

NDA 21870 / S-015

SUPPLEMENT APPROVAL

The Feinstein Institute for Medical Research
Attention: Dr. Thomas Chaly, PhD
350 Community Dr
Manhasset, New York 11030

Dear Dr. Chaly:

Please refer to the Supplemental New Drug Application (sNDA) 21870 dated June 12, 2018, received June 18, 2018, submitted under 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) [F-18] Fludeoxyglucose Injection.

We also reference your email of June 19, 2019, in which you have agreed to the FDA proposed labeling comments of June 13 and 14, 2019.

This Prior Approval Supplemental New Drug Application provides for:

1. An update to the labeling to be in compliance with the requirements published in the Federal Register on December 4, 2014; namely, the final rule “Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling,” referred to as the “Pregnancy and Lactation Labeling Rule” (PLLR, or final rule, 79 FR 72064).
2. An update to the Manufacturer and Distributor from “The Feinstein Institute for Medical Research / North Shore/LIJ Health System” to “The Feinstein Institute for Medical Research / Northwell Health”

APPROVAL & LABELING

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.

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 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.

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).

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 submissions should be submitted with a cover letter and FDA Forms 356h, 1571, 1572 and 3674 (as applicable).

The Electronic Common Technical Document (eCTD) is CDER and CBER standard format for electronic regulatory submissions. The following submission types: NDA, ANDA, BLA, Master File, Commercial: Pre-INDs, INDs and Exploratory INDs **must be** submitted in eCTD format.

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>.

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>.

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The FDA Electronic Submissions Gateway (ESG) is the central transmission point for sending information electronically to the FDA and enables the secure submission of regulatory information for review. For additional information, see FDA.gov.³

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 Director
Division of Medical Imaging Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Enclosure: Content of Labeling / Prescribing Information

³ <http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway>

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
06/27/2019 02:00:03 PM

LIBERO L MARZELLA
06/27/2019 04:49:47 PM