CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

18-612/S025

20-066/S007

APPROVAL LETTER

41.1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-612/S-025
NDA 20-066/S-007

DEC 23 1998

David Schifkovitz
Associate Director, Regulatory Affairs
SmithKline Beecham Consumer Healthcare
1500 Littleton Road
Parsippany, NJ 07054

Mr. Schifkovitz:

Please refer to your supplemental new drug applications (NDA) dated May 15, 1998, received May 18, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nicorette (nicotine polacrilex gum), 2 mg (NDA 18-612/S-025) and Nicorette (nicotine polacrilex gum), 4 mg (NDA 20-066/S-007).

We acknowledge receipt of your submissions dated June 23 and June 26, July 10, September 10 and 28, November 2, and December 1 and 22, 1998.

The user fee goal date for these supplemental new drug applications is May 18, 1999.

These supplemental new drug applications provide for the over-the-counter (OTC) marketing of mint flavored Nicorette 2 mg and 4 mg gum for use by adults only.

We have completed the review of these supplemental new drug 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 draft labeling dated May 15, 1998. Accordingly, these supplemental new drug applications are approved effective on the date of this letter.

Please submit 20 copies of the FPL for each drug product as soon as they are available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-

weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplements 18-612/S-025 and NDA 20-066/S-007." Approval of these submissions by FDA is not required before the labeling is used.

We acknowledge your commitment to submit within 60 days draft labeling which incorporates the revisions specified in your letter dated December 22, 1998.

We remind you of your Phase 4 commitments. Specifically, we request that you commit to continue your Phase 4 marketing and surveillance activities specified in your submission dated February 6, 1996. These should now pertain to both unflavored and mint Nicorette.

We request that you commit also to market the mint flavor of Nicorette in a manner which will ensure compliance with the approved labeling. The plan includes the following elements:

A. Targeting any advertisement to adult smokers, making labeling available in Spanish by request, and featuring and reaching a variety of ethnic audiences.

B. "Trial size" or "sample" packs will not be offered.

C. Packaging of each gum piece in a child resistant blister.

D. Restriction of distribution to drugstores, mass merchandisers and supermarkets where other OTC drugs are sold. The products will not be distributed to other channels, including convenience stores or vending machines. Training of retailers will be provided regarding the marketing restrictions.

E. Offer of incentives to retailers to shelve Nicorette with other OTC drugs.

F. Availability of a free smoking cessation program (toll-free phone number on labeling).

G. If, through the surveillance program, violations of the conditions of sale are identified the retailer will be retrained to bring the store into compliance, or, distribution to the outlet in question will cease.

Protocols, data, and final reports should be submitted to your IND(s) for these products and a copy of the cover letter sent to these new drug applications. Should an IND not be required to meet your Phase 4 commitments, please submit protocols, data and final report to these new drug applications as correspondence. In addition, under 21 CFR 314.82(b)(2)(vii), we request that you include a status summary of each commitment in your annual report to these new drug

applications. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplemental new drug applications, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

In addition, please submit four copies of the introductory promotional materials that you propose to use for these products. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to the Division of Over-the-Counter Drug Products, one copy to the Division of Anesthetic, Critical Care, and Addiction Drug Products, and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

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

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

Please submit one market package of each drug product when it is available.

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

If you have any questions regarding these applications, please contact Sakineh Walther, R.N., Project Manager, at (301) 827-2222.

Sincerely yours,

/S/

Debra L. Bowen, M.D.
Acting Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

/S/

Cynthia G. McCormick, M.D.
Director
Division of Anesthetic, Critical Care,
and Addiction Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

cc:
Archival NDA 20-066
Archival NDA 18-612
HFD-560 DivFiles
HFD-560/Walther/Robinson/Cothran/Chin/Katz
HFD-170/Kumar/Kramer/Klein/Winchell/Geyer/Jean
HFD-170/Theodorakis/Dsa
HFD-715/Permutt/Welch
HFD-870/Doddapaneni/Uppoor
HFD-95/DDMS
DISTRICT OFFICE

Drafted by:SWalther September 21, 1998
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APPROVAL (AP)