DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22119/S-001

SUPPLEMENT APPROVAL

The Feinstein Institute for Medical Research
North Shore/LIJ Health System
Cyclotron/Radiochemistry Facility
Attention: Thomas Chaly, Ph.D.
350 Community Drive
Manhasset, NY 11030

Dear Dr. Chaly:

Please refer to your Supplemental New Drug Application (sNDA) dated December 22, 2010, received December 23, 2010, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ammonia [N-13] Injection.

This "Prior Approval" supplemental new drug application provides for changes within Section 11 text and Table 3, as discussed during the teleconference of December 15 and outlined in the FDA Information Request of December 17, 2010.

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements and any 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/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes approved in this supplemental application.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

REPORTING REQUIREMENTS

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

SUBMISSION REQUIREMENTS

All submissions regarding NDA 22119, should be submitted in *triplicate* hard copies (one original plus two desk copies) with a cover letter and Form FDA 356(h), along with **an electronic copy on CD-Rom (PDF)**, as with all submissions to the FDA CDER – Division of Medical Imaging Products, as follow:

Courier/Overnight/Postal
Rafel Dwaine Rieves, M.D., Director
Division of Medical Imaging Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Attention: FDA Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

Or solely electronic submission via Gateway / Global Submit Review (GSR) – See the following links for information:

http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm

http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm153574.htm

If you have any questions regarding NDA 22119, contact Ms. Thuy Nguyen, M.P.H., Senior Regulatory Health Project Manager at (301) 796-1427 or Thuy.Nguyen@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Rafel Dwaine Rieves, M.D.
Director
Division of Medical Imaging Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

ENCLOSURE: Content of Labeling

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

/s/

THUY M NGUYEN
01/05/2011

RAFEL D RIEVES
01/05/2011