DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202158/S-003

SUPPLEMENT APPROVAL

NorthStar Medical Radioisotopes, LLC
Attention: James W. Brodack, PhD, RAC (US, Global)
Vice President Regulatory Affairs/Quality Assurance
1800 Gateway Blvd
Beloit, WI 53511

Dear Dr. Brodack:

Please refer to your Supplemental New Drug Application (sNDA) dated March 23, 2018, received March 23, 2018, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for RadioGenix System (Technetium Tc99m generator) injection, 6Ci.

This "Changes Being Effected" new drug application provides for the following changes:

Updated package insert to include the following:

- 2.5 RadioGenix System Maintenance
  - Added Discarded Material, Type A Kit for the RadioGenix System (p/n 40P06162)
  - Updated part number for Source Vessel Kit for RadioGenix System
- 2.6 Directions for Eluting RadioGenix System
  - Item 1 – Updated part number for Source Vessel Kit for RadioGenix System
- 16.1 How Supplied
  - Table 13 – Updated part numbers for Source Vessel Kit for RadioGenix System, catheter, and manifold
  - Table 17 – Added Discarded Material, Type A Kit for RadioGenix System and note below table
- 16.2 Storage and Handling, Storage section
  - Updated part number for Source Vessel Kit for RadioGenix System
  - Added Discarded Material, Type A Kit for RadioGenix System (p/n 40P06162)
- Added document number and revision to end of the package insert

Updated Operator's Guide to include the following:

- Added note to Discarded Material Kit for RadioGenix System table
- Kits Compatible with the RadioGenix System section
  - Added Discarded Material Kit Type A for RadioGenix System (p/n 40P06162)
  - Updated part number for Source Vessel Kit for RadioGenix System

APPROVAL & LABELING

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.

We note that your March 23, 2018, submission includes final printed labeling (FPL) for your package insert. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as 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 that include labeling changes 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, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

REPORTING REQUIREMENTS

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

If you have any questions, call Alberta Davis-Warren, Regulatory Project Manager, at (301) 796-3908.

Sincerely,

{See appended electronic signature page}

Libero Marzella, MD, PhD
Director
Division of Medical Imaging Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
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/

LIBERO L MARZELLA
05/22/2018