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APPLICATION NUMBER:

21-853

OTHER ACTION LETTER(s)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 21-853

Ross Products Division, Abbott Laboratories
Attention: Elizabeth M. Zola, Pharm.D.
Associate Director, Regulatory Affairs
625 Cleveland Avenue
Columbus, OH 43215-1754

Dear Dr. Zola:

Please refer to your new drug application (NDA) dated January 9, 2004, received January 12, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Omacor (omega-3-acid ethyl esters) Capsules, 1 g.

We acknowledge receipt of your submissions dated January 20, April 2, May 10, 12, and 24, June 2, July 1 and 20, August 17, September 2, 3, 8, 10, 14, 17, 21, 24, and 29, October 5, 18, 21, 22 (2), 28 (2), and 29, and November 1, 8 (3), 9, and 10, 2004.

This application proposes the adjunctive use of Omacor to diet [ ] in combination with an HMG-CoA reductase inhibitor to reduce triglyceride (TG) levels in adult patients with [ ] hyperlipidemia [ ] b(4)

We have completed our review of this application, as amended, and it is approvable. Before the application may be approved, however, it will be necessary for you to provide the following information.

[

]

Furthermore, insufficient data were provided to ensure that co-administration of Omacor with LDL-lowering drugs, such as HMG-CoA reductase inhibitors (statins), will not attenuate the clinical effectiveness of the statin either due to the pharmacodynamic effect or in relation to any pharmacokinetic interactions. An approval for use of Omacor in patients with [ ] in combination with statins, will require additional evidence to support a presumed anti-atherosclerotic effect. b(4)

Comments on labeling specific to this use of Omacor will be deferred until we receive your complete response to this letter.

Within 10 days after the date of this letter, you are required to amend this application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. If you do not follow one of these options, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

Under 21 CFR 314.102(d), you may request a meeting or telephone conference with the Division of Metabolic and Endocrine Drug Products to discuss what further steps need to be taken before the application may be approved.

The drug product may be considered misbanded under the Federal Food, Drug, and Cosmetic Act if it is marketed with these changes before approval of this application.

If you have any questions, call Valerie Jimenez, Regulatory Project Manager, at (301) 827-9090.

Sincerely,

{See appended electronic signature page}

Robert J. Meyer, M.D.
Director
Office of New Drug Evaluation II
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Robert Meyer
11/10/04 03:43:53 PM