DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-165/S-020

GlaxoSmithKline Consumer Healthcare
Attention: Mr. Parker J. Holmes
Manager, Regulatory Affairs
1500 Littleton Road,
Parsippany, N.J 07054-3884

Dear Mr. Holmes:

Please refer to your supplemental new drug application dated February 13, 2002, received February 14, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for NicoDerm CQ (nicotine transdermal system) clear and opaque, 21mg, 14mg, and 7 mg.

Your submission of February 13, 2002, constituted a complete response to our August 17, 2001 letter.

This Changes Being Effected in 30 days supplemental new drug application provides for revised labeling, replacing the current pregnancy warning with the following:

> **If you are pregnant or breast-feeding, only use this medicine on the advice of your health care provider.** Smoking can seriously harm your child. Try to stop smoking without using any nicotine replacement medicine. This medicine is believed to be safer than smoking. However, the risks to your child from this medicine are not fully known.

In addition, we note the three minor editorial changes have been made to the user's guide labeling which involve a change in the location of the text.

We completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (user's guide and carton labels submitted February 13, 2002), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit the FPL for all Stock Keeping Units (SKUs) electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may 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 individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-165/S-020." Approval of this submission by FDA is not required before the labeling is used.

In addition, please note the following minor editorial revision should be made at the next printing and noted in the following annual report:

- On the end flap of all the cartons an apostrophe should be inserted in the word "family's" in the sentence "For your family's protection, NicoDerm CQ patches are supplied in child resistant pouches."

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), 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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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

Sincerely,

{See appended electronic signature page}

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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Linda Katz

8/13/02 08:20:00 AM