



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

April 30, 2013

Jill Escher  
Escher Fund for Autism

exemption 6

Dear Ms. Escher:

Your petition to the Food and Drug Administration requesting FDA to take action and revoke approval for the drug Diclegis (doxylamine succinate and pyridoxine hydrochloride) pending fetal germline impact assessment, and to issue additional pregnancy label warnings for all drugs regarding potential for fetal germ cell perturbation, was received by this office on 04/30/2013. It was assigned docket number FDA-2013-P-0522/CP1, and it was filed on 04/30/2013. 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,

A handwritten signature in cursive script, reading "Gloria Ortega", is positioned above the printed name.

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