ANDA 217193

ANDA APPROVAL

InvaGen Pharmaceuticals, Inc.
550 South Research Place
Central Islip, NY 11722
Attention: Krishna Kilgore Velaga
Director of Regulatory Affairs

Dear Krishna Kilgore Velaga:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on April 13, 2022, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Lanreotide Injection, 60 mg/0.2 mL, 90 mg/0.3 mL, and 120 mg/0.5 mL, Single-Dose Prefilled Syringes.

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 the complete response letter issued by this office on May 16, 2023, and to any amendments thereafter.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug meets the requirements for approval under the FD&C Act. Accordingly the ANDA is **approved**, effective on the date of this letter. We have determined your Lanreotide Injection, 60 mg/0.2 mL, 90 mg/0.3 mL, and 120 mg/0.5 mL, Single-Dose Prefilled Syringes to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Somatuline Depot Injection, 60 mg/0.2 mL, 90 mg/0.3 mL, and 120 mg/0.5 mL of Ipsen Pharma.

Reference is also made to FDA's Competitive Generic Therapy Designation – Grant letter dated May 2, 2022.

We note that InvaGen Pharmaceuticals, Inc. (InvaGen) was granted a Competitive Generic Therapy (CGT) designation for Lanreotide Injection, 60 mg/0.2 mL, 90 mg/0.3 mL, and 120 mg/0.5 mL, Single-Dose Prefilled Syringes. However, as noted in the May 2, 2022, CGT Designation – Grant Letter, your drug products are not eligible for CGT exclusivity under section 505(j)(5)(B)(v) of the FD&C Act because there were unexpired patents or exclusivities listed in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book) for the RLD at the time of submission of your ANDA.

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

COMPENDIAL STANDARDS

A 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 Act § 501(b), 21 USC 351(b)). FDA typically 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 as 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 regarding 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/abbreviated-new-drug-application-anda/requirements-and-resources-approved-andas.

Sincerely yours,

{See appended electronic signature page}

For Edward M. Sherwood
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

John Ibrahim

Digitally signed by John Ibrahim
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