DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Building #51
Silver Spring, MD 20993

MAY 29 2014

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

Re: Docket No. FDA-2013-P-1640

Dear Mr. Karst:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on December 5, 2013. Your petition requests that the FDA require the sponsors of all marketing applications for over-the-counter transdermal nicotine patches to include permanent, smudge-resistant product identifying labeling on the backing membrane of the drug products.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

for Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research