NDA 210089

NDA APPROVAL

Cis Bio International
C/O Curium US LLC
Attention: Ms. Bridget Martin, US Agent
2703 Wagner Place
Maryland Heights, MO 63043

Dear Ms. Martin:

Please refer to your New Drug Application (NDA) dated and received on June 11, 2019, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for Pulmotech MAA (Kit for the Preparation of Technetium Tc99m Albumin Aggregated Injection) for injectable suspension.

This New Drug Application provides for the use of Technetium Tc 99m Albumin Aggregated Injection, a radioactive diagnostic agent, indicated for:

- Lung scintigraphy as an adjunct in the evaluation of pulmonary perfusion in adults and pediatric patients.
- Scintigraphy of peritoneovenous shunt as an aid in the evaluation of its patency in adults.

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.

Additionally, the approved expiration dating period for Pulmotech™ MAA (Kit for the Preparation of Technetium Tc 99m Albumin Aggregated Injection) is 12-months when stored at 2 to 25ºC (36 to 77ºC).

We note that your submission of March 16, 2020, 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 printed labeling 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 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 via publicly available labeling repositories.

We acknowledge your submission of March 16, 2020, containing final printed carton and container labels.

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.

Because none of these criteria apply to your application, you are exempt from this requirement.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the Prescribing Information, Medication Guide, and Patient Package Insert (as applicable) to:

OPDP Regulatory Project Manager
US Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

[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.

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs.*[3]

As required under 21 CFR 314.81(b)(3)(i) (or, beginning on March 23, 2020, under 21 CFR 601.12(f)(4)), 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] For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see FDA.gov.[6]

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81) until 11:59pm on March 22, 2020. On March 23, 2020, this approved NDA will be deemed to be an approved biologics license application (BLA) under section 351(a) of the Public Health Service Act (see section 7002(e)(4)(A) of the Biologics Price Competition and Innovation Act of 2009). Beginning on March 23, 2020, you will be required to comply with reporting requirements for an approved BLA (21 CFR 600.80, 600.81, and 600.14).

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 Director
US FDA - CDER: Division of Medical Imaging and Radiation Medicine

ENCLOSURES:

- Content of Labeling
- Carton and Container Labels

[3] When final, this guidance will represent the FDA's current thinking on this topic. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.
[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/AboutFDA/CentersOffices/CDER/ucm090142.htm

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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
03/20/2020 03:00:05 PM

LIBERO L MARZELLA
03/20/2020 03:04:50 PM