DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

OCT 18 2013

Jill Escher
Escher Fund for Autism
1590 Calaveras Avenue
San Jose, CA 95126

Re: Docket No. FDA-2013-P-0522

Dear Ms. Escher:

I am writing to inform you that the Food and Drug Administration (FDA or the Agency) has not yet resolved the issues raised in your citizen petition received on May 8, 2013. Your petition requests that the Agency revoke approval for Diclegis (doxylamine succinate and pyridoxine hydrochloride) pending fetal germline safety assessment, and revise pregnancy drug labeling rules to alert consumers to the potential for fetal germ cell perturbation.

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,

Nancy K. Hayes

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