CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

NDA 21-768

Approval Letter(s)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-768

Weill Medical College of Cornell University
Citigroup Biomedical Imaging Center
Attention: Shankar Vallabhajosula, Ph.D.
516 East 72nd Street
New York, NY 10021

Dear Dr. Vallabhajosula:

Please refer to your new drug application (NDA) dated March 10, 2004, received March 24, 2004, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Fludeoxyglucose F 18 Injection.

We acknowledge receipt of your submissions dated March 10, 11, and 23; April 22; May 24 and 25; June 24 and 30; July 13; and August 2, 2004.

This new drug application provides for the use of Fludeoxyglucose F 18 Injection:

1. In positron emission tomography (PET) imaging for assessment of abnormal glucose metabolism to assist in the evaluation of malignancy in patients with known or suspected abnormalities found by other testing modalities, or in patients with an existing diagnosis of cancer.
2. In positron emission tomography (PET) imaging in patients with coronary artery disease and left ventricular dysfunction, when used together with myocardial perfusion imaging, for the identification of left ventricular myocardium with residual glucose metabolism and reversible loss of systolic function.
3. In positron emission tomography (PET) imaging in patients for the identification of regions of abnormal glucose metabolism associated with foci of epileptic seizures.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, immediate container and carton labels). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-768**." Approval of this submission by FDA is not required before the labeling is used.

If you choose to use a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are deferring submission of your pediatric studies for the cardiac and oncology indications for ages ≥ 1 year to 16 years until August 5, 2014.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required post-marketing study commitments. The status summary of these post-marketing studies shall be reported annually according to 21 CFR 314.81, and should include expected summary completion and final report submission dates, any changes in plans since the last annual report. These commitments are listed below.

1. Deferred pediatric studies under PREA for the cardiac and oncology indications in pediatric patients ages ≥ 1 year to 16 years old.

   Final Report Submission: August 5, 2014

Submit pediatric post-marketing study commitment protocols and all study final reports to this NDA. All submissions, including supplements, relating to these pediatric post-marketing study commitments must be prominently labeled **"Pediatric Post-marketing Study Protocol", "Pediatric Post-marketing Study Final Report", or "Pediatric Post-marketing Study Correspondence."**

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this Division (HFD-160) and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications
Food and Drug Administration
5600 Fishers Lane, HFD-42
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

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 Thuy M. Nguyen, M.P.H., Regulatory Health Project Manager, at (301) 827-7510.

Sincerely,

{See appended electronic signature page}

George Q. Mills, M.D., M.B.A.
Division Director
Division of Medical Imaging and
Radiopharmaceutical Drug Products, HFD-160
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

George Mills
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