DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Building #51
Silver Spring, MD 20993

AUG 0 5 2013

2635 13 AUG 12 P4:21

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

Re: Docket No. FDA-2013-P-0148

Dear Mr. Fuson:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on February 6, 2013. Your petition requests that the Agency amend the strength adopted by FDA for Lovaza (omega-3-acid ethyl esters) Capsules, including the strength listing in the Orange Book.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive 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 request.

Sincerely,

Jane Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research