



NDA 20-451/S-016

Axcan Scandipharm Inc.
c/o CanReg Inc.
Attention: Irma Monaco, B.Sc.
450 North Lakeshore Drive
Mundelein, IL 60060

Dear Ms. Monaco:

Please refer to your supplemental new drug application dated March 28, 2005, received March 29, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Photofrin (porfimer sodium) for Injection, 75 mg.

We also refer to your August 10, 2005 amendment.

This supplemental new drug application proposes the addition of two adverse events to the Adverse Event section of the Package Insert.

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.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert text submitted March 28, 2005). As agreed, the word "exaggerated" will be removed from the fourth paragraph in ADVERSE REACTIONS.

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 supplement NDA 20-451/S-016.**" Approval of this submission by FDA is not required before the labeling is used.

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 Paul Zimmerman, Project Manager, at (301) 594-5775.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D.
Acting Director
Division of Drug Oncology Products
Office of Oncology Drug Products
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
9/29/2005 06:10:47 PM