Attachment II

Sample Formats—

Form FDA 356h

for

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

Date: 25-Jan-2011
APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

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

APPLICANT INFORMATION

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PRODUCT DESCRIPTION

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

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_Route of Administration:

Injection

Intravenous

(PROPOSED) INDICATION(S) FOR USE: In Positron Emission Tomography for ...

APPLICATION DESCRIPTION

APPLICATION TYPE

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<tr>
<th>(check one)</th>
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IF AN NDA, IDENTIFY THE APPROPRIATE TYPE

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IF AN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION

Name of Drug

Holder of Approved Application

TYPE OF SUBMISSION (check one)

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IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION:

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<th>CBE</th>
<th>CBE-30</th>
<th>Prior Approval (PA)</th>
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REASON FOR SUBMISSION: Complete new application that has never before been submitted.

PROPOSED MARKETING STATUS (check one)

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NUMBER OF VOLUMES SUBMITTED

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ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of the Application.)

Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

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1. Index
2. Labeling (check one) √ Draft Labeling   □ Final Printed Labeling
3. Summary (21 CFR 314.50 (c))
4. Chemistry section
   A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)
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14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b)(2) or (j)(2)(A))
15. Establishment description (21 CFR Part 600, if applicable)
16. Debarment certification (FD&C Act 308 (k)(1))
17. Field copy certification (21 CFR 314.50 (l)(3))
18. User Fee Cover Sheet (Form FDA 3397)
19. Financial Information (21 CFR Part 54)
20. OTHER (Specify)

CERTIFICATION
I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:
1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 608, and/or 820.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
7. Local, state, and Federal environmental impact laws.
If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.
The data and information in this submission have been reviewed and, to the best of my knowledge, are certified to be true and accurate.

Signatures:

Name: ____________________________  Title: ____________________________

Address: __________________________

Telephone Number: __________________________

Public reporting burden for this collection of information is estimated to average 24 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.
APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(TITLE 21, CODE OF FEDERAL REGULATIONS, PARTS 314 & 601)

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Sodium Fluoride F 18 Injection none

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DOSEAGE FORM:

ROUTE OF ADMINISTRATION:

Intravenous

(APPROVED) INDICATION(S) FOR USE:

In Positron Emission Tomography for ...

APPLICATION DESCRIPTION

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FORM FDA 356h (10/05) PAGE 1 OF 4
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**CODE NAME** (If any)  

**POSAL FORM**  

**STRENGTHS:**  

**ROUTE OF ADMINISTRATION:**  

**(PROPOSED) INDICATION(S) FOR USE:**  

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- 505 (b)(2)  

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- LABELING SUPPLEMENT  
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- OTHER  

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