CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

18-612/S025

20-066/S007

CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-066/S-007

MAY 27 1998

SmithKline Beecham Cosumer Healthcare
1500 Littleton Road
Parsippany, New Jersey 07054-3884

Attention: David Schifkovitz
Associate Director, Regulatory Affairs

Dear Mr. Schifkovitz:

We acknowledge receipt of your supplemental application for the following:

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

NDA Number: 20-066

Supplement Number: S-007

Date of Supplement: May 15, 1998

Date of Receipt: May 18, 1998

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on July 17, 1998 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/ 5/26/98

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