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.

EATON LABORATORIES,
Norwich, N.Y., July 10, 1967.

Urgent: Drug Recall—Furacin® Solution Aerosol, 1 oz., all lots.

DEAR DOCTOR: There is a possibility that absorption of hexylene glycol, one of the components of the base used in Furacin *Aerosol* may cause coma if used in relatively large quantities on severely burned patients.

We have discontinued sales of the product and are withdrawing all existing stocks of Furacin *Aerosol* from the market.

Please destroy any of the *Aerosol* which you have in your possession. (Do not incinerate.) Prescriptions for the product will not be filled.

This problem concerns only the base of the *Aerosol* formulation. No other Furacin formulation contains hexylene glycol. This notice does not involve any other Furacin product.

We have had two reports of possible reactions of this class involving the use of the *Aerosol*, both occurring in infants with large area burns. Both children recovered upon cessation of therapy. In both cases, there is evidence to indicate that other causes may have been involved.

We regret that this action is necessary. Your cooperation is sincerely appreciated.

EATON LABORATORIES.

MEAD-JOHNSON LABORATORIES,
Evansville, Ind., June 30, 1967.

DEAR DOCTOR: The Food and Drug Administration has requested that we call your attention to current medical journal advertisements for Oracon and Questran which the FDA regards as misleading.

Oracon®

The ad claims that the drug provides ". . . oral contraception with effects which closely parallel those of the natural hormonal cycle" and also contains a related slogan implying such effects are "So Close to Nature." The FDA points out that not neary all effects of oral contraceptives parallel those of the natural hormonal cycle and that some of the effects of these drugs are of profound or undetermined nature.

The ad emphasizes the low incidence of certain less serious side effects such as amenorrhea, breakthrough bleeding, weight gain, etc. However, it fails to give adequate emphasis to more serious known side effects—or adequate emphasis to the possible occurrence of thrombophlebitis, pulmonary embolism or cerebral vascular accident.

The FDA points out that the pregnancy rates claimed in the ad were incorrectly based on 1065 women instead of only 880, and that the ad improperly features a pregnancy rate of 0.2 per 100 woman-years. While available data do not provide a reliable scientific basis for a statement of true pregnancy rates, experience reported to us shows that the unadjusted rate for all women who were given Oracon was 2.0 per 100 woman-years. The rate of 0.2 used in the ad included only those patients who insisted that they had adhered to the regimen.

Questran®

The FDA considers the summary of warning information in the journal advertisement for Questran to be inadequate in that it did not contain any information on precautions and warnings. We have attached a revised "Brief Sum-