



ANDA 215503

**ANDA APPROVAL**

Hikma Pharmaceuticals USA, Inc.  
703 Palomar Airport Road  
Suite 280  
Carlsbad, CA 92011  
Attention: Jonathan Endo  
Regulatory Affairs Manager

Dear Jonathan Endo:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on September 8, 2021, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Liraglutide Injection, 18 mg/3 mL (6 mg/mL) Single-Patient-Use Prefilled Pens.

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 tentative approval letter issued by this office on June 21, 2024, 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 Liraglutide Injection, 18 mg/3 mL (6 mg/mL) Single-Patient-Use Prefilled Pens to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Victoza Injection, 18 mg/3 mL (6 mg/mL), of Novo Nordisk, Inc. (Novo), NDA - 022341.

The RLD upon which you have based your ANDA, Novo's Victoza Injection, 18 mg/3 mL (6 mg/mL), is subject to periods of patent protection. The following patents and expiration dates (with pediatric exclusivity added) are currently listed in the Agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"):

<u>U.S. Patent Number</u>	<u>Expiration Date</u>
8,114,833 (the '833 patent)	February 13, 2026
9,265,893 (the '893 patent)	March 23, 2033
9,968,659 (the '659 patent)	July 9, 2037

Your ANDA contains paragraph IV certifications to the '833 and '893 patents, under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Liraglutide Injection, 18 mg/3 mL (6 mg/mL) Single-Patient-Use Prefilled Pens, under this ANDA. You have notified the Agency that Hikma Pharmaceuticals USA, Inc. (Hikma) complied with the requirements of section 505(j)(2)(B) of the FD&C Act. Litigation was initiated within the statutory 45-day period against Hikma for infringement of the '833 and '893 patents in the United States District Court for the District of Delaware [Novo Nordisk Inc. and Novo Nordisk A/S v. Hikma Pharmaceuticals USA Inc., Civil Action No. 21-01783]. You have also notified the Agency that this case was dismissed.

With respect to the '659 patent, your ANDA contains a statement under section 505(j)(2)(A)(viii) of the FD&C Act that this is a method-of-use patent that does not claim any indication or other conditions of use for which you are seeking approval under 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



Paul  
Levine

Digitally signed by Paul Levine

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