DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

March 8, 2013

FILE COPY

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

Dear Mr. Dormer:

Your petition to the Food and Drug Administration requesting action to be taken regarding the safety concerns for CINRYZE[1] and BERINERT,[2] C1 Esterase Inhibitors (Human) ("C 1-INH") products for the treatment of hereditary angioedema, was received by this office on 03/08/2013. It was assigned docket number FDA-2013-P-0283/CP1, and it was filed on 03/08/2013. 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,

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