CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

NDA 21-443

Medical Review(s)

DIVISION DIRECTOR'S SUMMARY MEMO TO FILE

DATE OF REVIEW: August 5, 2004

NDA: 21-768

DRUG: Fludeoxyglucose F 18 Injection

SUBMISSION DATE: March 10, 2004

USER FEE GOAL DATE: January 24, 2005

CATEGORY: Original NDA

SPONSOR: Weill Medical College of Cornell University
Citigroup Biomedical Imaging Center

RELATED DMF: 16623

REVIEW TEAM:

Chemistry:	R.Kasliwal/E.Leutzinger
Microbiology:	B.Riley/P.Cooney
Project Mgt:	T.Nguyen

BACKGROUND

Under the current law [section 121(c)(2) of the Food and Drug Administration Modernization Act (FDAMA) and section 501(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act], PET producers may continue to produce compounded PET drug products without FDA approval until two years after the date that the FDA completes its new approval procedures and current good manufacturing practice regulations for PET products, as long as the activities are within the meaning of the term "compounded positron emission tomography drug" and are in compliance with the USP General Chapter <823> titled "Radiopharmaceuticals for Positron Emission Tomography - Compounding" and any applicable USP monographs.

However, the PET provisions of FDAMA encourage the voluntary submission of such applications. The Weill Medical College of Cornell University, Citigroup Biomedical Imaging Center has taken the initiative of seeking NDA approval at this time for Fludeoxyglucose F 18 Injection.

SUMMARY

The NDA process has incorporated a chemistry review, microbiology review, and onsite inspection.

CHEMISTRY REVIEW

The primary chemistry review has been performed by Ravindra K. Kasliwal, Ph.D. His primary chemistry review has been concurred on the secondary review by the chemistry Team Leader, Eldon Leutzinger, Ph.D.

The chemistry review recommendations and conclusions for approvability are the following:

- The application is recommended for approval action for manufacturing and controls under section 505 of the Act.

- Manufacturing facilities were inspected on June 15 and June 16, 2004, and have been determined to be in acceptable compliance with the currently applicable standards for PET drugs products (i.e., USP chapter <823>).

- No recommendations were given for Phase 4 (Post-Marketing) commitments, agreements and/or risk management steps.

MICROBIOLOGY REVIEW

The microbiology review has been performed by Bryan S. Riley, Ph.D., and his primary microbiology review has been concurred on the secondary review by the microbiology Team Leader, Peter Cooney, Ph.D.

The microbiology review recommendations and conclusions for approvability are the following:

- This submission is recommended for approval on the basis of product quality microbiology.

- No recommendations were given on Phase 4 commitments and/or agreements.

EXCLUSIVITY SUMMARY

The Exclusivity Summary Checklist has been completed and this approval is for a single active ingredient product.

Previously approved under section 505 of the Act: NDA# 20-306: Fludeoxyglucose F 18 Injection.

PEDIATRIC PAGE

As noted, each of the approved indications must have pediatric studies.

A deferral, based on too few children with disease to study, has been granted with a due date for completion of studies by August 5, 2014, for the following two indications:

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.

Pediatric studies have been completed for the third indication listed below:

3. In positron emission tomography (PET) imaging in patients for the identification of regions of abnormal glucose metabolism associated with foci of epileptic seizures.

DIVISION DIRECTOR'S SUMMARY COMMENTS

A. I concur with the chemistry and the microbiology review comments and recommendations as stated in these reviews.

B. I concur with the pediatric study deferral for the stated two indications.

C. I concur with the Exclusivity Summary.

REGULATORY ACTION

A. Approval, effective the date of the regulatory action letter for the stated three indications for use as recommended in the agreed-upon labeling text:

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.

B. The 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.

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

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/s/

George Mills
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MEDICAL OFFICER