DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 73-652 (100 mg)
73-671 (50 mg)

JAN 28 1993

Zenith Laboratories Inc.
Attention: Diane Servello
140 LeGrand Ave.
Northvale, NJ 07647

Dear Madam:

This is in reference to your abbreviated new drug applications dated October 12, and November 15, 1990, respectively, submitted pursuant to Section 505(j) of the Food, Drug, and Cosmetic Act, for Nitrofurantoin Capsules USP, (Macrocrystalline).

Reference is also made to your amendments dated September 24, and December 15, 1992, January 5 and January 21, 1993.

We have completed the review of these abbreviated applications and have concluded that the drugs are safe and effective for use as recommended in the submitted labeling. Accordingly, the applications are approved. The Division of Bioequivalence has determined your 50 mg and 100 mg capsules to be bioequivalent to those of the listed drug (Macrodantin® Capsules, 50 mg and 100 mg of Norwich Eaton Pharmaceuticals, Inc.). Your dissolution testing should be incorporated into the stability and quality control program using the same method as proposed in your application.

Under 21 CFR 314.70, certain changes in the conditions described in these abbreviated applications require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for these abbreviated applications are set forth in 21 CFR 314.80-81. The Office of Generic Drugs should be advised of any change in the marketing status of these drugs.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-240). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign, at the time of their initial use, be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-240) with a completed Form FD-2253.

Sincerely yours,

Roger L. Williams, M.D.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research