



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

December 27, 2004

FILE COPY

Dr. David L. Rosen
Gray Cary
1625 Massachusetts Avenue, N.W., Suite 300
Washington, D.C. 20036-224

On behalf of Andrx Pharmaceuticals, Inc.

Dear Dr. Rosen:

Your petition requesting the Food and Drug Administration to re-evaluate FDA's policy concerning the marketing of "authorized generic" versions of brand name prescription drugs, was received by this office on 12/27/2004. It was assigned docket number 2004P-0563/CP 1 and it was filed on 12/27/2004. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management

04P-0563

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