proven to alter the morbidity and mortality of atherosclerotic disease. The claim in the ads that Choloxin (sodium dextrothyroxine) is "significant in its accepted physiologic mode of action" is considered to oversimplify the extent of knowledge of its mode of action. Further, the reference to "over 6,000 patients treated in clinical studies" overstates pertinent clinical experience, since only 2,967 patients were in the diagnostic categories for which the drug is currently indicated.

The FDA also considers the summary of warning information in the ads to be incomplete. The enclosed "Brief Summary" contains information in capital letters that was not present in the current ads, but will be incorporated into future ads for Choloxin. We are discontinuing the ads in question. The safety and efficacy of Choloxin are not in question when used in accordance with the official package circular, which remains unchanged.

Sincerely,

THOMAS A. GARRETT,
Vice President, Medical Affairs.

(NOTE.—This revised "Brief Summary" for use in future medical journal advertising contains additional phrases and items (printed in capital letters) from the official package insert which remains unchanged.)

SUMMARY

THE USE OF CHOLOXIN® (SODIUM DEXTROTHYROXINE) DOES NOT REPLACE OR DIMINISH THE DESIRABILITY OF DIETARY MANAGEMENT OF HYPERCHOLESTEROLEMIA, THE INFLUENCE OF LOWERED SERUM CHOLESTEROL ON MORBIDITY AND MORTALITY OF ATHEROSCLEROTIC DISEASE CANNOT BE ASSESSED UNTIL LONG-TERM CLINICAL TRIALS HAVE BEEN COMPLETED.

INDICATIONS: THIS IS NOT AN INNOCUOUS DRUG. Strict Attention should be paid to the indications and contraindications. Indicated for treatment of hypercholesterolemia in euthyroid patients with no known evidence of organic heart disease. Also indicated for treatment of hypothyroidism in patients with cardiac disease who cannot tolerate other types of thyroid medication.

CONTRAINDICATIONS: (1) Known organic heart disease, INCLUDING ANGINA PECTORIS; HISTORY OF MYOCARDIAL INFARCTION; CARDIAC ARRHYTHMIA OR TACHYCARDIA, EITHER ACTIVE OR IN PATIENTS WITH DEMONSTRATED PROPENSITY FOR ARRHYTHMIAS; rheumatic heart disease; HISTORY OF CONGESTIVE HEART FAILURE; AND DECOMPENSATED OR BORDERLINE COMPENSATED CARDIAC STATUS. (2) Hypertensive states (OTHER THAN MILD, LABILE SYSTOLIC HYPERTENSION). (3) Advanced liver or kidney disease. (4) Pregnancy. (5) Nursing mothers. (6) History of iodism.

A *relative* contraindication is impaired liver or kidney function; WHEN EITHER OR BOTH ARE PRESENT, THE ADVANTAGES OF SODIUM DEXTROTHYROXINE THERAPY MUST BE WEIGHED AGAINST THE POSSIBILITY OF DELETERIOUS RESULTS.

WARNINGS: Because the effects of anticoagulants may be potentiated, REDUCE DOSAGE OF ANTICOAGULANTS BY ONE-THIRD ON INITIATION OF THERAPY and readjust as necessary ON THE BASIS OF WEEKLY TESTS OF PROTHROMBIN TIME. Concentration of Factors VII, VIII, IX, and platelet activity SHOULD ALSO BE MONITORED, since these factors may be decreased. CONSIDER WITHDRAWAL OF CHOLOXIN (SODIUM DEXTROTHYROXINE) 2 WEEKS BEFORE SURGERY IF USE OF ANTICOAGULANTS IS CONTEMPLATED.

Careful consideration of dosage schedule in hypothyroid patients WITH CARDIAC DISEASE is required, and the drug should be withdrawn or dosage reduced if AGGRAVATION OF ANGINA, INCREASED MYOCARDIAL ISCHEMIA, CARDIAC FAILURE, OR CLINICALLY SIGNIFICANT ARRHYTHMIA develops. HYPOTHYROID PATIENTS ARE MORE SENSITIVE THAN EUTHYROID PATIENTS, ESPECIALLY IF TREATED CONCOMITANTLY WITH OTHER THYROID PREPARATIONS; SPECIAL CONSIDERATION TO THE DOSAGE OF THE LATTER MUST BE GIVEN.

Thyroid preparations may enhance the effects of epinephrine injections, predisposing to arrhythmias OR CORONARY INSUFFICIENCY. DRUG WITHDRAWAL OR CAREFUL OBSERVATION OF PATIENTS RECEIVING SUCH INJECTIONS IS RECOMMENDED, ESPECIALLY BEFORE ELECTIVE SURGERY.