



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

December 12, 2013

FILE COPY

Hyman, Phelps, & McNamara, PC
Kurt R. Karst
700 Thirteenth Street, NW., Suite 1200
Washington, DC 20005-5929

Dear Mr. Karst:

Your petition to the Food and Drug Administration requesting that the Agency Require certain appearance changes to Over-the-Counter Transdermal Nicotine Patches drug products to help avoid accidental pediatric exposure to nicotine was received by this office on 12/5/2013. It was assigned docket number FDA-2013-P-1640/CP1, and it was filed on 12/12/2013. 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,


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