CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-066/S010

CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NDA 18-612/S-028
NDA 20-066/S-010

Bennett, Turner & Coleman
Attention: Alan R. Bennett
Suite 750
1900 K Street, NW
Washington DC 20006

Dear Mr. Bennett:

We acknowledge your letter dated July 11, 2000, submitted on behalf of SmithKline Beecham Consumer Healthcare, LP concerning the pregnancy/breast-feeding warning required on the product labeling for Nicorette orange gum (NDA 20-066/S-010 and NDA 18-612/S-028). We confirm your understanding that the currently approved pregnancy/breast-feeding warning that should be used for the Nicorette mint and orange gum products reads as follows:

> Nicotine can increase your baby's heart rate; if you are pregnant or nursing a baby, seek the advice of a health professional before using this product.

While the Agency is currently reviewing its position regarding the pregnancy and breast-feeding warnings of nicotine products, you must use the warning specified above for the Nicorette mint and orange gum products.

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

Sincerely,

/S/

Linda M. Katz, M.D., M.P.H.
Deputy Director 7/19/00
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-066/S-010

MAR 1 2000

SmithKline Beecham Consumer Healthcare, L.P.
1500 Littleton Road
Parsippany, New Jersey 07054-3884

Attention: David Schifkovitz, Associate Director, Regulatory Affairs

Dear Mr. D. Schifkovitz:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Nicorette®(nicotine polacrilex) 4mg Gum

NDA Number: 20-066

Supplement Number: S-010

Date of Supplement: Feburary 21, 2000

Date of Receipt: February 22, 2000

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on April 22, 2000, in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Food and Drug Administration
Division of Over-the-Counter Drug Products, HFD-560
Office of Drug Evaluation V
Center for Drug Evaluation and Research
Attention: Document Control Room
5600 Fishers Lane
Rockville, MD 20857

Sincerely,

/S/

Maria Rossana R. Cook, M.B.A.
Chief, Project Management Staff
Division of Over-the-Counter Drug Products, HFD-560
Office of Drug Evaluation V
Center for Drug Evaluation and Research

SmithKline Beecham
Consumer Healthcare

September 19, 2000

NDA 20-066

Linda Katz, M.D., M.P.H.
Director
Division of Over the Counter Drug Products
Food and Drug Administration
Center for Drug Evaluation and Research
Document Control Room, HFD-560
9201 Corporate Boulevard
Rockville, MD 20850

Re: NDA 20-066/S-010
Nicorette 4 mg Gum (Orange)

Dear Dr. Katz,

Please refer to our July 10, 2000 Amendment to the Supplemental New Drug Application for NDA 20-066/S-010 and the September 19, 2000 FAX from Daniel Keravich.

SmithKline Beecham commits to implementing the labeling included in the July 10, 2000 submission for NDA 20-066/S-010 within 90 days of approval of this supplement.

Sincerely,

David Schifkovitz
Director, Regulatory Affairs
SmithKline Beecham Consumer Healthcare

NDA 20-066
HFD-560 Division Files

1500 Littleton Road, Parsippany, NJ 07054-3884. Telephone (973) 889-2100. Fax (973) 889-2390

NDA 20-066/S-010

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

JUN 22 2000

Dear Mr. Schifkovitz:

Please refer to your supplemental new drug application (NDA) dated February 21, 2000, received February 22, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for orange (citrus) flavored Nicorette® (nicotine polacrilex) 4mg gum (NDA-20-066/S-010).

We acknowledge receipt of your submissions dated April 28, 2000, May 1, 2000, May 11, 2000 and communication dated June 20, 2000.

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

We have completed the review of this application, as amended, and it is approvable. Before this application may be approved, however, it will be necessary for you to submit revised printed labeling following further label negotiations based on our fax letter to the company dated June 21, 2000. (Attachment 1).

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

Within 10 days after the date of this letter, you are required to amend the application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. In the absence of any such action FDA may proceed to withdraw the application. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

The drug product may not be legally marketed until you have been notified in writing that the application is approved.

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

Sincerely,

/S/

Linda M. Katz, M.P.H., M.D.
Deputy Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Attachment/1

File 20-066 53.1

SmithKline Beecham
Consumer Healthcare

R&D

June 20, 2000

JUN 21 2000

Linda Katz, MD
Deputy Director
Division of Over The Counter Drug Products

RE: NDA 18-612/SCF-028 (nicotine polacrilex gum 2 mg)
~~NDA 20-066/SCF-010 (nicotine polacrilex gum 4 mg)~~
Orange Nicorette
Response to June 20, 2000 FAX (D. Keravich to D. Schifkovitz)

Dear Dr. Katz,

Please refer to SmithKline Beecham's February 22, 2000 submission of the above referenced supplemental new drug applications for Nicorette Orange (2 mg and 4 mg nicotine polacrilex gum). Please refer also to Daniel Keravich's FAX of June 20, 2000 requesting (1) submission of revised draft labeling for these supplements and (2) justification for the use of a modified "Drug Facts" labeling format for the 48 count packages in these two supplements. Please see corresponding sections below:

(1) We are reviewing the labeling revisions provided as attachments to the June 20th FAX. We view these revisions as minor editorial and layout changes that do not result in any significant objections by SmithKline Beecham. Our art group is in the process of incorporating these comments into draft labeling that I hope to send to your office by Friday, June 22.

(2) Our use of the modified Drug Facts format for the 48 count packages sizes for 2 mg and 4 mg Orange Nicorette was based on the criteria stated in §201.66(d)(10). That is, even after taking into account the smaller print size allowances, FDA required information exceeds 60% of the total surface area available to bear labeling. The actual number measured in our assessments is 66%. The large amount of text, spare out requirements for lot code, expiration date, UPC and the opening instruction pictograms moved us to the current layout. This was further complicated by equipment restrictions on where lot code imprinting must occur and placement of "source tags" to assist in our program for theft prevention. Examples of several different layouts we evaluated in our assessment of space requirements are attached.

I feel it is important to note that SmithKline Beecham recognizes the importance placed behind your Divisions efforts to standardize OTC labeling via Drug Facts format. We have made every effort to comply with the Drug Facts requirements by incorporating the learnings from approval of our Clear

NicoDerm CQ product with Drug Facts labeling and the guidance on Nicorette Drug Facts labeling provided in your FAX of January 19, 2000 for NDA 18-612/S028 and NDA 20-066/S008. These learnings were used to develop the labeling submitted in the Orange Nicorette supplements and subsequently used to produce launch quantites of Nicorette Orange. We would like to continue to work closely with your Divison in making further refinements to all labeling used in the nicotine replacement category. Our hope is that a reasonable allowance can be made for approval of launch product using the labeling submitted in the February 22, 2000 supplements and that additional changes/refinements can be implemented in a reasonable time post approval.

Please contact my office at (973) 889-2509 with any questions.

Sincerely,

David Schifkovitz
Director of Regulatory Affairs