DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 76-568 [4 mg (base), Mint]
76-569 [2 mg (base), Mint]

Watson Laboratories, Inc.
Attention: Linval A. M. Francis
33 Ralph Avenue
P.O. Box 30
Copiague, NY 11726-0030

Dear Sir,

This is in reference to your abbreviated new drug applications (ANDAs) dated December 11, 2002, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Nicotine Polacrilex Gum USP, 2 mg (base) (Mint) and 4 mg (base) (Mint).

Reference is also made to your amendments to each application dated October 20, 2003; January 26, February 20, March 26, May 7, and July 1, July 2, July 12, and July 21, 2004.

We have completed the review of these abbreviated applications and have concluded that the drugs are safe and effective for Over-the-Counter (OTC) use as recommended in the submitted labeling. Accordingly, the applications are approved. The Division of Bioequivalence has determined your Nicotine Polacrilex Gum USP, 2 mg (base) (Mint) and 4 mg (base) (Mint), to be bioequivalent to the listed drug Nicorette Mint®, 2 mg (base) and 4 mg (base), respectively, of GlaxoSmithKline. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your applications.

Under Section 506A of the Act, certain changes in the conditions described in these abbreviated applications require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for these abbreviated applications 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,

(b)(6)

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research