



NDA 18-612/S-031
NDA 20-066/S-013

GlaxoSmithKline Consumer Healthcare
Attention: Frances T. Germann
Manager, Regulatory Affairs
1500 Littleton Road
Parsippany, NJ 07054-3884

Dear Ms. Germann:

Please refer to your supplemental new drug applications dated February 8, 2002, received February 11, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nicorette Gum (2 mg and 4 mg nicotine polacrilex).

We acknowledge receipt of your submissions dated July 22, 2002.

These Changes Being Effected supplemental new drug applications provide for final printed labeling which incorporates the pregnancy/breastfeeding warning requested in our letter dated August 17, 2001.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted final printed labeling (User's Guide, Audiotape, and Committed Smoker's Enrollment Form submitted February 8, 2002, and immediate container and carton labels submitted July 22, 2002). Accordingly, these supplemental applications are approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a Dear Health Care Professional letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

NDA 18-612/S-031

NDA 20-066/S-013

Page 2

If you have any questions, call Elaine Abraham, Project Manager, at (301) 827-2301.

Sincerely,

{See appended electronic signature page}

Linda Katz, M.D., M.P.H.

Deputy Director

Division of Over-the-Counter Drug Products

Office of Drug Evaluation V

Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
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/s/

Linda Katz
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