DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020451/S-020

**SUPPLEMENT APPROVAL and POSTMARKETING COMMITMENT FULFILLED**

Pinnacle Biologics, Inc.
Attention: Guillermo A. Herrera
Chairman and Chief Executive Officer
2801 Lakeside Drive, Suite 209
Bannockburn, IL 60015

Dear Mr. Herrera:

Please refer to your Supplemental New Drug Application (sNDA) dated May 12, 2009, received May 13, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Photofrin (porfimer sodium) for Injection.

We acknowledge receipt of your amendments dated October 25, 2010; and April 1 (electronic), 2011.

This "Prior Approval" supplemental new drug application (S-020) provides for updating the Clinical Pharmacology, Pharmacokinetics section of the Package Insert.

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

## CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements and any annual reportable changes not included in the enclosed labeling. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes approved in this supplemental application.

## POSTMARKETING COMMITMENT FULFILLED

We have received your submission dated May 12, 2009, which contains the final report for the following postmarketing commitment listed in the December 27, 1995, approval letter for this application:

1314-2 Conduct Phase 4 studies to gather further pharmacokinetic data in patients with hepatic impairment and in patients who have received more than one course of therapy. Pharmacokinetics will also be characterized in male and female patients.

We have reviewed your submission and have determined that you have fulfilled the pharmacokinetics characterization in patients who have received more than one course of therapy, and because based on the rationale you provided, we have determined that a study in patients with hepatic impairment is no longer needed.

This completes all of your postmarketing commitments acknowledged in our December 27, 1995, letter.

## PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) 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

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

## LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

## REPORTING REQUIREMENTS

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, Regulatory Project Manager, at (301) 796-1489.

Sincerely,

*{See appended electronic signature page}*

Robert L. Justice, M.D., M.S.
Director
Division of Drug Oncology Products
Office of Oncology Drug products
Center for Drug Evaluation and Research

ENCLOSURE:
Package Insert

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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ROBERT L JUSTICE
04/04/2011