

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: 19-304/S005**

**PHARMACOLOGY REVIEW(S)**

## REVIEW AND EVALUATION OF PHARMACOLOGY/TOXICOLOGY DATA:

### KEY WORDS:

Reviewer Name: Ronald W. Steigerwalt, Ph.D. Pharmacology Team Leader

Division Name: Division of Metabolic and Endocrine Drug Products (DMEDP)

HFD#510

Review Completion Date: August 6, 1999

Review number: 1 (for this reviewer)

IND/NDA NUMBER: NDA 19-304

Serial number/date/type of submission: S-005/ June 30, 1999

Information to sponsor: Yes ( ) No (X)

Sponsor (or agent): Abbott Laboratories; 100 Abbott Park Road; D-491, AP6B-1SW; Abbott Park, IL 60064-6108

### DRUG

Trade Name: TRICOR®

Generic Name: Fenofibrate Capsules, micronized

Chemical Name: 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester

Relevant INDs/NDAs/DMFs: NDA 19-304 approved in 1993.

Drug Class: Fibrate

Indication: Cholesterol lowering drug

Clinical formulation: Tricor, crospovidone, iron oxide, lactose, magnesium stearate, pregelatinized starch, sodium lauryl sulfate and titanium dioxide.

Route of administration: Oral

Proposed clinical protocol or Use: Supplement S-005 includes a new indication as follows: Tricor is indicated as adjunctive therapy to diet for the reduction of LDL-C, Total-C, Triglycerides and Apo B in adult patients with primary hypercholesterolemia or mixed dyslipidemia (Fredrickson Types IIa and IIb) with triglycerides less than 250 mg/dL.

SUMMARY: No nonclinical studies were necessary to support the proposed changes to the NDA. A single study assessing the effects of tricor on P450 enzymes in human liver microsomes will be evaluated by the Division of Biopharmaceutics. There were no changes made to the carcinogenesis, mutagenesis impairment of fertility, pregnancy and nursing mothers sections of the label. Therefore, there are no pharmacology issues to be resolved in this supplement.

APPEARS THIS WAY  
ON ORIGINAL

**RECOMMENDATIONS:**

From a pharmacology standpoint, the supplement 005 may be approved. No further action is necessary from pharmacology.

**RS**

8/6/99

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Ronald W. Steigerwalt, Ph.D.  
Pharmacology Team Leader

cc: IND Arch  
HFD510  
HFD510/Steigerwalt/Simoneau/  
Review Code: AP  
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**APPEARS THIS WAY  
ON ORIGINAL**