



FOI

Food and Drug Administration
Rockville MD 20857

AUG 19 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# 20-468 Nasacort AQ (triamcinolone acetonide) Nasal Spray
MACMIS ID# 6971**

Dear Ms. Agar:

As part of its routine monitoring activities, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed a broadcast television ad disseminated by Rhone-Poulenc Rorer Pharmaceuticals Inc.'s (RPR) for Nasacort AQ Nasal Spray. DDMAC has determined that this tv ad lacks fair balance and is therefore in violation of the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Furthermore, it appears that this broadcast ad was not submitted upon first dissemination as required by 21 CFR 314.81(b)(3)(i).

Fair Balance Lacking in "Major Statement"

The communication of risk information of the "major statement" (regarding major side effects and contraindications, including warnings and precautions) conveyed by the voice-over lacks fair balance. The verbal communication of this risk information has been minimized because it is not presented with a prominence, speed, or audibility reasonably comparable with the product benefit information.

DDMAC requests that the distribution and use of this violative broadcast ad and any similar ads containing these claims cease immediately. RPR's written response should be received by DDMAC no later than September 2, 1998.

Ms. Kristine M. Agar
Rhone-Poulenc Rorer Pharmaceuticals Inc.
NDA#: 20-468

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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# 6971 in addition to the NDA number.

Sincerely,

/S/

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