



NDA 21-249/S-019  
NDA 21-656/S-013

Abbott Laboratories  
Attention: Nancy Aiello  
Regulatory Affairs Manager  
200 Abbott Park Road  
Department PA71/Bldg. AP30-1E  
Abbott Park, IL 60064-6157

Dear Ms. Aiello:

Please refer to your supplemental new drug applications dated May 7, 2007 (NDA 21-249) and February 21, 2007 (NDA 21-656), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Advicor (Niacin Extended Release/Lovastatin) Tablets and TriCor (fenofibrate) Tablets, respectively.

These supplemental new drug applications provide for revised bottle labels to harmonize across the Abbott product line.

We completed our review of these applications. These applications are approved, effective on the date of this letter, for use as recommended in the attached agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (immediate container labels).

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH  
Food and Drug Administration  
5515 Security Lane  
HFD-001, Suite 5100  
Rockville, MD 20852

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

If you have any questions, call Kati Johnson, Regulatory Project Manager, at (301) 796-1234.

Sincerely,

*{See appended electronic signature page}*

Mary H. Parks, MD  
Director  
Division of Metabolism & Endocrinology Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

Enclosure:

Advicor 500/20 mg bottle label: Identifier 04-A010/R1  
Advicor 750/20 mg bottle label: Identifier 04-A011/R1  
Advicor 1000/20 mg bottle label: Identifier 04-A012/R1  
Advicor 1000/40 mg bottle label: Identifier 04-A013/R1  
Tricor 48 mg bottle label: Identifier DN1080V2  
Tricor 145 mg bottle label: Identifier DN1079V2

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/s/

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Eric Colman  
4/15/2008 09:00:13 AM  
Eric Colman for Mary Parks