DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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January 6, 2014

Joel S. Lippman, M.D., MPH
Executive Vice President & Chief Medical Officer
Noven Pharmaceuticals, Inc.
350 5th Avenue 37th Floor
New York, NY 10118

Dear Dr. Lippman:

Your petition to the Food and Drug Administration requesting the Agency to refuse to approve any ANDA that cites as its reference listed drug (RLD) Daytrana TDS unless and until the sponsor of such ANDA demonstrates in a usability study conducted in adults, adolescents, and children under "real world" conditions that its proposed generic drug product is not inferior to Daytrana TDS with respect to patch adhesion performance, was received by this office on 12/24/2013. It was assigned docket number FDA-2013-P-1710/CP1, and it was filed on 1/6/2014. 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,

Karen Kennard

Karen Kennard
Director
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)