DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 22 1997

TRANSMITTED VIA FACSIMILE

Robert W. Pfeifer, M.S., R.Ph.
Manager, Medical and Regulatory Affairs
Roxane Laboratories, Inc.
P.O. Box 16532
Columbus, Ohio 43216-6532

RE: NDA# 20-228
Ipratropium Bromide Inhalation Solution 0.02%
MACMIS ID# 6172

Dear Mr. Pfeifer:

This letter concerns promotional materials for ipratropium bromide inhalation solution 0.02% disseminated by Roxane Laboratories, Inc., (Roxane) under Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI) approved new drug application (NDA) 20-228 for Atrovent.

The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed these promotional materials (journal ad RX 2089A and sell sheet 2089) and has determined that they are false and/or misleading and therefore violate the Federal Food, Drug, and Cosmetic Act (Act) and implementing regulations.

These materials promote the ipratropium bromide product as the "first generic form Atrovent/ipratropium bromide." However, this NDA'd ipratropium bromide inhalation solution is a non-branded version of the Atrovent product, that is manufactured, labeled, and distributed by Roxane. Therefore, this private label product should not be promoted as a "generic" because that term has a well-accepted meaning and connotation (i.e., with reference to bioequivalence data, "Orange Book" listing, and substitutability subject to state law). Moreover, Dey Laboratories holds the first approved generic application (ANDA #74-755) to market ipratropium bromide inhalation solution 0.02%

In addition, the promotional materials lack information concerning the quantity of ipratropium bromide (i.e., 0.02% inhalation solution) the same as corresponding information on the approved product labeling, as required by 21CFR 202.1(a)(2).

Finally, Roxane's December 2, 1997, FDA-Form 2253 submission identifies this product as ANDA# 20-228. As indicated above, this product is marketed under an approved NDA, held by BI. As such, in order to file promotional materials under BIPI's NDA# 20-228 and name, DDMAC requests that Roxane provide us with written authorization from BIPI that such direct submission of Roxane marketed promotional materials to NDA# 20-228 is authorized.

Roxane should cease dissemination and use of these and similarly violative materials. Roxane should provide a written response, including a list of all violative materials and its plan of action. Roxane's written response should be received by DDMAC no later than January 8, 1998 and should be directed 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# 6111 in addition to the NDA number.

Sincerely,

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