CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761406Orig1s000
761406Orig2s000

OTHER ACTION LETTERS

U.S. FOOD & DRUG ADMINISTRATION

BLA 761406/Original 2

PROVISIONAL DETERMINATION

Biocon Biologics Inc.
Attention: Arlene Wolny
Head of Global Regulatory Affairs
245 Main Street, 2nd Floor
Cambridge, MA 02142

Dear Arlene Wolny:

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 (PHS) Act for Yesintek (ustekinumab-kfce) injection.

BLA 761406 seeks licensure of:

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

This BLA proposes the use of Yesintek (ustekinumab-kfce) injection for adult and pediatric patients 6 years and older with moderate to severe plaque psoriasis (Ps) who are candidates for phototherapy or systemic therapy, adult and pediatric patients 6 years and older with active psoriatic arthritis (PsA), adult patients with moderately to severely active Crohn's disease (CD), and adult patients with moderately to severely active ulcerative colitis.

For administrative purposes, we have split BLA 761406 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.

All future submissions to these BLAs should specify the BLA number and the Original number to which each submission pertains.

We have completed a provisional review of this application, as amended. A final determination under sections 351(i) and 351(k) of the PHS Act that:

- Yesintek (ustekinumab-kfce) injection 45 mg/0.5 mL single-dose prefilled syringe for subcutaneous use would be 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 would be interchangeable with Stelara (ustekinumab) injection 45 mg/0.5 mL single-dose vial for subcutaneous use

- Yesintek (ustekinumab-kfce) injection 90 mg/mL single-dose prefilled syringe for subcutaneous use would be interchangeable with Stelara (ustekinumab) injection 90 mg/mL single-dose prefilled syringe for subcutaneous use

- Yesintek (ustekinumab-kfce) injection 130 mg/26 mL (5 mg/mL) single-dose vial for intravenous use would be interchangeable with Stelara (ustekinumab) injection 130 mg/26 mL (5 mg/mL) single-dose vial for intravenous use

is currently subject to unexpired exclusivity for the first interchangeable biosimilar biological products, and thus may not be made before the exclusivity has expired. See section 351(k)(6) of the PHS Act. We have not identified any deficiencies that would justify a complete response action at this time; however, we also cannot approve your application because of the unexpired first interchangeable exclusivity. We have therefore provisionally determined that your 351(k) application meets the interchangeability criteria under section 351(k) of the PHS Act.

This provisional determination is based upon information available to the Agency at this time (i.e., information in your application and that the manufacturing of the biological product complies with the standards established in the BLA as well as the requirements in applicable regulations). This determination is subject to change on the basis of any new information that may come to our attention.

To obtain approval of this application, submit an amendment no more than six months prior to the date you believe that your application will be eligible for approval. In your cover letter, clearly identify your amendment as **"REQUEST FOR APPROVAL"**. This amendment should provide the legal/regulatory basis for your request for approval and

should include a copy of any relevant supporting documentation, as appropriate. In addition to a safety update, the amendment should also identify changes, if any, in the application, i.e., updated labeling; chemistry, manufacturing, and controls data; and risk evaluation and mitigation strategy (REMS). If there are no changes, clearly state so in your cover letter. Any changes require our review before approval, and the goal date for our review will be set accordingly.

BLA 761406/Original 2 is not approved and Yesintek (ustekinumab-kfce) cannot be legally marketed as an interchangeable biosimilar product unless and until you have been notified in writing that BLA 761406/Original 2 is approved after any necessary additional review. Enclosed are the currently agreed upon labeling (text for the Prescribing Information, Medication Guide, Instructions for Use, Carton and Container labeling). If you believe that there are grounds for issuing the approval letter before the expiration of the exclusivity period, you should amend your application accordingly.

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.

Refer to the “Required Pediatric Assessments” section of the BLA Approval letter for BLA 761406/Original 1.

If you have any questions, contact Kimberle Searcy, Regulatory Project Manager, at 240-402-4454.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURES:

- Content of Labeling
  - Prescribing Information

- Medication Guide
- Instructions for Use

- 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/

TATIANA OUSSOVA
11/29/2024 12:08:15 PM