NDA 202158/S-017

SUPPLEMENT APPROVAL

NorthStar Medical Radioisotopes, LLC
Attention: Kiel J. Johnson
Regulatory Affairs Supervisor
1800 Gateway Blvd
Beloit, WI 53511

Dear Mr. Johnson:

Please refer to your supplemental new drug application (sNDA) dated April 15, 2021, received April 15, 2021, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for RadioGenix System (technetium Tc 99m generator) solution.

This "Changes Being Effected" sNDA provides for removing from the labeling the text that references discarding the first elution from every new Potassium Molybdate Mo-99 Source Vessel in the dosage and administration section and the warning regarding "Unintended Re-186 Exposure".

APPROVAL & LABELING

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

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 FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information), 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.

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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).

Submit the final user manual Operator Guide that is identical to the user manual Operator Guide submitted on July 1, 2021, as soon as it is available, but no more than 30 days after they are printed.

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.

FULFILLMENT OF POSTMARKETING REQUIREMENT(S)/COMMITMENT(S)

We have received your submission dated June 11, 2021, containing the final report for the following postmarketing commitment listed in the October 1, 2019, approval letter.

3722-2 Determine and monitor the amount of Re-186 present in Potassium Molybdate Mo-99 Source Vessels that will be used in the RadioGenix System, following a sampling plan representing different sublots of molybdenum target disks. Establish an acceptable range of Re-186 in the source vessel which can ensure limiting Re-186 in the Tc-99m product to a level that meets USP requirements for all other beta and gamma-

[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

emitting radionuclidic impurities. Propose periodic testing of Mo-99 source vessels after the establishment of Re-186 specification.

We have reviewed your submission and concluded that the above commitment was fulfilled.

We remind you that there are postmarketing requirements and postmarketing commitments listed in the February 8, 2018 and October 1, 2019 letters that are still open.

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, M.D., Ph.D.
Director
Division of Imaging and Radiation Medicine
Office of Specialty Medicine
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

LIBERO L MARZELLA
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