DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FoI

APR 24 1998

TRANSMITTED VIA FACSIMILE

Ms. Barbara A. Thompson
Assistant Director, Advertising Policy
Regulatory Affairs
Glaxo Wellcome Inc.
5 Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

Re: NDA# 20-692
Serevent Diskus (salmeterol xinofoate inhalation powder) 50 mg
MACMIS ID#: 6575

Dear Ms. Thompson:

This letter concerns promotional materials for Serevent Diskus (salmeterol xinofoate inhalation powder) 50 mg disseminated by Glaxo Wellcome Inc. (GW) (e.g., brochures SER902RO and SER903RO) that contain misleading efficacy claims that violate the Federal Food, Drug, and Cosmetic Act and implementing regulations.

These promotional materials include the taglines "Effective asthma control" and "Long-lasting symptom control." These efficacy claims are misleading because they do not accurately communicate the qualified role Serevent Diskus, as a long-term control therapy, plays in overall asthma treatment (i.e., it can only effectively help control asthma when used with other necessary asthma medications, such as short-acting beta agonists, and possibly other controller asthma medications, such as inhaled corticosteroids). Because Serevent Diskus is not a monotherapy for the disease of asthma, these promotional claims represent the efficacy of this drug beyond that which has been demonstrated by substantial evidence. GW should scrutinize other instances for compliance where promotional claims have been misleadingly expanded.

GW's written response should be received by May 8, 1998, and should include a list of all similarly violative materials and a description of your method for discontinuing their use. The response should be directed to the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, Rm 17-B-20, 5600 Fishers Lane, Rockville, Maryland 20857. DDMAC reminds GW that only written communications are considered official.

In future correspondence regarding this particular matter, please refer to MACMIS ID# 6575 in addition to the NDA number.

Sincerely,

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