DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-761/S-16

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

Attention: Tacy Pack
Sr. Associate Director, DRA Product Labeling

Dear Ms. Pack:

Please refer to your supplemental new drug application dated July 20, 2001, received July 23, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Alupent (metaproterenol sulfate) Inhalation Solution 15 mg/2.5 mL (0.6%) and 10 mg/2.5 mL (0.4%) unit dose vials.

We acknowledge receipt of your submissions dated October 12, 2001.

This "Changes Being Effected in 30 days" supplemental new drug application provides for revised labeling for this product.

We have completed the review of this supplemental application, and it is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Ms. Sandy Barnes, Chief, Project Management Staff, at (301) 827-1075.

Sincerely,

{See appended electronic signature page}

Guirag Poochikian, Ph.D.
Chemistry Team Leader
Division of Pulmonary and Allergy Drug Products, HFD-570
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Guiragos Poochikian

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