DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Larry Miles
Pinnacle Biologics, Inc.
2801 Lakeside Drive, Suite 210
Bannockburn, IL 60015

RE: NDA 020451
PHOTOFRIN® (porfimer sodium) for injection, for intravenous use
MA 178

Dear Larry Miles:

The U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, an exhibit booth panel (exhibit panel), "Tradeshow Booth Backdrop - NSCLC" (US/PHO/PM/0072) for PHOTOFRIN® (porfimer sodium) for injection, for intravenous use (Photofrin) submitted by Pinnacle Biologics, Inc. (Pinnacle) under cover of Form FDA 2253. FDA has determined that the exhibit panel is false or misleading. Thus, the exhibit panel misbrands Photofrin and makes the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The exhibit panel is misleading because it presents efficacy claims and representations for Photofrin but fails to communicate **any** risk information. For example, the exhibit panel includes the following claims and representations (emphasis original):

- "**ATTACK CANCER MARGINS WITH NON-THERMAL LIGHT *WITH PHOTODYNAMIC THERAPY***"

- Endobronchial cancer images are prominently displayed of "**Pre Treatment**," "**During Treatment**," and "**Post Treatment**" for "**PARTIAL AIRWAY OBSTRUCTION *Adenoid Cystic Carcinoid***" and "**CENTRAL AIRWAY OBSTRUCTION *Adenocarcinoma***," to show improvement with the use of treatment

- "*Indication for Usage Endobronchial Cancer: Treatment of microinvasive endobronchial non-small-cell lung cancer (NSCLC) in patients for whom surgery and radiotherapy are not indicated.*"

In addition, the exhibit panel is shown to be surrounded by other booth graphics (i.e., a podium, banner, and panel) that include the Photofrin logo with the claim, "*PDT with* **PHOTOFRIN® *TARGETING ~~CANCER MARGINS~~***" (in pertinent part, emphasis original). The exhibit panel, however, entirely omits all risk information. We acknowledge that the exhibit panel includes the statement, "Please see full Prescribing Information for PHOTOFRIN

(porfimer sodium) for injection at: *www.photofrin.com*" at the bottom of the exhibit panel. However, this does not mitigate the omission of risk information from the exhibit panel. By omitting the risks associated with Photofrin, the exhibit panel fails to provide material information about the consequences that may result from the use of Photofrin and creates a misleading impression about the drug's safety.

Conclusion and Requested Action

For the reasons described above, the exhibit panel misbrands Photofrin and makes the distribution of the drug in violation of the FD&C Act.

This letter notifies you of our concerns and provides you with an opportunity to address them. FDA requests that Pinnacle take immediate action to address any violations (including, for example, ceasing and desisting promotional communications that are misleading as described above). Please submit a written response to this letter within 15 working days from the date of receipt, addressing the concerns described in this letter, listing all promotional communications (with the 2253 submission date) for Photofrin that contain representations like those described above, and explaining your plan for the discontinuation of such communications, or for ceasing distribution of Photofrin.

If you believe that your product is not in violation of the FD&C Act, please include in your submission to us your reasoning and any supporting information for our consideration within 15 working days from the date of receipt of this letter.

The concerns discussed in this letter do not necessarily constitute an exhaustive list of potential violations. It is your responsibility to ensure compliance with each applicable requirement of the FD&C Act and FDA implementing regulations.

Please direct your response to the **Food and Drug Administration, Center for Drug Evaluation and Research, Office of Prescription Drug Promotion, 5901-B Ammendale Road, Beltsville, Maryland 20705-1266**. A courtesy copy can be sent by facsimile to (301) 847-8444. Please refer to MA 178 in addition to the NDA number in all future correspondence relating to this particular matter. All correspondence should include a subject line that clearly identifies the submission as a Response to Untitled Letter. You are encouraged, but not required, to submit your response in eCTD format. All correspondence submitted in response to this letter should be placed under eCTD Heading 1.15.1.6. Additionally, the response submission should be coded as an Amendment to eCTD Sequence 0212 under NDA 020451. Questions related to the submission of your response letter should be emailed to CDER-OPDP-RPM@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

George Tidmarsh, M.D., Ph.D.
Director
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

CARTER M BEACH
09/09/2025 05:10:57 PM
On behalf of George Tidmarsh, M.D., Ph.D