



NDA 213150/S-007

SUPPLEMENT APPROVAL

Tolmar International Limited
c/o Tolmar, Inc.
Attention: Renu Gambhir, PhD
Senior Director, Regulatory Affairs
701 Centre Ave
Fort Collins, CO 80526

Dear Dr. Gambhir:

Please refer to your Supplemental New Drug Application (sNDA) dated and received November 6, 2024, and your amendments, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Fensolvi (leuprolide acetate) for injectable suspension.

This Prior Approval Supplemental New Drug Application provides for changes to the packaging and container labels for Fensolvi (leuprolide acetate) to remove fill weights, and to only list the net quantity of contents.

APPROVAL & LABELING

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

CARTON AND CONTAINER LABELS

We acknowledge your April 14, 2025, submission containing final printed carton and container labeling.

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 Oluwafunmike (Funke) Ajomale, Regulatory Business Process Manager, at oluwafunmike.ajomale@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Supervisor
Division of Product Quality Assessment IV
Office of Product Quality Assessment I
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):

Carton and Container Labeling



Ramesh
Raghavachari

Digitally signed by Ramesh Raghavachari
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