DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 25 1998

TRANSMITTED VIA FACSIMILE

C. Richard Tamorria, Ph.D.
Senior Associate Director
Drug Regulatory Affairs
Boehringer Ingelheim Pharmaceuticals, Inc.
900 Ridgebury Road
P.O. Box 368
Ridgefield, CT 06877

NDA# 20-394
Atrovent (ipratropium bromide) 0.06% Nasal Spray
MACMIS ID# 6440

Dear Dr. Tamorria:

As part of its routine monitoring program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has become aware of promotional activities by Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI) that promote an unapproved use for Atrovent (ipratropium bromide) 0.06% nasal spray. DDMAC considers such promotional activities including such claims to be false or misleading and therefore violative of the Federal Food, Drug, and Cosmetic Act and its implementing regulations. DDMAC requests that further distribution and use of promotional labeling containing this violative claim and other promotional activity supporting this claim cease immediately.

At the BIPI exhibit at the annual meeting of the American Academy of Allergy, Asthma, and Immunology, held in Washington, DC from March 14-17, 1998, BIPI distributed a journal article reprint by Hayden, Diamond, et al., ("Effectiveness and Safety of Intranasal Ipratropium Bromide in Common Colds, Annals of Internal Medicine. 125:89-97, 1996) that promotes the use of Atrovent Nasal Spray 0.06% for specific relief of sneezing associated with common colds. However, the INDICATIONS AND USAGE and CLINICAL TRIALS sections of the approved product labeling specifically excludes sneezing from the list of common cold symptoms relieved by Atrovent 0.06% Nasal Spray. Therefore, DDMAC considers BIPI's dissemination of the Hayden article reprint containing this unapproved use, as well as similar verbal representations made by the BIPI sales representative disseminating this reprint at this exhibit, to be false or misleading. Furthermore, it appears that this reprint was not submitted as required by 21 CFR 314.81(b)(3)(i).

BIPI's written response should be received by DDMAC no later than April 8, 1998, describing the corrective steps that the Company has taken to ensure that these activities and the use of these materials have been suspended. Please direct your response to the undersigned at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, Rm 17B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds BI that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID# 6440 in addition to the NDA number.

Sincerely,

Joan Hankin, JD
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications