brian Strongin, R.Ph., M.B.A., Regulatory Project Manager at (301) 827-7473.

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

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
8/1/03 02:15:12 PM
for Dr. Robert Justice