DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 203665

Houston Cyclotron Partners LP
Attention: Carrie Staton, PharmD
8285 El Rio #160
Houston, TX 77054

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 8, 2011, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Fludeoxyglucose F18 Injection USP, 20-500 mCi/mL at EOS.

Reference is also made to your amendments dated March 1, August 28, September 19, October 19, November 26, and December 14, 2012, and to the suitability petition submitted under section 505(j)(2)(c) of the Act and approved by the agency on May 20, 2011. This petition permits the agency to file this ANDA for a drug product that differs in strength (total drug content) from that of the reference listed drug product (RLD). Specifically, your product provides 20-500 mCi/mL of Fludeoxyglucose F18 Injection, USP at EOS in comparison to the RLD product of Feinstein Institute for Medical Research which provides 20-300 mCi/mL of Fludeoxyglucose F18 Injection, USP at EOS.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined that your Fludeoxyglucose F18 Injection, USP can be expected to have the same therapeutic effect as that of an equivalent dose of the reference listed drug product (RLD) upon which the agency relied as the basis of safety and effectiveness.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Office of Prescription Drug Promotion with a completed Form FDA 2253 at the time of their initial use.

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 in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). 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 via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Gregory P. Geba, M.D., M.P.H.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

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

/s/

ROBERT L WEST

02/14/2013

Deputy Director, Office of Generic Drugs, for
Gregory P. Geba, M.D., M.P.H.