DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JAN 31 2014

Kurt R. Karst
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W., Suite 1200
Washington, DC 20005-5929

Re: Docket No. FDA-2013-P-0947

Dear Mr. Karst:

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 August 5, 2013. Your petition requests that the Agency amend the *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book) to designate one of the approved Abbreviated New Drug Applications listed in the Orange Book for cefdinir for oral suspension as an additional reference listed drug for the purposes of submitting an application for a generic version of this drug product.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. 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