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APPLICATION NUMBER:

20-066/S010

APPROVAL LETTER

NDA 20-066/S-010

SEP 25 2000

SmithKline Beecham Consumer Healthcare
Attention: Mr. David Schiffkovitz
Director, Regulatory Affairs
1500 Littleton Road
Parsippany, NJ 07054-3884

Dear Mr. Schiffkovitz:

Please refer to your supplemental new drug application dated February 21, 2000, received February 22, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nicorette® Gum, 4 mg.

We acknowledge receipt of your submissions dated July 10, 2000 and September 19, 2000. Your submission of July 10, 2000, constituted a complete response to our June 22, 2000 action letter.

This supplemental new drug application provides for the addition of an orange flavored gum to the Nicorette Line.

We have completed the review of this supplemental new drug application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text dated February 21, 2000. Accordingly, the supplemental new drug application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling text dated February 21, 2000, and must be formatted in accordance with the requirements of 21 CFR 201.66. Marketing the product with FPL that is not identical to the approved labeling text and "Drug Facts" format may render the product misbranded and an unapproved new drug.

As agreed in your letter dated September 19, 2000, the labeling dated July 10, 2000, will be implemented within **90 days** of the approval date of this supplemental new drug application.

Furthermore, please be reminded that the flag "New Flavor" should be removed after six months of marketing.

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please mount individually ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-066/S-010." Approval of this submission by FDA is not required before that labeling is used.

In addition, please submit one copy of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. For administrative purposes, this submission should be sent to the NDA and should be identified as correspondence to approved NDA 20-066.

If a letter communicating important information about this drug product (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 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.

If you have any questions, please call Daniel P. Keravich, M.S., M.B.A., Regulatory Project Manager, at 301-827-2248.

Sincerely,


Linda M. 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