



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

April 19, 2013

Joy J. Liu
ROPES & GRAY LLP
One Metro Center
700 12th Street, NW, Suite 900
Washington, DC 20005

Dear Ms. Liu:

Your petition to the Food and Drug Administration on behalf of Bayer HealthCare Pharmaceuticals Inc. requesting the FDA to recognize 5-year exclusivity for dienogest, the new active moiety in NATAZIA®, pursuant to sections 505(c)(3)(E)(ii) and 505(j)(5)(F)(ii) of the FDCA, was received by this office on 04/19/2013. It was assigned docket number FDA-2013-P-0471/CP1, and it was filed on 04/19/2013. 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 it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Gloria Ortega
Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)