CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: 74-507

Trade Name: Nicotine Polacrilex Gum, 2mg

Generic Name: Nicotine Polacrilex Gum, 2mg

Sponsor: Circa Pharmaceuticals, Inc.

Approval Date: March 15, 1999

INDICATION(s): Stop Smoking Aid

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION: 74-507

CONTENTS

	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
Tenative Approval Letter	X			
Approvable Letter				X
Printed Labeling	X	(sent 7/26)		
Medical Review(s)				
Chemistry Review(s)	X			
EA/FONSI				X
Pharmacology Review(s)				X
Statistical Review(s)				X
Microbiology Review(s)				X
Clinical Pharmacology Biopharmaceutics Review(s)				X
Bioequivalence Review(s)	X			
Administrative/ Correspondence Document(s)	X			

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Application Number: 74-507

APPROVAL LETTER

ANDA 74-507

MAR 15 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 June 16, 1994, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Nicotine Polacrilex Gum USP, 2 mg (base).

Reference is also made to your amendments dated January 8, March 3, March 9, and March 10, 1999.

We note and agree with your proposed surveillance and marketing plan, described in your submissions 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, 2 mg (base) to be bioequivalent to the listed drug (Nicorette Gum, 2 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,

5/99

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

CENTER FOR DRUG EVALUATION AND RESEARCH

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TENTATIVE APPROVAL LETTER

4.1

ANDA 74-507

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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 June 16, 1994, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Nicotine Polacrilex Gum, 2 mg (base).

Reference is also made to your amendments dated August 15, 1994; August 4 and December 14, 1995; March 27, 1996; August 14, and September 12, 1997; and May 5, July 29, October 5, and November 5, 1998.

We have completed the review of this abbreviated application and have concluded that, based upon the information you have presented to date, the drug is safe and effective for use as recommended in the submitted labeling. Therefore, the application is **tentatively approved.** This determination is based upon information available to the Agency at this time, (i.e., information in your application and the status of current good manufacturing practices (CGMPs) of the facilities used in the manufacturing and testing of the drug product), and is subject to change on the basis of new information that may come to our attention.

The listed reference drug product upon which you have based your application is subject to a period of new product (NP) market exclusivity and therefore, final approval of your application may not be made effective pursuant to 21 U.S.C. 355(j)(4)(D) of the Act until the period has expired, i.e., currently February 9, 1999.

Please provide the Agency at least 30 but not more than 45 days prior to the expiration of the reference listed drug product's market exclusivity, currently February 9, 1999, an amendment to this application. This amendment should identify changes, if any, in the conditions under which the product was tentatively approved, and should include updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. The amendment should also include an updated exclusivity statement to address the new product exclusivity previously granted to the reference listed drug, Nicorette Gum of Smithkline Beecham Consumer Healthcare, L.P. This submission should be designated as a MINOR AMENDMENT in your cover letter. In addition to, or instead of, the amendment requested above, the Agency may, at any time prior to the final date of approval, request that you submit an amendment containing the information described above.

Failure to submit such an amendment requested by the Agency will prompt a review of the application which may result in rescission of this tentative approval letter.

Any significant changes in the conditions outlined in this abbreviated application requires Agency approval before the changes may be made effective.

Prior to issuance of a final approval letter by the Agency, your product will not be deemed approved for marketing under 21 U.S.C. 355 and will not be listed in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list (also known as the "Orange Book"), published by the Agency. Should you believe that there are grounds for issuing the final approval letter prior to February 9, 1999, you should amend your application accordingly.

At the time you submit any amendments, you should contact Kassandra Sherrod, Project Manager, at (301) 827-5849, for further instructions.

The introduction or delivery for introduction into interstate commerce of the drug before the effective approval date is prohibited under 21 U.S.C. 331(d).

Sincerely yours,

Roger L. Williams, M.D.
Deputy Center Director for
Pharmaceutical Science
Center for Drug Evaluation and Research