Attachment III

Sample Formats —
Form FDA 356h

for

Ammonia N 13 Injection
Fleudioxyglucose F 18 Injection (FDG F 18)
and
Sodium Fluoride F 18 Injection

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: April 30, 2000
See OMB Statement on page 2.

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
TELEPHONE NO. *(Include Area Code)*	FACSIMILE (FAX) Number *(Include Area Code)*
APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued):*	AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP Code telephone & FAX number)* IF APPLICABLE

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (If previously issued)

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*	PROPRIETARY NAME *(trade name)* IF ANY
Fludeoxyglucose F 18 Injection	

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)*	CODE NAME *(If any)*

DOSAGE FORM: **Sterile, Pyrogen Free Injection**	STRENGTHS: _____**mCi/mL**	ROUTE OF ADMINISTRATION: **Intravenous**

(PROPOSED) INDICATION(S) FOR USE: 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 diagnoses 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.

APPLICATION INFORMATION

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☐ BIOLOGICS LICENSE APPLICATION (21 CFR part 601)

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☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ SUPAC SUPPLEMENT
☐ EFFICACY SUPPLEMENT ☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☐ OTHER

REASON FOR SUBMISSION **Complete new application that has never before been submitted**

PROPOSED MARKETING STATUS *(check one)* ☒ PRESCRIPTION PRODUCT (Rx) ☐ OVER THE COUNTER PRODUCT (OTC)

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(Title 21, Code of Federal Regulations, 314 & 601)

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Sodium Fluoride F 18 Injection	

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)*	CODE NAME *(If any)*

DOSAGE FORM: **Sterile, Pyrogen Free Injection**	STRENGTHS: _____**mCi/mL**	ROUTE OF ADMINISTRATION: **Intravenous**

(PROPOSED) INDICATION(S) FOR USE: **In Positron Emission Tomography for bone imaging agent to define areas of altered osteogenic activity**

APPLICATION INFORMATION

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CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)* | CODE NAME *(If any)*

DOSAGE FORM: **Sterile, Pyrogen Free Injection**	STRENGTHS: _____**mCi/mL**	ROUTE OF ADMINISTRATION: **Intravenous**

(PROPOSED) INDICATION(S) FOR USE**: For positron emission tomographic (PET) imaging of the myocardium under rest or pharmacologic stress conditions to evaluate myocardial perfusion in patients with suspected or existing coronary artery disease.**

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