# CENTER FOR DRUG EVALUATION AND RESEARCH

*APPLICATION NUMBER:*

**40098**

# APPROVAL LETTER

ANDA 40-098

SEP 20 1996

MOVA Pharmaceutical Corporation
Attention: Dale Robson
P.O. Box 8639
Caguas, Puerto Rico 00726

Dear Madam:

This is in reference to your abbreviated new drug application dated February 25, 1994, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Acetaminophen and Codeine Phosphate Oral Solution USP, 120 mg/12 mg per 5 mL.

Reference is also made to your amendment dated April 22, 1996.

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 Acetaminophen and Codeine Phosphate Oral Solution USP, 120 mg/12 mg per 5 mL, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Tylenol with Codeine Elixir, 120 mg/12mg per 5 mL, of R. W. Johnson Pharmaceutical Research Institute).

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. 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-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 be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-240) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

/S/

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

9-20-96

cc: ANDA #40-098
Division File
Field Copy
HFD-600/Reading File
HFD-82 (AP)
HFD-8/PSavino
HFD613/ J. Phillips

Endorsements:

HFD-647/LTang/5-6-96 5-21-96

HFD-647/JSimmons/5-10-96 5.23.96

HFD-613/AVezza/5-13-96 5/28/96

HFD-613/JGrace/5-13-96 5/28/96

HFD-647/TAmes/5-17-96 5/24/96

5/6/96

5/19/96

F/T by pah/5-?-96

40098N04.LLT/5-6-96/disk approval #5

Approval