U.S. FOOD & DRUG ADMINISTRATION

ND A219189

ANDA APPROVAL

Ionetix Corporation
ttention: Jill Wilson
Vice President, R AQ

Dear Jill Wilson:

This letter is in reference to your abbreviated new drug application (ND A) received for review on May 29, 2024, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic ct (FD&C ct) for Gallium Ga 68 Gozetotide Injection, 18.5 MBq/mL to 185 MBq/mL (0.5 mCi/mL to 5 mCi/mL) Single-Dose Pre-filled Syringe.

Your product is a combination product as defined by 21 CFR 3.2(e) and is comprised of drug and device constituent parts.

Reference is also made to any amendments submitted prior to the issuance of this letter.

We have completed the review of this ND Aand have concluded that adequate information has been presented to demonstrate that the drug meets the requirements for approval under the FD&C ct. ccordingly the ND Ais **approved**, effective on the date of this letter. We have determined your Gallium Ga 68 Gozetotide Injection, 18.5 MBq/mL to 185 MBq/mL (0.5 mCi/mL to 5 mCi/mL) Single-Dose Pre-filled Syringe to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Gallium Ga 68 Gozetotide Injection, 18.5 MBq/mL to 185 MBq/mL (0.5 mCi/mL to 5 mCi/mL) of UCSF Radiopharmaceutical Facility, ND A- 212643.

Please note that if FD Arequires a Risk Evaluation and Mitigation Strategy (REMS) for a listed drug, an ND Areferencing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C ct.

COMPENDIAL STANDARDS

drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standard for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C ct § 501(b), 21 USC 351(b)). FD Atypically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise

official USP monographs. More information on the USP-NF is available on USP's website at https://www.uspnf.com/.

REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL

Under applicable statutes, regulations, and guidances, your ANDA may be subject to certain requirements and recommendations post approval, including requirements for labeling changes to approved ANDAs, postmarketing reporting, promotional materials, and annual facility fees, among others. For information on post-approval requirements and recommendations for ANDAs and a list of resources for ANDA holders, we refer you to https://www.fda.gov/drugs/buying-using-medicine-safely/postmarketing-requirements-and-resources-approved-drugs.

Sincerely yours,

{See appended electronic signature page}

For Kendra S. Stewart, R.Ph., PharmD.
CAPT, United States Public Health Service
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

Catherine l
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