DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205636

TENTATIVE APPROVAL

Teva Pharmaceutical Products R. & D., Inc.
74 NW 176th Street
Miami, FL 33169

Attention: William Kiddell,
Associate Director, Respiratory

Dear Mr. Kiddell:

Please refer to your New Drug Application (NDA) dated May 05, 2014, received May 05, 2014, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for ProAir RespiClick (albuterol sulfate) inhalation powder 90mcg.

We acknowledge receipt of your amendments dated May 23, June 12, and 23, July 28, and 31, August 08, and 29, November 19, December 04, 2014, and January 20, and 26, February 11, 19, 26, and 27, and March 03, and March 04, 2015.

This NDA provides for the use of ProAir RespiClick (albuterol sulfate) inhalation powder for treatment or prevention of bronchospasm in adults and adolescents age 12 years and older, and prevention of exercise induced bronchospasm in adults and adolescents age 12 years and older.

We have completed our review of this application, as amended. It is tentatively approved under 21 CFR 314.105 for use as recommended in the agreed-upon enclosed labeling (text for the information for use insert**)** and submitted labeling (text for the package insert submitted March 04, 2015, text for the patient information submitted March 04, 2015, carton and immediate container labels submitted March 03, and 04, 2015). This determination is based upon information available to the Agency at this time, [i.e., information in your application and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product]. This determination is subject to change on the basis of any new information that may come to our attention.

The listed drug upon which your application relies is subject to a period of patent and/or exclusivity protection and therefore final approval of your application under section 505(c)(3) of the Act [21 U.S.C. 355(c)(3)] may not be made effective until the period has expired.

Your application contains certifications to patents under section 505(b)(2)(A)(iv) of the Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of, this drug product under this application ("Paragraph IV certifications"). Section 505(c)(3)(C) of the Act provides that approval of a new drug application submitted pursuant to

section 505(b)(2) of the Act shall be made effective immediately, unless an action is brought for infringement of one or more of the patents that were the subject of the paragraph IV certifications. This action must be taken prior to the expiration of 45 days from the date the notice provided under section 505(b)(3) is received by the patent owner/approved application holder. You notified us that you complied with the requirements of section 505(b)(3) of the Act. However, because the 45-day period described in section 505(c)(3)(C) of the Act has not yet expired, final approval cannot be granted.

To obtain final approval of this application, submit an amendment two or six months prior to the: 1.) expiration of the patent(s) and/or exclusivity protection or 2.) date you believe that your NDA will be eligible for final approval, as appropriate. In your cover letter, clearly identify your amendment as **"REQUEST FOR FINAL APPROVAL"**. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of any relevant court order or judgment settlement, or licensing agreement, as appropriate. In addition to a safety update, the amendment should also identify changes, if any, in the conditions under which your product was tentatively approved, 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 final approval and the goal date for our review will be set accordingly

Until we issue a final approval letter, this NDA is not deemed approved.

Please note that this drug product may not be marketed in the United States without final agency approval under Section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under Section 501 of the Act and 21 U.S.C. 331(d).

EXPIRATION DATING PERIOD

An expiry of thirty-six (36) months for the products as packaged is granted.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, 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 note that if this application is ultimately approved, you will need to meet these requirements.

If you have any questions, call Leila P. Hann, Senior Regulatory Project Manager, at (301) 796-3367.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary, Allergy, and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURES:
Content of labeling: Information for Use

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

BADRUL A CHOWDHURY
03/05/2015