DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

TRANSMITTED BY FACSIMILE

Joy E. Ferrell
Senior Director, Regulatory Affairs
GlaxoSmithKline
PO Box 13398
Five Moore Drive
Research Triangle Park, NC 27709

RE: NDA 20-121
Flonase (fluticasone propionate) Nasal Spray, 50 mcg
MACMIS ID#: 11542

Dear Ms. Ferrell:

This letter notifies GlaxoSmithKline (GSK) that the Division of Drug Marketing, Advertising, and Communications (DDMAC) has identified direct-to-consumer (DTC) advertisements (ads) for Flonase (fluticasone propionate) Nasal Spray that are in violation of the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations. Specifically, misleading claims about Flonase Nasal Spray have been broadcast in a 60 second radio ad ("Be Aware") and disseminated in a full-page print ad appearing in daily newspapers, including *The Washington Post* and *USA Today*. Our specific objections follow.

Background

Flonase is a prescription corticosteroid nasal spray indicated for the management of the nasal symptoms of seasonal allergic rhinitis (SAR), perennial allergic rhinitis (PAR), and perennial non-allergic rhinitis (PNAR). Allegra, Clarinex, and Zyrtec are oral prescription antihistamines ("allergy medicines") indicated for the relief of nasal and non-nasal symptoms for one or more types of allergic rhinitis (SAR or PAR). Therefore, although Flonase is approved to relieve the nasal symptoms from more types of rhinitis than oral allergy medicines (including PNAR), Flonase is not approved to relieve as many symptoms (e.g., non-nasal symptoms such as, itchy/watery/red eyes) caused by seasonal or perennial allergic rhinitis. FDA is not aware of any data demonstrating that Flonase provides comparable or superior effectiveness to any oral prescription antihistamines for these conditions.

Misleading "Allergy Relief" Effectiveness Claim

The radio and full-page DTC print ad contain the same or similar claims and representations. Pertinent sections of the print ad include the following claims and representations:

What you don't know about Clarinex®, Zyrtec®, and Allegra® may cost you.

- **Be aware.**

Many prescription plans are raising the co-payment cost of Clarinex®, Zyrtec®, and Allegra®. But **99%** of prescription plans cover **FLONASE**.*

- **Call your Doctor about FLONASE.**

Don't let allergy relief cost you more this year. Ask your doctor about **FLONASE**. It's FDA-approved to relieve The nasal symptoms from More triggers than any Leading^ allergy medicine.

* MediMedia USA Formulary Compass--December 2002.

^ Allegra, Claritin, Zyrtec, Flonase, Nasonex, and Clarinex are among the leading prescription allergic rhinitis products. Source: Scott-Levin's *Source Prescription Audit (SPA)* from Verispan: October 2001-September 2002.

Promotional materials are misleading if they state or suggest that a drug is useful in a broader range of patients or conditions than has been demonstrated by substantial evidence or substantial clinical experience. The clear implication of the radio and print ads is that Flonase can be substituted for (i.e., works as well as) the antihistamines for "allergy relief," and that Flonase is actually more useful than the other allergy medicines. The ads misleadingly suggest that because Flonase is comparable or superior to the other "allergy medicines," the consumer need consider only the possible insurance co-payment cost in considering switching to Flonase.

Flonase, however, a topical nasal spray, is neither therapeutically equivalent to the oral antihistamines nor interchangeable with or substitutable for them. Unlike Allegra, Clarinex, and Zyrtec, Flonase has not been demonstrated to be safe and effective in treating any of the non-nasal symptoms of SAR, PAR, or PNAR. It is therefore not therapeutically interchangeable with those allergy medicines. The inclusion of the word "nasal" in a single disclosure in the middle of these ads does not mitigate the overall misleading impression that Flonase will relieve "allergies" as well as or better than these antihistamines.

Conclusions and Requested Actions

GSK should immediately discontinue the radio and print ads and all other promotional materials and activities for Flonase that contain the same or similar violative presentations. GSK should submit a written response to DDMAC on or before July 3, 2003, describing its intent and plans to comply with the above. In its letter to DDMAC, GSK should include the date on which these ads and other similarly violative materials were discontinued.

GSK should direct its response to Joan Hankin by facsimile at (301) 594-6771, or in writing at the Food and Drug Administration, Division of Drug Marketing, Advertising, and Communications HFD-42, Rm. 8B-45, 5600 Fishers Lane, Rockville, Maryland 20857. In all future correspondence on this matter, please refer to MACMIS ID# 11542 well as the NDA number. DDMAC reminds GSK that only written communications are considered official.

Sincerely,

{See appended electronic signature page}

Joan Hankin
Consumer Promotion Analyst
Division of Drug Marketing,
Advertising, and Communications

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

/s/

Joan Hankin
6/19/03 01:03:27 PM

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Don't let allergy relief cost you more this year. Ask your doctor about **FLONASE.** It's FDA-approved to relieve the nasal symptoms from more triggers than any leading† allergy medicine.

Call 1.800.427.5295 to learn more or visit our Web site at www.flonase.com.

Now is the best time to talk to your doctor about FLONASE Nasal Spray.

Results may vary. If side effects occur, they are generally mild, and may include headache, nosebleed, or sore throat. For best results, use daily. Maximum relief may take several days. Available by prescription only.

GlaxoSmithKline

When you get it all, all it takes is Flonase®

(fluticasone propionate)

Nasal Spray, 50 mcg