



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-393/S-007
NDA 20-394/S-008

Boehringer Ingelheim
900 Ridgebury Road
P.O. Box 368
Ridgefield, CT 06877-0368

Attention: Kelly Billingham
Associate Director, BIPI DRA Product Labeling

Dear Ms. Billingham:

Please refer to your supplemental new drug application(s) dated June 1, 2007, received June 4, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Atrovent® (ipratropium bromide) Nasal Spray 0.03% and 0.06%.

These “Changes Being Effected” supplemental new drug application(s) provide for the harmonization of Atrovent Nasal Spray 0.03% and 0.06% package inserts with that of your other ipratropium products labeling.

We have completed our review of these applications. These applications are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed labeling (text for the package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, “SPL for approved NDA 20-393/S-007 and NDA 20-394/S-008.”

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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

All 15-day alert reports, periodic (including quarterly) adverse drug experience reports, field alerts, annual reports, supplements, and other submissions should be addressed to the original NDAs 20-393 and 20-394 for this drug product, not to this NDA. In the future, do not make submissions to this NDA except for the final printed labeling requested above.

If you have any questions, call Miranda Raggio, Regulatory Project Manager, at (301) 796-2109.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.

Director

Division of Pulmonary and Allergy Drug Products

Office of Drug Evaluation II

Center for Drug Evaluation and Research

Enclosure: Approved Labeling

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

/s/

Miranda Raggio
11/30/2007 03:43:03 PM