

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

21-654/S018

Trade Name: Omacor Capsules

Generic Name: (omega-3-acid ethyl esters)

Sponsor: Reliant Pharmaceuticals, Inc

Approval Date: January 24, 2008

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RESEARCH**

APPLICATION NUMBER:

21-654/S018

APPROVAL LETTER



NDA 21-654/S-018

Reliant Pharmaceuticals, Inc.
Attention: Mary R. Chin
Senior Manager, Regulatory Affairs
110 Allen Road
Liberty Corner, NJ 07938

Dear Ms. Chin:

Please refer to your supplemental new drug application dated July 26, 2007, received July 27, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Omacor® (omega-3-acid ethyl esters) Capsules.

This "Changes Being Effected in 30 days" supplemental new drug application provides for revision to several analytical methods for the drug product.

We completed our review of this supplemental new drug application. This supplement is approved.

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

If you have any questions, call Rebecca McKnight, Regulatory Health Project Manager, at (301) 796-1765.

Sincerely,

{See appended electronic signature page}

James D. Vidra, Ph.D.
Branch Chief
Branch VII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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/s/



Jim Vidra
1/24/2008 11:20:06 AM

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APPLICATION NUMBER:

21-654/S018

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW # 1		1. ORGANIZATION: PME	2. NDA Number: 21-654	
3. Name and Address of Applicant (City & State) Reliant Pharmaceuticals, Inc. 110 Allen Road Liberty Corner, NJ 07938			4. Supplement(s) Number(s) Date(s) SCS-018 7/27/07	
5. Drug Name Lovaza®		6. Nonproprietary Name omega-3-acid ethyl esters	7. Amendments - Dates	
8. Supplement Provides For: a revision to several analytical methods for Lovaza™ (omega-3-acid ethyl ester) capsules.				
9. Pharmacological Category As an adjunct to diet to reduce triglyceride levels.		10. How Dispensed Rx	11. Related NDAs	
12. Dosage Form(s) Capsules		13. Potency 1 g		
14. Chemical Name and Structure: <u>'Omega-3-acid ethyl esters' is European Pharmacopeia monograph item with a minimum content specification for ethyl esters of EPA and DHA. It is a yellow liquid from distilled fish oil.</u> <i>EPA ethyl ester:</i>  Formula: C ₂₂ H ₃₄ O ₂ Molecular Weight: 330.51 CAS # 86227-47-6 <i>DHA ethyl ester:</i>  Formula C ₂₄ H ₃₆ O ₂ Molecular Weight: 356.55 CAS # 81926-94-5			15. Records/Reports Current Yes <input checked="" type="checkbox"/> No Reviewed Yes No <input checked="" type="checkbox"/>	
16. Comments: This CBE-30 supplement is proposing a revision to the current five analytical methods used for Lovaza™ (omega-3-acid ethyl ester) capsules testing. These analytical methods are being revised by the applicant to reduce the sample preparation due to excellent precision observed. The proposed change for the reduced testing for these five analytical methods is well supported by the analytical data and the provided justification.				
17. Conclusions and Recommendations: The application is recommended for an 'approval' action from CMC perspective.				
18. Reviewer:				
Name Kris Raman, Ph.D.		Signature		Date Completed 12/27/07

2 Page(s) Withheld

✓ § 552(b)(4) Trade Secret /
Confidential

 § 552(b)(4) Draft Labeling

 § 552(b)(5) Deliberative Process

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/s/

Kris Raman
1/17/2008 07:47:50 AM
CHEMIST

Jim Vidra
1/17/2008 01:10:45 PM
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