See List of Applications

SUPPLEMENT APPROVAL

Tolmar, Inc.
Attention: Renu Gambhir, PhD
Senior Director, Regulatory Affairs
701 Centre Avenue
Fort Collins, CO 80526

Dear Dr. Gambhir:

Please refer to your supplemental New Drug Application(s) (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following products:

Supplemental Application	Product Information	Submit Date	FDA Received Date
NDA 021343/S-055	Eligard (leuprolide acetate) for injectable suspension, 7.5 mg	August 27, 2024	August 27, 2024
NDA-021379/S-058	Eligard (leuprolide acetate) for injectable suspension, 22.5 mg	August 27, 2024	August 27, 2024
NDA-021488/S-052	Eligard (leuprolide acetate) for injectable suspension, 30 mg	August 27, 2024	August 27, 2024
NDA-021731/S-055	Eligard (leuprolide acetate) for injectable suspension, 45 mg	August 27, 2024	August 27, 2024

These Prior Approval supplemental new drug applications provide for changes to the packaging and container labels for all strengths of Eligard to remove fill weights, and to only list the net quantity of contents.

APPROVAL & LABELING

We have completed our review of these supplemental applications. They are 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

http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (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.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in these supplemental applications, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

CARTON AND CONTAINER LABELS

Submit final printed carton and container labels that are identical to enclosed carton and container labels and carton and container labels submitted on August 27, 2024, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 021343/S-055, NDA-021379/S-058, NDA-021488/S-052 and NDA-021731/S-055.**" Approval of this submission by FDA is not required before the labeling is used.

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 Utkarsh Desai, Regulatory Business Process Manager, at Utkarsh.Desai@fda.hhs.gov or (301) 796 - 8114.

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
- Syringe A and Syringe B Labeling

Ramesh Raghavachari

Digitally signed by Ramesh Raghavachari
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