

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

18-612/S025

20-066/S007

CHEMISTRY REVIEW(S)

Chemistry Review # 1	1. Division HFD-170	2. NDA No 18-612
3. Name and Address of Applicant SmithKline Beecham; Consumer Healthcare 1500 Littleton Rd Parsippany, NJ 07054-3884 Attn: David Schifkovitz; tel. 973-889-2509		4. Supplement Number Date SE4-025 5/15/98
5. Name of Drug Nicorette Gum (2 mg)	6. Nonproprietary Name Nicotine polacrilex gum (2 mg)	
7. Supplement Provides for: a change in the formulation of the gum.		8. Amendment(s)
9. Pharmacological Category	10. How Dispensed OTC	11. Related Documents <u> </u>
12. Dosage Form Gum	13. Potency 2 mg per gum	
14. Chemical Name and Structure see USAN/USP		
15. Comments <u> </u>		
<p>16. Conclusions and Recommendations This supplemental application is approvable from the chemistry standpoint provided a satisfactory EER is received for the facilities. <u> </u></p> <p>The Applicant should provide a written commitment to cooperate with the Agency in resolving any issues that may result from the validation of the regulatory procedures by the Agency.</p> <p>CC: NDA 18-612\S-025 HFD-560/Division File HFD-170/MTheodorakis HFD-170/ADSa <u> </u> HFD-170/IKumar <u> </u></p>		
17. Name Michael C. Theodorakis, Ph.D. Senior Review Chemist	Signature <u> </u> <i>ISI</i>	Date <u> </u> 11/25/98

Note to Project Manager: Please add standard methods validation statement.

ISI

11-25-98
11-25-98 ✓

OTC CHEMISTRY ROUTING FORM

To Be Completed by Document Room

OTC NDA No <i>20066</i>	Supplement No/Document Code <i>AZ</i> SCS-005	Receipt Date of OTC supplement <i>5-18-98</i>
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List related NDAs from the Form 356h *SE4-007*

RECEIVED
6.1.98

To Be Completed by HFD-560 Project Manager

PDUFA Due Date for OTC supplement ---	Previous SSMRD <i>170</i>	Previous chemist <i>/S/</i>
Is there a corresponding Rx NDA? <input type="checkbox"/> Yes <input type="checkbox"/> No	Corresponding Rx NDA No./SSMRD	PDUFA Due Date of Rx supplement

To be Completed by the DNDCIII Deputy Director

Assigned Chem Team <i>170</i>	Chem Team Leader <i>/S/</i>	Date Assigned <i>5/29/98 /S/</i>
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To be Completed by the Chemistry Team Leader

Chem Reviewer for OTC portion <i>Michael Theodorakis</i>	Date assigned <i>5/28/98</i>	Comment <i>/S/</i>
Chem Reviewer for Rx portion	Date assigned	

To be Completed by Chemistry TIA

Date received by TIA <i>MAY 29 1998 /S/</i>	Date data logged into system <i>MAY 29 1998 /S/</i>	Date returned to OTC_PM <i>MAY 29 1998 /S/</i>
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To be Completed by the Project Manager

Today's date _____ *S. Watter*

Please return to _____ by _____
OTC Project Manager Date (2 wks post receipt date)

cc:Orig NDA\HFD-560 Div. File\HFD-560 Katz\HFD560 PM\HFD-358Stone\HFD-830Dunn

May 1, 1997

Connie: Please also add NDA 18-612/SE4-025. Receipt date 5/18/98 - other info the same.