DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20852-1448

AUG 2 3 2013

Robert A. Dormer
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W.
Suite 1200
Washington, D.C. 20005-5929

Re: Docket Number FDA-2013-P-0283

Dear Mr. Dormer:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet completed its response to the issues raised in your citizen petition dated March 8, 2013, and filed with the Division of Dockets Management on the same date. In your petition, you raise a number of issues related to CINRYZE and BERINERT, Cl Esterase Inhibitor (Human) products for the treatment of hereditary angioedema, and request that FDA take a variety of actions to address these issues.

FDA is currently considering the issues raised by your citizen petition. However, the Agency will require additional time to issue a final response because your petition raises complex issues requiring further 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 we have reached a decision on your requests.

Sincerely yours,

Karen Midthun, M.D.
Director
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration

cc: Division of Dockets Management
(HFA-305)