



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

August 5, 2013

FILE COPY

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

Dear Mr. Karst:

Your petition to the Food and Drug Administration requesting that FDA designate one of the approved Abbreviated New Drug Applications ("ANDAs") listed in the Orange Book for Cefdinir for Oral Suspension an RLD for purposes of submitting an application for a generic version of this drug product, was received by this office on 8/05/2013. It was assigned docket number FDA-2013-P-0947/CP1, and it was filed on 8/05/2013. 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 black ink that reads "Karen Kennard". The signature is written in a cursive style.

Karen Kennard
Director
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)