



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

FEB 07 2014

Catherine Gilfedder  
Corporate Social Responsibility Advocate  
Reprieve  
P.O. Box 72054  
London UK, EC3P 3BZ

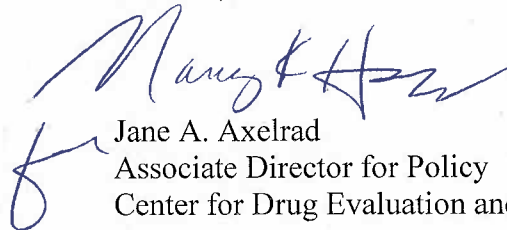
Re: Docket No. FDA-2013-P-0990

Dear Ms. Gilfedder:

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 August 12, 2013, addressing Reglan (metoclopramide hydrochloride).

FDA has been unable to reach a decision on your petition because it raises significant issues requiring careful consideration. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)).

Sincerely,

A handwritten signature in blue ink, which appears to read "Jane A. Axelrad", is written over the typed name and title.

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