



NDA 21936/S-012

**SUPPLEMENT APPROVAL**

Boehringer Ingelheim Pharmaceuticals, Inc.  
900 Ridgebury Rd.  
P.O. Box 368  
Ridgefield, CT 06877-0368

Attention: Ingeborg Army-Cornejo, MD  
Sr. Associate Director, Regulatory Affairs

Dear Dr. Army-Cornejo:

Please refer to your Supplemental New Drug Application (sNDA) dated September 7, 2018, received September 7, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Spiriva Respimat (tiotropium bromide) Inhalation Spray.

This Prior Approval supplemental new drug application provides for labeling revisions to the Instructions for Use (IFU) regarding the pack size.

**APPROVAL & LABELING**

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

**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 <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Instructions for Use.), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

**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 Jessica Lee, Regulatory Project Manager, at 301-796-3769.

Sincerely,

*{See appended electronic signature page}*

Sally M. Seymour, MD  
Acting Director  
Division of Pulmonary, Allergy, and Rheumatology  
Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

ENCLOSURE(S):

Content of Labeling  
Prescribing Information  
Instructions for Use

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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.**  
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/s/  
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SALLY M SEYMOUR  
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