

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Application Number** 21-330

**CHEMISTRY REVIEW(S)**

(B)

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**FOOD and DRUG ADMINISTRATION  
CENTER of DRUG EVALUATION and RESEARCH  
DIVISION OF ANESTHETICS, CRITICAL CARE and ADDICTION  
DRUG PRODUCTS (DACCADP)  
HFD-170**

**NDA:21-330**

CHEMISTRY REVIEW #: **1**

REVIEW DATE: **19-AUG-2001**

**SUBMISSION TYPE DOCUMENT DATE CDER DATE DATE ASSIGNED**

ORIGINAL	15-DEC-2000		
AMENDMENT	08-FEB-2001		
AMENDMENT	16-FEB-2001		
AMENDMENT [SU]	07-MAY-2001	08-MAY-2001	
AMENDMENT [BC]	14-MAY-2001		
AMENDMENT	05-JUL-2001		

**NAME & ADDRESS OF APPLICANT:**

GlaxoSmithKline,  
Consumer Healthcare  
1500 Littleton Road  
Parsippany, NJ 07054-3884

Attn.: David Schiffkovitz  
Director, Regulatory Affairs  
  
tel.: 973-889-2509

**DRUG PRODUCT NAME**

Proprietary:

Nonproprietary/USAN: nicotine polacrilex lozenge

Code Name/#:

Chem. Type/Ther. Class: 1 P

**PHARMACOL. CATEGORY/INDICATION:**

**DOSAGE FORM:** Lozenge

**STRENGTHS:** 2 mg, 4 mg, Maximum Daily Dose (MDD): 60 mg

**ROUTE OF ADMINISTRATION:** Oral

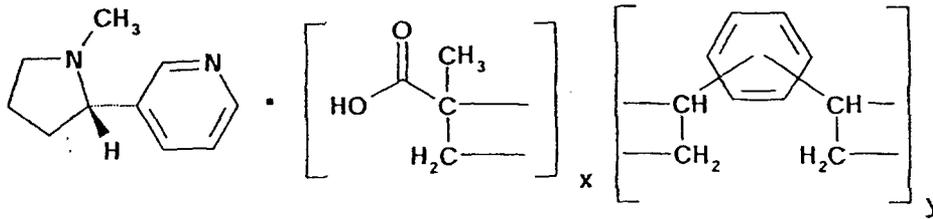
**DISPENSED:** Rx    OTC   x  

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CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOL.WT:

*Structure*

The structure of nicotine polacrilex (NPA) is as follows:



Empirical formula:  $C_{10}H_{14}N_2(C_4H_6O_2)_x(C_{10}H_{10})_y$

Relative molecular mass: —

where: x = number of — units per NPA molecule  
 y = number of — units per NPA molecule

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 ON ORIGINAL

**CONCLUSIONS & RECOMMENDATIONS:**

This NDA is approvable from the chemistry standpoint. It is recommended that the deficiencies listed in the Draft of Chemist's Part, Letter to Applicant be conveyed to the Applicant immediately.

CC:

NDA 21-330

HFD-170/Division File

HFD-170/MTheodorakis

HFD-170/DKoble

HFD-170/JMilstein

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Michael C. Theodorakis, Ph.D.  
Senior Review Chemist

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Dale L. Koble, Ph.D.  
Chemistry Team Leader

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Dale Koble  
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**FOOD and DRUG ADMINISTRATION  
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DRUG PRODUCTS (DACCADP)  
HFD-170**

**NDA:21-330**

CHEMISTRY REVIEW #: 2

REVIEW DATE: 28-AUG-2002

SUBMISSION TYPE DOCUMENT DATE CDER DATE DATE ASSIGNED  
AMENDMENT #11 11-MAR-2002

**NAME & ADDRESS OF APPLICANT:**

GlaxoSmithKline,  
Consumer Healthcare  
1500 Littleton Road  
Parsippany, NJ 07054-3884

Attn.: David Schiffkovitz  
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**DRUG PRODUCT NAME**

Proprietary:

Nonproprietary/USAN: nicotine polacrilex lozenge

Code Name/#:

Chem.Type/Ther.Class: 3 S

**PHARMACOL.CATEGORY/INDICATION:**

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**STRENGTHS:** 2 mg, 4 mg, Maximum Daily Dose (MDD): 60 mg

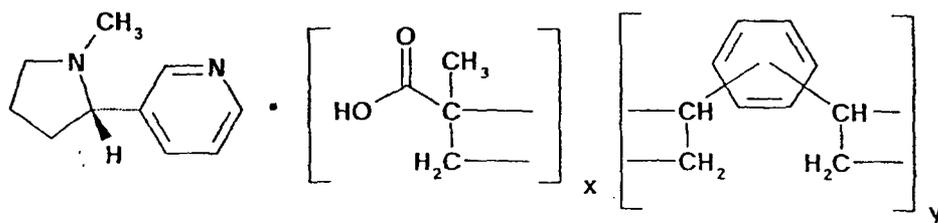
**ROUTE OF ADMINISTRATION:** Oral

**DISPENSED:** Rx  OTC

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HFD-170/Division File

HFD-170/MTheodorakis

HFD-170/DKoble

HFD-170/VKao

Michael C. Theodorakis, Ph.D.  
Senior Review Chemist

Dale L. Koble, Ph.D.  
Chemistry Team Leader

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HFD-170**

**NDA:21-330**

**CHEMISTRY REVIEW #:** 3

**REVIEW DATE:** 24-OCT-2002

**SUBMISSION TYPE    DOCUMENT DATE    CDER DATE    DATE ASSIGNED**

AMENDMENT	September 6, 2002		
AMENDMENT	October 16, 2002		
AMENDMENT	October 25, 2002		
AMENDMENT	October 26, 2002		

**NAME & ADDRESS OF APPLICANT:**

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Nonproprietary/USAN:            nicotine polacrilex lozenge

Code Name/#:

Chem.Type/Ther.Class:            3 S

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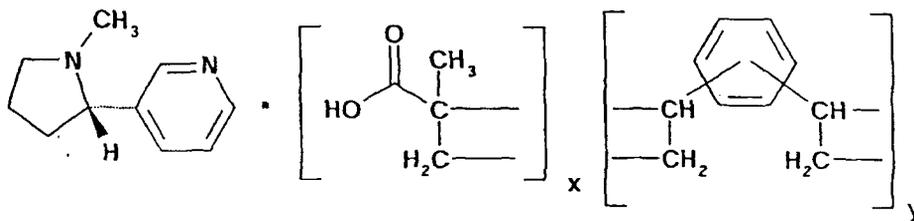
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**DISPENSED:**            Rx  OTC

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