DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL - 9 1998

TRANSMITTED VIA FACSIMILE

Ms. Kathryn A. Roberts
Senior Manager, Worldwide Regulatory Affairs
Rhone-Poulenc Rorer Pharmaceuticals Inc.
500 Arcola Road
P.O. Box 1200
Collegeville, PA 19426-0107

RE: **NDA#** 18-117
Azmacort (triamcinolone acetonide) Inhalation Aerosol
MACMIS ID# 6786

Dear Ms. Roberts:

This letter concerns promotional materials for Azmacort (triamcinolone acetonide) Inhalation Aerosol disseminated by Rhone-Poulenc Rorer Pharmaceuticals Inc. (RPR). The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed promotional materials (e.g., Kansas MGD Healthcare Update Sheet 5/98 MRM980026) and concluded that they include a false or misleading promotional statement or implication about Azmacort ("Azmacort delivers the right dose to the right place every time") that is in violation of the Federal Food, Drug, and Cosmetic Act (Act) and implementing regulations.

On February 26, 1998, DDMAC objected to this type of claim that refers to deposition of the drug into the lungs based on positron emission tomography (PET) imaging technology. This claim is misleading because it implies clinical benefit based on lung deposition data when such data have not been correlated with clinical effect. The claim is not referenced by any supportive clinical data. As discussed on February 26, 1998, clinical pharmacology PET imaging is not a validated surrogate measure of the clinical effect of orally inhaled drug products and is an inappropriate substitute for valid clinical comparisons of orally inhaled drug products. Use of such data to make implicit or explicit conclusions of clinical significance when no such clinical significance has been demonstrated is misleading. Moreover, this clinical pharmacology claim of *in vivo* performance of inhaled drug delivery is intermingled with clinical efficacy and safety claims to suggest that the drug deposition data confers clinical significance in the treatment of asthma when no such significance has been demonstrated.

Furthermore, the phrases "right dose" and "right place" imply clinical superiority over other orally inhaled steroid products with respect to safety and efficacy (i.e., any other dose to any

other place is wrong or inappropriate). Such an implied clinical superiority claim suggesting that Azmacort is more effective and safer than other inhaled steroid asthma products is false or misleading because it has not been demonstrated by substantial evidence (i.e., adequate and well-controlled studies).

As mentioned above, this issue was the subject of prior correspondence between DDMAC and RPR (DDMAC letters dated, February 26, March 16, March 18, and April 6, 1998). The materials objected to in this letter were disseminated subsequent to RPR's commitment to revise its violative promotional materials. Therefore, DDMAC requests that RPR immediately cease the dissemination and use of this managed care sheet and other materials with similarly violative claims.

RPR's written response should be received by July 23, 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, 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 # 6786 in addition to the NDA number.

Sincerely,

/S/

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