CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

202049Orig1s000

Trade Name:	Bronchitol Inhalation Powder
Generic or Proper Name:	mannitol
Sponsor:	Chiesi USA, Inc.
Approval Date:	October 30, 2020
Indication:	Provides for the use of Bronchitol (mannitol) Inhalation Powder as an add-on maintenance therapy to improve pulmonary function in adult patients 18 years of age and older with cystic fibrosis. Bronchitol is to be used only in adults who have passed the Bronchitol Tolerance Test.

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Reviews / Information Included in this NDA Review.

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APPROVAL LETTER

NDA 202049

NDA APPROVAL

Chiesi USA, Inc.
175 Regency Woods Place
Suite 600
Cary, NC 27518

Attention: Vicki Gunto, PhD, RAC
US Head of Regulatory Affairs, R&D-Pipeline

Dear Dr. Gunto:

Please refer to your new drug application (NDA) dated May 17, 2012, received May 18, 2012, and your amendments, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Bronchitol (mannitol) Inhalation Powder.

We acknowledge receipt of your amendment dated May 1, 2020, which constituted a complete response to our June 19, 2019, action letter.

This new drug application provides for the use of Bronchitol (mannitol) Inhalation Powder as an add-on maintenance therapy to improve pulmonary function in adult patients 18 years of age and older with cystic fibrosis. Bronchitol is to be used only in adults who have passed the Bronchitol Tolerance Test.

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, Healthcare Practitioner Instructions for Use, Patient Package Insert, and Patient Instructions for Use), as well as annual reportable changes not included in the enclosed labeling. Information on submitting SPL files using eLIST may

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

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.

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 *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 NDA 202049.** 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 BRONCHITOL (MANNITOL) INHALATION POWDER shall be 36 months from the date of manufacture when stored at 20-25°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.

Because this drug product for this indication has an orphan drug designation, you are exempt from this requirement.

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-*

[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.

Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs.[3]

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.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

REPORTING REQUIREMENTS

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

If you have any questions, call Ngoc-Linh Do, Regulatory Project Manager, at 301-348-1896.

Sincerely,

{See appended electronic signature page}

Sally Seymour, MD
Director
Division of Pulmonology, Allergy, and Critical Care
Office of Immunology and Inflammation
Center for Drug Evaluation and Research

ENCLOSURE(S):

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

[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

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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/

SALLY M SEYMOUR
10/30/2020 09:26:25 AM