

NDA 208054/S-034

SUPPLEMENT APPROVAL

Dr. Norman W. Baylor, PhD
Biologics Consulting Group, Inc.
1555 King St, Suite #300
Alexandria, VA 22314

Dear Dr. Baylor (for Sponsor: Blue Earth Diagnostics),

Please refer to the Supplemental New Drug Application (sNDA) 208054, dated and received on November 24, 2020, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Axumin® (Fluciclovine F18).

This sNDA includes the patient preparation instructions to void prior to administration of Fluciclovine (F18).

APPROVAL & LABELING

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

We note that your submission of May 21, 2021, includes Final Printed Labeling (FPL) for your Prescribing Information. We have not reviewed this FPL. You are responsible for assuring that the wording in this FPL is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

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 with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in 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 from 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>.

Also within 14 days, amend all pending supplemental applications that include labeling changes 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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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 You must submit final promotional materials and Prescribing Information, 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 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).

SUBMISSION REQUIREMENTS

All formal official submissions should be submitted electronically with a cover letter and applicable FDA Forms, as follows:

The Electronic Common Technical Document (eCTD) is CDER and CBER standard format for electronic regulatory submissions.

For eCTD submissions, the FDA Electronic Submissions Gateway (ESG) is the central transmission point, and you should obtain an ESG account. For additional information, see FDA.gov.⁶

Submissions that do not adhere to the requirements stated in the eCTD Guidance will be subject to rejection. For more information please visit: <http://www.fda.gov/ectd>.

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

⁴ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

⁵ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

⁶ <http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway>

SECURE EMAIL

Secure Email is required for all email communications from the FDA to the Sponsors and / or Sponsor's Authorized Representatives when confidential information is included in the message.

Sponsors and Sponsor's Authorized Representatives must each establish a Secure Email account with the FDA to receive email communications from the FDA that include confidential information (e.g., information requests (IRs), meeting responses, courtesy copies of FDA letters, labeling revisions, trade secrets, manufacturing, or patient information, etc).

To establish a Secure Email with the FDA, send an email request: SecureEmail@fda.hhs.gov.

Note: A secure email may not be used for formal official regulatory submissions.

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}

Libero Marzella, MD, PhD
Division of Imaging and Radiation Medicine (DIRM)
Office of Specialty Medicine
Center for Drug Evaluation and Research
US Food and Drug Administration

Enclosure: Prescribing Information (Labeling)

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
05/21/2021 10:30:03 AM

LIBERO L MARZELLA
05/21/2021 11:29:23 AM