

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER: 19-304/S005

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW

1. ORGANIZATION CDER/HFD-510 Division of Metabolism and Endocrine Drug Products		2. NDA # 19-304	
3. NAME AND ADDRESS OF APPLICANT Abbot Laboratories. D-491/AP6B-1 100 Abbott Park Road Abbott Park, IL 60064-3500 (847)937-6844, Ms. Marilou Reed		4. SUPPLEMENT(S) SCM-005 30-June-1999 Rec.1-July-1999	
		5. Name of the Drug: Tricor, micronized	
		6. Nonproprietary Name fenofibrate capsules	
7. SUPPLEMENTS PROVIDES FOR: Additional indication for reduction of LDL-C, total cholesterol, triglycerides and Apo B in adult patients with primary hypercholesterolemia or mixed dyslipidemia with triglyceride less than 250 mg/mL		8. AMENDMENT	
9. PHARMACOLOGICAL CATEGORY Lipid-lowering agent	10. HOW DISPENSED Rx	11. RELATED -N. A. -	
12. DOSAGE FORM Capsules	13. POTENCY 67 mg/capsule		
14. CHEMICAL NAME AND STRUCTURE See Chem. Rev. # 1 for DMF _____			
15. COMMENTS: (A) The 6/30/99 supplement is an efficacy supplement. There is no change in chemistry, manufacturing and controls of the drug product, Tricor, micronized. (B) The sponsor has filed a categorical exemption to prepare an environment assessment because the estimated concentration of the active moiety at the point of entry into the aquatic environment will be below 1 part per billion (see p. 002 in Sec. 4 of Vol. 2). According to 21 CFR 25.31(b), this supplement is qualified for a categorical exclusion.			
16. CONCLUSIONS AND RECOMMENDATIONS Adequate. The supplement can be approved from chemistry viewpoint.			
17. REVIEWER NAME (AND SIGNATURE) Chien-Hua Niu, Ph.D. R/D Initialized by		DATE COMPLETED 28-Sept-1999 /S/	
filename: _____			

/S/
10/4/99