BLA 761406/Original 2

BLA APPROVAL

Biocon Biologics Inc.
Attention: Raja Sekhar Vanga
Vice President – Regulatory Affairs
245 Main St, 2nd Floor
Cambridge, MA 02142

Dear Raja Sekhar Vanga:

Please refer to your biologics license application (BLA) dated and received November 29, 2023, and your amendments, submitted under section 351(k) of the Public Health Service Act for Yesintek (ustekinumab-kfce) injection.

We acknowledge receipt of your amendment dated January 15, 2025, which constituted a request for approval following our November 29, 2024, provisional determination letter.

BLA 761406 initially provided for:

- Yesintek (ustekinumab-kfce) injection 45 mg/0.5 mL single-dose prefilled syringe for subcutaneous use as biosimilar to and interchangeable with Stelara (ustekinumab) injection 45 mg/0.5 mL single-dose prefilled syringe for subcutaneous use,
- Yesintek (ustekinumab-kfce) injection 45 mg/0.5 mL single-dose vial for subcutaneous use as biosimilar to and interchangeable with Stelara (ustekinumab) injection 45 mg/0.5mL single-dose vial for subcutaneous use,
- Yesintek (ustekinumab-kfce) injection 90 mg/mL single-dose prefilled syringe for subcutaneous use as biosimilar to and interchangeable with Stelara (ustekinumab) injection 90 mg/mL single-dose prefilled syringe for subcutaneous use, and
- Yesintek (ustekinumab-kfce) injection 130 mg/26 mL single-dose vial for intravenous use as biosimilar to and interchangeable with Stelara (ustekinumab) injection 130 mg/26 mL single-dose vial for intravenous use.

For administrative purposes, BLA 761406 was split as follows:

- BLA 761406/Original 1 – biosimilarity
- BLA 761406/Original 2 – interchangeability

The subject of this correspondence is BLA 761406/Original 2. A separate correspondence was issued for BLA 761406/Original 1 on November 29, 2024.

LICENSING

We have approved BLA 761406/Original 2 for Yesintek (ustekinumab-kfce) as interchangeable biosimilar products effective this date. You are hereby authorized to introduce or deliver for introduction into interstate commerce, Yesintek, under your existing Department of Health and Human Services U.S. License No. 2324.

Yesintek is indicated for treatment of:

Adult patients with:

- moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy
- active psoriatic arthritis (PsA)
- moderately to severely active Crohn's disease (CD)
- moderately to severely active Ulcerative colitis (UC)

Pediatric patients 6 years and older with:

- moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy
- active psoriatic arthritis (PsA)

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture ustekinumab-kfce at your facility in Bengaluru, India. You may label your product with the proprietary name, Yesintek, and market it as 45 mg/0.5 mL injection in a single-dose prefilled syringe and 90 mg/ mL injection in a single-dose prefilled syringe for subcutaneous use, 45 mg/0.5 mL injection in a single-dose vial for subcutaneous use, and 130 mg/26 mL injection in a single-dose vial for intravenous use.

DATING PERIOD

The dating period for Yesintek 45 mg/0.5 mL prefilled syringe shall be 18 months from the date of manufacture when stored at 2°C to 8 °C. The dating period for Yesintek 90 mg/mL prefilled syringe shall be 6 months from the date of manufacture when stored at 2 °C to 8 °C. The dating period for Yesintek 45 mg/0.5 mL vial and 130 mg/26 mL vial shall be 12 months from the date of manufacture when stored at 2 °C to 8 °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)

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

We have approved the stability protocols in your license application for the purpose of extending the expiration dating period of your drug substance and drug product under 21 CFR 601.12.

FDA LOT RELEASE

You are not currently required to submit samples of future lots of Yesintek to the Center for Drug Evaluation and Research (CDER) for release by the Director, CDER, under 21 CFR 610.2. We will continue to monitor compliance with 21 CFR 610.1, requiring completion of tests for conformity with standards applicable to each product prior to release of each lot.

Any changes in the manufacturing, testing, packaging, or labeling of Yesintek, 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, Instructions for Use, and Medication Guide). 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 (October 2009)*.[2]

The SPL will be accessible via 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

[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.

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

At this time, no pediatric assessment will be required under PREA.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs*.[3]

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 601.12(f)(4)]. Form FDA 2253 is available at FDA.gov.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

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

[3] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

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.

If you have any questions, contact Chau Nguyen, Regulatory Project Manager at chau.nguyen@fda.hhs.gov or (240)-402-0022.

Sincerely,

{See appended electronic signature page}

Tatiana Oussova, MD, MPH
Deputy Director of Safety
Division of Dermatology and Dentistry
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

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

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/

TATIANA OUSSOVA
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