



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

F.O.I
Food and Drug Administration
Rockville MD 20857

MAY - 7 1998

TRANSMITTED VIA FACSIMILE

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

RE: NDA# 19-798
Nasacort (triamcinolone acetonide) Nasal Inhaler
MACMIS ID# 6610

Dear Ms. Agar:

As part of its routine monitoring program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has become aware of misleading promotional materials by Rhône-Poulenc Rorer Pharmaceuticals Inc. (RPR) for Nasacort (triamcinolone acetonide) Nasal Inhaler. Specifically, RPR displayed a convention booth panel for Nasacort that featured a number "1" in the "N" of the Nasacort tradename. The use of this "N1" in the promotional logotype falsely or misleadingly implies a claim of superiority in violation of the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

As addressed by the Division of Pulmonary Drug Products' May 20, 1996, approval letter for pediatric supplement NDA# 19-798/S-006, and confirmed by RPR on April 25, 1997, the number "1" should have been removed from all Nasacort promotional materials by May 20, 1997. Therefore, DDMAC requests that further use of this violative promotional material and any other promotional activity supporting this claim cease immediately.

RPR's written response should be received by DDMAC no later than May 21, 1998, describing the corrective steps that the Company has taken to ensure that these activities and the use of these materials have been suspended. Please direct your response to the undersigned by facsimile at (301) 827-2831 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.

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In all future correspondence regarding this particular matter, please refer to MACMIS ID# 6610 in addition to the NDA number.

Sincerely,

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