CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION: 75-351

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Application Number: 75-351

APPROVAL LETTER

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Approval Package for:

Application Number:75-351

Trade Name: Aspirin, Butalbital, Caffeine and Codeine Phosphate Capsules USP,

Generic Name: Aspirin Butalbital, Caffeine and Codeine Phosphate Capsules USP,

Sponsor: Endo Pharmaceuticals Inc.

Approval Date: March 5, 1999

INDICATION(s): for the relief of the symptom complex of tension (or muscle contraction) headache

ANDA 75-351

MAR 5 1999

Endo Pharmaceuticals, Inc.
Attention: Carol Patterson
500 Endo Boulevard
Garden City, NY 11530

Dear Madam:

This is in reference to your abbreviated new drug application dated March 31, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Butalbital, Aspirin, Caffeine and Codeine Phosphate Capsules USP, 50 mg/325 mg/ 40 mg/30 mg.

Reference is also made to your amendments dated November 20, December 15, and December 23, 1998; and January 21, January 25, and February 25, 1999.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Butalbital, Aspirin, Caffeine and Codeine Phosphate Capsules USP, 50 mg/325 mg/40 mg/30 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Fiorinal® with Codeine Capsules, 50 mg/325 mg/ 40 mg/30 mg, of Novartis Pharmaceuticals Corp.). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

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

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

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-40). 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 be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research