ANDA 74-507 March 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,

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