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ANDA APPROVAL

RegCon Solutions, LLC
U.S. Agent for SABA İlaç Sanayi ve Ticaret A.Ş.
9920 Pacific Heights Blvd., Suite 250
San Diego, CA 92121
Attention: Lauren Ford
President

Dear Lauren Ford:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on June 20, 2023, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for formoterol Tartrate Inhalation Solution, 15 mcg (base)/2 mL Unit-Dose Vials.

Reference is also made to any amendments submitted prior to the issuance of this letter.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug meets the requirements for approval under the FD&C Act. Accordingly the ANDA is **approved**, effective on the date of this letter. We have determined your formoterol Tartrate Inhalation Solution, 15 mcg (base)/2 mL Unit-Dose Vials to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Brovana Inhalation Solution, 15 mcg/2 mL, of Lupin Inc., NDA 021912.

Please note that if FD&C Act requires a Risk Evaluation and Mitigation Strategy (REMS) for a listed drug, an ANDA referencing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C Act.

COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standard for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FD&C Act typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website as <https://www.uspnf.com/>. A

REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL

Under applicable statutes, regulations, and guidelines, your ANDA may be subject to certain requirements and recommendations post approval, including requirements regarding changes to approved ANDAs, postmarketing reporting, promotion limitations, and notification requirements, among others. For information on post-approval requirements and recommendations for ANDAs and list of resources for ANDA holders, write for you to <https://www.fda.gov/drugs/bbr/vit-d-n-w-drug-application-and-requirements-and-resources-approval-and-s>.

Sincerely yours,

{See appended electronic signature page}

For Malik Imam, PharmD, MBA
CDR, United States Public Health Service
Deputy Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research



Catherine U
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