NDA 219622

NDA APPROVAL

Chiesi Farmaceutici S.p.A
c/o Chiesi USA
Attention: Wen-Yee Choi, Ph.D.
Sr. Global Regulatory Affairs Manager
175 Regency Woods Place, Suite 600
Cary, NC 27518

Dear Dr. Choi:

Please refer to your new drug application (NDA) received July 14, 2025, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Trimbow (beclomethasone dipropionate/formoterol fumarate/glycopyrrolate) inhalation aerosol.

This NDA provides for the use of Trimbow (beclomethasone dipropionate/formoterol fumarate/glycopyrrolate) inhalation aerosol for the maintenance treatment of asthma in adult patients aged 18 years and older.

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 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 FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Patient Package Insert, and Instructions for Use) 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 *SPL Standard for Content of Labeling Technical Qs and As.*[2]

The SPL will be accessible via publicly available labeling repositories.

[1] 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 https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

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 the guidance for industry *SPL Standard for Content of Labeling Technical Qs & As.* For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved NDA 219622**." Approval of this submission by FDA is not required before the labeling is used.

DATING PERIOD

Based on the stability data submitted to date, the expiry dating period for Trimbow (beclomethasone dipropionate/formoterol fumarate/glycopyrrolate) inhalation aerosol shall be 18 months from the date of manufacture when stored at 5°C ±3°C.

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.

We are waiving the pediatric studies requirement for ages 0 to 4 years because necessary studies are impossible or highly impracticable. This is because studies of asthma are impossible or highly impractical in the 0 to 4 years of age group due to the difficulty of formal diagnosis and the difficulty in performing accurate spirometry in this age group.

We are deferring submission of your pediatric studies for ages 5 to 11 and 12 to 17 years for this application because this product is ready for approval for use in adults and the pediatric studies have not been completed.

Your deferred pediatric studies required under section 505B(a) of the FDCA are required postmarketing studies. The status of these postmarketing studies must be reported annually according to 21 CFR 314.81 and section 505B(a)(4)(C) of the FDCA. These required studies are listed below.

4971-1 Conduct a randomized, double-blind, placebo-controlled, 6-week or greater duration, pharmacokinetics (PK), efficacy and safety study of inhaled beclomethasone dipropionate at the to-be-marketed doses in adolescents (12 to 17 years of age) compared to placebo with a primary endpoint of change from baseline in forced expiratory volume in one

second utilizing a to-be-marketed TRIMBOW pMDI drug delivery device platform.

Final Protocol Submission:	10/2029
Study Completion:	10/2031
Final Report Submission:	04/2032

4971-2 Conduct a randomized, double-blind, active-controlled, 4-week or greater duration, PK, efficacy and safety study of inhaled beclomethasone dipropionate/formoterol fumarate fixed dose combination at the to-be-marketed doses compared to valid beclomethasone dipropionate comparators in adolescents (12 to 17 years of age) with a primary endpoint of change from baseline in forced expiratory volume in one second utilizing a to-be-marketed TRIMBOW pMDI drug delivery device platform.

Final Protocol Submission:	04/2032
Study Completion:	04/2034
Final Report Submission:	10/2034

4971-3 Conduct a randomized, double-blind, active-controlled, 12-week or greater duration, PK, efficacy and safety study of inhaled TRIMBOW (beclomethasone dipropionate/formoterol fumarate/glycopyrronium bromide fixed dose combination) at the to-be-marketed doses compared to valid beclomethasone dipropionate/formoterol fumarate comparators in adolescents (12 to 17 years of age) with a primary endpoint of change from baseline in forced expiratory volume in one second utilizing a to-be-marketed TRIMBOW pMDI drug delivery device platform.

Final Protocol Submission:	10/2034
Study Completion:	10/2037
Final Report Submission:	04/2038

4971-4 Conduct a PK study of inhaled beclomethasone dipropionate in children (5 to less than 12 years of age) utilizing a to-be-marketed TRIMBOW pMDI drug delivery device platform.

Final Protocol Submission:	04/2030
Study Completion:	04/2031
Final Report Submission:	10/2031

4971-5 Conduct a randomized, double-blind, placebo-controlled, 6-week or greater duration, efficacy, safety, and dose-ranging study of inhaled beclomethasone dipropionate in children (5 to less than 12 years of age) with a primary endpoint of change from baseline in forced expiratory

volume in one second utilizing a to-be-marketed TRIMBOW pMDI drug delivery device platform.

Final Protocol Submission:	10/2031
Study Completion:	04/2034
Final Report Submission:	10/2034

4971-6 Conduct a PK study of inhaled beclomethasone dipropionate/formoterol fumarate fixed dose combination compared to a valid beclomethasone dipropionate comparator in children (5 to less than 12 years of age) utilizing a to-be-marketed TRIMBOW pMDI drug delivery device platform.

Final Protocol Submission:	10/2034
Study Completion:	10/2035
Final Report Submission:	04/2036

4971-7 Conduct a randomized, double-blind, active-controlled, 4-week or greater duration, efficacy, safety, and dose-ranging study of inhaled beclomethasone dipropionate/formoterol fumarate fixed dose combination compared to a valid beclomethasone dipropionate comparator in children (5 to less than 12 years of age) with a primary endpoint of change from baseline in forced expiratory volume in one second utilizing a to-be-marketed TRIMBOW pMDI drug delivery device platform.

Final Protocol Submission:	04/2036
Study Completion:	10/2038
Final Report Submission:	04/2039

4971-8 Conduct a PK study of inhaled TRIMBOW (beclomethasone dipropionate/formoterol fumarate/glycopyrronium bromide fixed dose combination) compared to a valid beclomethasone dipropionate/formoterol fumarate comparator in children (5 to less than 12 years of age) utilizing a to-be-marketed TRIMBOW pMDI drug delivery device platform.

Final Protocol Submission:	04/2039
Study Completion:	04/2040
Final Report Submission:	10/2040

4971-9 Conduct a randomized, double-blind, active-controlled, 12-week or greater duration, efficacy, safety, and dose-ranging study of inhaled TRIMBOW (beclomethasone dipropionate/formoterol fumarate/glycopyrronium bromide fixed dose combination) compared to a valid beclomethasone dipropionate/formoterol fumarate comparator in children (5 to less than 12 years of age) with a primary endpoint of change from baseline in forced

expiratory volume in one second utilizing a to-be-marketed TRIMBOW pMDI drug delivery device platform.

Final Protocol Submission:	10/2040
Study Completion:	10/2043
Final Report Submission:	04/2044

FDA considers the term *final* to mean that the applicant has submitted a protocol, the FDA review team has sent comments to the applicant, and the protocol has been revised as needed to meet the goal(s) of the study or clinical trial.[3]

Submit the protocol(s) to your IND 153868 with a cross-reference letter to this NDA. Reports of these required pediatric postmarketing studies must be submitted as an NDA or as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

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.*[4]

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the Prescribing Information, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at FDA.gov.[5] Information and Instructions for completing the form can be found at FDA.gov.[6]

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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

[3] See the guidance for Industry *Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act (October 2019).* https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.
[4] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[6] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at FDA.gov.[7]

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 standards 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)). FDA 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[8].

If you have any questions, contact Ji Shon, Regulatory Project Manager, at 301-837-7607 or Ji.Shon@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Banu Karimi-Shah, MD
Division Director
Division of Pulmonology, Allergy, and Critical Care
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert
  - Instructions for Use
- Carton and Container Labeling

[7] https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products
[8] https://www.uspnf.com/

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/

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