

NDA 021870/S-018

SUPPLEMENT APPROVAL

The Feinstein Institute for Medical Research Attention: Thomas Chaly Director, Cyclotron-Radiochemistry Department 350 Community Drive Manhasset, NY 11030

Dear Dr. Chaly:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 26, 2022, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Fludeoxyglucose F18 Injection.

This "Changes Being Effected" supplemental new drug application provides for labeling changes as specified in the agency's supplement request letter dated 05/05/2022.

APPROVAL & LABELING

We acknowledge your December 8, 2022, submission. We have completed our review of this supplemental application. 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(I)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the prescribing information) 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 titled *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/GuidanceS/UCM072392.pdf.

The SPL will be accessible via 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

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action letter, with the content of labeling [21 CFR 314.50(I)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, 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).

CARTON AND CONTAINER LABELS

We acknowledge your December 8, 2022, submission containing carton and container labeling.

REPORTING REQUIREMENTS

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

If you have any questions, call Teicher Agosto, Regulatory Business Process Manager, at (240) 402 - 3777.

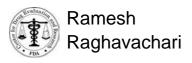
Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D., Chief, Branch I Division of Post-Marketing Activities I Office of Lifecycle Drug Products Office of Pharmaceutical Quality Center for Drug Evaluation and Research

Enclosure(s):

Carton and Container Labeling



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Digitally signed by Ramesh Raghavachari Date: 11/09/2023 03:27:00PM GUID: 502d0913000029f375128b0de8c50020