BLA 761480

BLA APPROVAL

Lupin Limited (Biotech Division)
c/o Lupin Pharmaceuticals, Inc.
Attention: Debashis Mohanty
Director - RA
400 Campus Drive
Somerset, NJ 08873

Dear Debashis Mohanty:

Please refer to your biologics license application (BLA) received June 2, 2025, and your amendments, submitted under section 351(k) of the Public Health Service Act for Ranluspec (ranibizumab-hkdz) injection.

This BLA seeks licensure of Ranluspec (ranibizumab-hkdz) biosimilar to and interchangeable with US-Lucentis (ranibizumab injection) as follows:

- Ranluspec (ranibizumab-hkdz) 0.3 mg (0.05 mL of 6 mg/mL) injection, for intravitreal use in a single-dose glass vial as biosimilar to and interchangeable with US-Lucentis (ranibizumab injection) 0.3 mg (0.05 mL of 6 mg/mL) injection, for intravitreal use in a single-dose prefilled syringe (PFS).
- Ranluspec (ranibizumab-hkdz) 0.5 mg (0.05 mL of 10 mg/mL) injection, for intravitreal use in a single-dose glass vial as biosimilar to and interchangeable with US-Lucentis (ranibizumab injection) 0.5 mg (0.05 mL of 10 mg/mL) injection, for intravitreal use in a single-dose PFS.
- Ranluspec (ranibizumab-hkdz) 0.3 mg (0.05 mL of 6 mg/mL) injection, for intravitreal use in a single-dose PFS as biosimilar to and interchangeable with US-Lucentis (ranibizumab injection) 0.3 mg (0.05 mL of 6 mg/mL) injection, for intravitreal use in a single-dose PFS.
- Ranluspec (ranibizumab-hkdz) 0.5 mg (0.05 mL of 10 mg/mL) injection, for intravitreal use in a single-dose PFS as biosimilar to and interchangeable with US-Lucentis (ranibizumab injection) 0.5 mg (0.05 mL of 10 mg/mL) injection, for intravitreal use in a single-dose PFS.

LICENSING

We have approved your BLA for Ranluspec (ranibizumab-hkdz) effective this date. You are hereby authorized to introduce or deliver for introduction into interstate commerce, Ranluspec under your existing Department of Health and Human Services U.S. License No. 2052. Ranluspec is indicated for neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema,

diabetic retinopathy, myopic choroidal neovascularization.

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture Ranluspec drug substance at Lupin Limited (Biotech Division) in Pune, Maharashtra, India. The final formulated drug product will be manufactured, filled, labeled, and packaged at Lupin Limited in Nagpur, Maharashtra, India, with an additional labeling and secondary packaging at (b) (4) You may label your product with the proprietary name, Ranluspec, and market it in both single-dose vial and single-dose prefilled syringe (PFS) presentations for intravitreal injection. The single dose vial is provided as 10 mg/mL (2.3 mg in 0.23 mL) and 6 mg/mL (1.38 mg in 0.23 mL) in 2 mL glass vials. The PFS presentation is provided as 10 mg/mL (1.65 mg in 0.165mL) and 6 mg/mL (0.99 mg in 0.165 mL) in 0.5 mL single use (b) (4) luer lock syringe, featuring an ink dose mark of 50 and a stopper. Both the vial and PFS presentations allow for delivery of either 0.5 mg or 0.3 mg doses in 0.05 mL injection volume.

DATING PERIOD

The dating period for Ranluspec vials shall be 36 months from the date of manufacture when stored at 5 ± 3°C. The dating period for Ranluspec PFS shall be 12 months from the date of manufacture when stored at 5 ± 3°C. The date of manufacture shall be defined as the date of final sterile filtration of the formulated drug product. The dating period for your drug substance shall be (b) (4) months from the date of manufacture when stored at (b) (4) °C.

Results of ongoing stability studies should be submitted throughout the dating period, as they become available, including the results of stability studies from the first three production lots.

Any changes in the manufacturing, testing, packaging, or labeling of Ranluspec, or in the manufacturing facilities, will require the submission of information to your BLA for our review and written approval, consistent with 21 CFR 601.12.

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, via the FDA automated drug registration and listing system (eLIST), the content of labeling

[21 CFR 601.14(b)] in structured product labeling (SPL) format.[1] Content of labeling must be identical to the enclosed labeling text for the Prescribing Information. Information on submitting SPL files using eLIST may be found in guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to 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 "**Final Printed Carton and Container Labeling for approved BLA 761480**." Approval of this submission by FDA is not required before the labeling is used.

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(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We have determined that, at this time, no pediatric studies will be required under PREA for your BLA.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs*.

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

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[1] See http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[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.

601.12(f)(4)]. Form FDA 2253 is available at FDA.gov.[3] Information and Instructions for completing the form can be found at FDA.gov.[4]

REPORTING REQUIREMENTS

You must submit adverse experience reports under the adverse experience reporting requirements at 21 CFR 600.80.

Prominently identify all adverse experience reports as described in 21 CFR 600.80.

You must submit distribution reports under the distribution reporting requirements at 21 CFR 600.81.

You must submit reports of biological product deviations under 21 CFR 600.14. You should promptly identify and investigate all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution. If the deviation involves a distributed product, may affect the safety, purity, or potency of the product, and meets the other criteria in the regulation, you must submit a report on Form FDA 3486 to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Compliance Risk Management and Surveillance
5901-B Ammendale Road
Beltsville, MD 20705-1266

Biological product deviations, sent by courier or overnight mail, should be addressed to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Compliance Risk Management and Surveillance
10903 New Hampshire Avenue, Bldg. 51, Room 4207
Silver Spring, MD 20903

Your product is a Part 3 combination product (21 CFR 3.2(e)); therefore, you must also comply with postmarketing safety reporting requirements for an approved combination product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at FDA.gov.

[3] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

If you have any questions, contact Lois Almoza, MS, Acting, Chief Project Management Staff, at (240) 402-5146 or Lois.Almoza@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

William M. Boyd, MD
Division of Ophthalmology
Office of Specialty Medicine
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
- Carton and Container Labeling

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/

WILLIAM M BOYD
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