

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-654

Approval Letter(s)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 21-654

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 new drug application provides for the use of Omacor (omega-3-acid ethyl esters) Capsules as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with TG levels \geq 500 mg/dL.

We have completed our review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed-upon labeling text. Accordingly, the application is approved, effective on the date of this letter.
(b) (4)

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the immediate container labels submitted November 8, 2004). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "FPL for approved NDA 21-654." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit the content of labeling in electronic format as described in 21 CFR 314.50(1)(5) and in the format described at the following website: <http://www.fda.gov/oc/datacouncil/spl.html>.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Metabolic and Endocrine Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

We conclude that your submitted stability data support an 18-month expiry for this product.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

The MedWatch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biologics qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for this product. To participate in the program, please see the enrollment instructions and program description details at www.fda.gov/medwatch/report/mmp.htm.

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

Enclosure:
Package Insert
Container Labels: 28 Capsules Professional Sample
120 Capsules

**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 04:01:55 PM