



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

February 6, 2013

John H. Fuson
Crowell & Moring LLP
1001 Pennsylvania Ave. NW
Washington, DC 20004

Dear Mr. Fuson:

Your petition to the Food and Drug Administration requesting to amend FDA's adopted strength for Lovaza (omega-3-acid ethyl esters) Capsules, including the strength listing in the Orange Book, was received by this office on 2/6/2013. It was assigned docket number FDA-2013-P-0148/CP1, and it was filed on 2/6/2013. 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, reading "Gloria Ortega", is positioned above the typed name.

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