CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: 74-707

Trade Name: Nicotine Polacrilex Gum 4mg

Generic Name: Nicotine Polacrilex Gum 4mg

Sponsor: Circa Pharmaceuticals Inc.

Approval Date: March 19, 1999

INDICATION(s): Stop Smoking Aid

148

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION: 74-707

CONTENTS

	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
Tenative Approval Letter				X
Approvable Letter				X
Printed Labeling	X			
Medical Review(s)				
Chemistry Review(s)	X			
EA/FONSI				X
Pharmacology Review(s)				X
Statistical Review(s)				
Microbiology Review(s)				X
Clinical Pharmacology Biopharmaceutics Review(s)				X
Bioequivalence Review(s)	X			
Administrative/ Correspondence Document(s)	X			

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: 74-707

APPROVAL LETTER

ANDA 74-707

MAR 19 1999

Circa Pharmaceuticals, Inc.
Attention: Joyce Anne DelGaudio
33 Ralph Avenue
P.O. Box 30
Copiague, NY 11726-0030

Dear Madam:

This is in reference to your abbreviated new drug application dated July 6, 1995, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Nicotine Polacrilex Gum USP, 4 mg (base).

Reference is also made to your amendments dated March 28, and October 18, 1996; June 4, September 2, and November 20, 1998; and January 29, February 5, February 8, February 25, March 3, March 10, and March 17, 1999.

We note and agree with your proposed surveillance and marketing plan, described in your amendments dated March 3, and March 10, 1999, designed to assure patient compliance with the approved labeling. In addition to quarterly summaries, we request that you submit an integrated report of your findings for review by the agency at the end of 3 years to determine the need for continuation or change of your plan.

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 Over-The-Counter (OTC) labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Nicotine Polacrilex Gum USP, 4 mg (base) to be bioequivalent to the listed drug (Nicorette Gum, 4 mg (base) of Smithkline Beecham Consumer Healthcare LP).

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.

Sincerely yours,

/S/

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