tosis developed, and there was a steady increase in the number of platelets and granulocytes. On February 11, 1963, the hemoglobin was 84 per cent, white blood cell count—5800 with 30 per cent granulocytes, platelet count—208,000 and reticulocytes—5 per cent. He is still receiving steroid therapy and phenobarbital.

The enclosed copy is a revised package insert which will accompany the market package of Zarontin. The insert provides the latest essential information regarding precautions, side effects, pharmacology, indications, and dosage for the recommended use of this anticonvulsant. We would appreciate the submission of any report, at your earliest convenience, to the Company, of side effects or adverse reactions following the use of Zarontin.

Sincerely yours,

P. F. R. DE CAIRES, M.D.,
Director.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
FOOD AND DRUG ADMINISTRATION,
Washington, D.C., May 28, 1963.

IMPORTANT—DRUG WARNING

DEAR DOCTOR: New warnings are being required in the labeling of topical cortico-steroid preparations for ophthalmic use.

The warnings are shown in the attached memorandum prepared by our Bureau of Medicine.

We have requested all manufacturers of Topical Corticosteroid Preparations and Steroid Antimicrobial Combinations intended for Ophthalmic use to include the warnings in labeling and advertising of these preparations.

From time to time, the Food and Drug Administration, individually or in cooperation with professional or industry groups, will issue statements of important drug developments from the standpoint of new and serious adverse reactions, warnings, and contraindications.

The envelopes and letters in such cases will generally be marked to show that they transmit such information; for example, with a statement such as Drug Warning.

We will be glad to have you report to us any adverse reactions associated with the use of any drug. These reports will be given the most careful consideration.

Sincerely yours,

GEO. P. LARRICK,
Commissioner of Food and Drugs.

MAY 28, 1963.

MEMORANDUM

To: Geo. P. Larrick, Commissioner of Food and Drugs.
From: Ralph G. Smith, M.D., Acting Director, Bureau of Medicine.
Subject: Contraindications and Side Effects of Certain Opthalmic Preparations.

Recent information gathered by the medical staff of the Food and Drug Administration with the assistance of a number of outside medical experts shows a need to warn physicians of certain contraindications to and side effects in the ophthalmic use of topical corticosteroid preparations, including their combinations with antimicrobial drugs.

1. The following are the "*contraindications*":

a. acute herpes simplex, vaccinia, varicella, and most other viral diseases of the cornea and conjunctiva;

b. tuberculosis of the eye;

c. fungal diseases of the eye;

d. acute purulent untreated infections of the eye, which, like other diseases caused by microorganisms, may be masked or enhanced by the presence of the steroid. Purulent conjunctivitis and purulent blepharitis are not indications, but contraindications for topical steroid or steroid-antibiotic combinations. If conjunctivitis and blepharitis are listed as indications, they should be qualified as non-purulent, not purulent.