CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

216023Orig1s000

Trade Name:	POSLUMA
Generic or Proper Name:	flotufolastat F 18
Sponsor:	Blue Earth Diaganostics Ltd.
Approval Date:	May 25, 2023
Indication:	For positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer: • with suspected metastasis who are candidates for initial definitive therapy • with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level

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APPLICATION NUMBER:

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APPROVAL LETTER

NDA 216023

NDA APPROVAL

Blue Earth Diaganostics Ltd.
c/o Biologics Consulting Group Inc.
Attention: Dr. Norman W. Baylor, PhD
100 Daingerfield Rd, Suite 400
Alexandria, VA 22314

Dear Dr. Baylor,

Please refer to the New Drug Application (NDA) dated and received on May 25, 2022, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Posluma (flotufolastat F 18) injection.

This NDA provides for the use of Posluma (flotufolastat F 18) for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer with suspected metastatsis who are candidates for initial definitive therapy or with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level.

APPROVAL & LABELING

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 enclosed agreed-upon labeling.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.[1] Content of labeling must be identical to the enclosed labeling. Information on submitting SPL files using eLIST may be found in the Guidance for Industry *SPL Standard for Content of Labeling Technical Qs and As.*[2]

The SPL will be accessible via publicly available labeling repositories.

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the carton and container labeling submitted on May 22, 2023, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *SPL Standard for Content of Labeling Technical Qs & As.* For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved NDA 216023**." Approval of this submission by FDA is not required before the labeling is used.

DATING PERIOD

Based on the stability data submitted to date, the expiration date and time are provided on the container label. Use Posluma (flotufolastat F 18) injection within 10 hours from end of synthesis when stored at 20ºC to 25ºC.

ADVISORY COMMITTEE

Your application for Posluma (flotufolastat F 18) injection was not referred to an FDA advisory committee because this drug is not the first in its class.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for this application because studies would be impossible or highly impracticable because prostate cancer rarely or never occurs in the pediatric population.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs.*[3]

[3] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the Prescribing Information, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at FDA.gov.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

REPORTING REQUIREMENTS

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

POST APPROVAL FEEDBACK MEETING

New molecular entities qualify for a post approval feedback meeting. Such meetings are used to discuss the quality of the application and to evaluate the communication process during drug development and marketing application review. The purpose is to learn from successful aspects of the review process and to identify areas that could benefit from improvement. If you would like to have such a meeting with us, contact the Regulatory Project Manager for this application.

If you have any questions regarding this NDA, please contact Ms. Thuy M. Nguyen, MPH, Senior Regulatory Health Project Manager at: Thuy.Nguyen@fda.hhs.gov or (301) 796-1427.

Sincerely,

{See appended electronic signature page}

Alex Gorovets, MD
Deputy Director
Office of Specialty Medicine
Center for Drug Evaluation and Research
US Food and Drug Administration

Enclosure:

- Content of Labeling
  - Prescribing Information
- Carton/Container Labeling

[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

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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/

THUY M NGUYEN
05/25/2023 03:45:06 PM

ALEXANDER GOROVETS
05/25/2023 03:47:33 PM