NDA 019886/S-040

SUPPLEMENT APPROVAL

Pfizer, Inc.
Attention: Michelle Patel
Senior Manager, Pfizer Global Regulatory Affairs
66 Hudson Boulevard East
New York, NY 10001

Dear Michelle Patel:

Please refer to your supplemental new drug application (sNDA) dated and received November 10, 2025, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Synarel (nafarelin acetate).

We also refer to our letter dated June 12, 2025, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we have determined should be included in the labeling for the class of gonadotropin-releasing hormone (GnRH) agonists. This information pertains to the potential risk of serious risk of severe cutaneous adverse reactions.

This supplemental new drug application provides for revisions to the labeling for Synarel consistent with our June 12, 2025, Safety Labeling Change notification letter and as amended in our information request dated October 15, 2025, and the labeling comments issued on November 6, 2025.

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, Instructions for Use and Medication Guide 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.

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 supplemental application, you are exempt from this requirement.

PROMOTIONAL MATERIALS

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.[3] Information and Instructions for completing the form can be found at FDA.gov.[4]

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety- related information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety-related information that appears in the revised labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4).

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, contact Margaret Kober, Chief, Regulatory Project Management Staff, at 301-796-0934.

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[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database at: https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.
[3] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

Sincerely,

{See appended electronic signature page}

Aisha P. Johnson, MD, MPH, MBA
Deputy Director of Safety
Division of Urology, Obstetrics and Gynecology
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Instructions for Use
  - Medication Guide

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/

AISHA P JOHNSON
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