DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FDA

Food and Drug Administration
Rockville MD 20857

JUN 25 1998

TRANSMITTED VIA FACSIMILE

Ms. Kristine M. Agar
Manager, Marketed Product Practices
Worldwide Regulatory Affairs
Rhone-Poulenc Rorer Pharmaceuticals Inc.
500 Arcola Road
P.O. Box 1200
Collegeville, PA 19426-0107

RE: **NDA#** 19-798 Nasacort (triamcinolone acetonide) Nasal Inhaler
NDA# 20-468 Nasacort AQ (triamcinolone acetonide) Nasal Spray
MACMIS ID# 6773

Dear Ms. Agar:

This letter concerns Rhone-Poulenc Rorer Pharmaceuticals Inc.'s (RPR) promotional materials for the marketing of Nasacort (triamcinolone acetonide) Nasal Inhaler and Nasacort AQ Nasal Spray. The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed selected Nasacort promotional materials (cards MNA9800020 and NAJ498(20-25A) as part of its monitoring program and has concluded that RPR is disseminating materials that contain misleading promotional claims in violation of the Federal Food, Drug, and Cosmetic Act and implementing regulations.

These materials feature the headline and tagline claim "Nasacomfort" with "smiley face" graphic with the subheadline, "the great feeling of relief patients get from Nasacort." The Nasacomfort claim includes a footnoted reference statement "Based on a 12/9/97 survey of 401 allergy sufferers ages 18 and older, 91% reported feeling more comfortable after using Nasacort. Patients surveyed used either Nasacort AQ Nasal Spray or Nasacort Nasal Inhaler."

The "Nasacomfort" claim is misleading because the adult and pediatric surveys are inadequate in design to support the claim. The surveys lack a control group. Thus, it cannot be determined whether comfort after using the medication was due to the drug itself, or some other reason. Furthermore, patients' memory over the past 6 months, which is the period asked about, may not be reliable. In addition, it is not clear that the adult survey samples are representative of the profile of a typical Nasacort user (i.e., 67% were older than 45 and 76% were female).

Therefore, RPR should immediately cease its use of promotional materials and activities that contain the Nasacomfort claim. RPR's written response should be received by DDMAC no lager than July 10, 1998, describing the corrective steps that the Company has taken to ensure that the use of these materials have been suspended. Please direct your response to the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-240, Rm 17-B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds RPR that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID# 6773 in addition to the NDA number.

Sincerely,

/S/

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