CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

18-612/S-050
20-066/S-031

Trade Name: Nicorette

Generic Name: nicotine polacrilex gum, 2mg and 4mg

Sponsor: GlaxoSmithKline Consumer Healthcare, L.P.

Approval Date: June 13, 2008

Purpose: The nonprescription marketing of a new White Ice Mint flavor of 2mg and 4mg gum with associated packaging and labeling.

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

18-612/S-050 & 20-066/S-031

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	X
Other Action Letters	
Labeling	X
Summary Review	
Officer/Employee List	
Office Director Memo	
Cross Discipline Team Leader Review	
Medical Review(s)	
Chemistry Review(s)	X
Environmental Assessment	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/Biopharmaceutics Review(s)	
Other Reviews	X
Risk Assessment and Risk Mitigation Review(s)	
Proprietary Name Review(s)	
Administrative/Correspondence Document(s)	X

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

18-612/S-050 & 20-066/S-031

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 18-612/S-050
NDA 20-066/S-031

GlaxoSmithKline Consumer Healthcare, L.P.
Attention: Marissa M. Fletcher, Ph.D.
Manager, Regulatory Affairs
1500 Littleton Road
Parsippany, NJ 07054-3884

Dear Dr. Fletcher:

Please refer to your supplemental new drug applications for NDA 18-612 dated February 13, 2008, received February 13, 2008, and NDA 20-066 dated February 14, 2008 received February 14, 2008, submitted under section 505 (b) of the Federal Food, Drug, and Cosmetic Act for:

NDA Number	Name	Dosage Form
18-612/S-050	Nicorette	2 mg, nicotine polacrilex gum
20-066/S-031	Nicorette	4 mg, nicotine polacrilex gum

We also acknowledge receipt of your submissions dated March 21, and June 10, 2008 to both NDAs.

This supplemental new drug application provides for the nonprescription marketing of a new White Ice Mint flavor of 2 mg and 4 mg gum with associated packaging and labeling.

We have completed our review of these applications. These applications are 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 enclosed labeling (10-count blister card, 20-, 100- and 160-count carton labels and users guide for the 2 and 4 mg strengths), and must be formatted in accordance with the requirements of 21 CFR 201.66, where applicable.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions **"FPL for approved supplement NDA 18-612/S-050 and NDA 20-066/S-031."** Approval of these submissions by FDA is not required before the labeling is used.

We remind you that the word "New" must be removed from the label and labeling, wherever it appears, after the first six months of marketing.

Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

In addition, we remind you that the statement of identity phrase "STOP SMOKING AID" on the principal display panel should be capitalized at the time of next printing of the label or within 180 days, whichever is sooner.

Please submit one market package of the drug product when it is available.

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 Mary Lewis, Regulatory Project Manager, at (301) 796-0941.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

Enclosure

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

/s/

Joel Schiffenbauer
6/13/2008 09:57:13 AM

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

18-612/S-050 & 20-066/S-031

LABELING

Nicorette White Ice Mint 2mg / 20ct Carton Inside

Drug Facts

Active ingredient (in each chewing piece) — **Purpose**
Nicotine polacrilex (equal to 2mg nicotine) .... Stop smoking aid

Use • reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking

Warnings
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.

Do not use
- if you continue to smoke, chew tobacco, use snuff, or use a nicotine patch or other nicotine containing products

Ask a doctor before use if you have
- a sodium-restricted diet
- heart disease, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate.
- high blood pressure not controlled with medication. Nicotine can increase blood pressure.
- stomach ulcer or diabetes

Ask a doctor or pharmacist before use if you are
- using a non-nicotine stop smoking drug
- taking prescription medicine for depression or asthma. Your prescription dose may need to be adjusted.

Stop use and ask a doctor if
- mouth, teeth or jaw problems occur
- irregular heartbeat or palpitations occur
- you get symptoms of nicotine overdose such as nausea, vomiting, dizziness, diarrhea, weakness and rapid heartbeat

Keep out of reach of children and pets. Pieces of nicotine gum may have enough nicotine to make children and pets sick. Wrap used pieces of gum in paper and throw away in the trash. In case of overdose, get medical help or contact a Poison Control Center right away. ▼

Flip open for Directions and additional information
Retain this package for complete product information

Lift flap for $10.00 coupon

Nicorette White Ice Mint 2mg / 20ct Carton Outside

Drug Facts (continued)

Directions
- **if you are under 18 years of age, ask a doctor before use**
- before using this product, read the enclosed User's Guide for complete directions and other important information
- stop smoking completely when you begin using the gum
- **if you smoke 25 or more cigarettes a day:** use 4mg nicotine gum
- **if you smoke less than 25 cigarettes a day:** use according to the following 12 week schedule:

Weeks 1 to 6	Weeks 7 to 9	Weeks 10 to 12
1 piece every 1 to 2 hours	1 piece every 2 to 4 hours	1 piece every 4 to 8 hours

- nicotine gum is a medicine and must be used a certain way to get the best results
- chew the gum slowly until it tingles. Then park it between your cheek and gum. When the tingle is gone, begin chewing again, until the tingle returns.
- repeat this process until most of the tingle is gone (about 30 minutes)
- do not eat or drink for 15 minutes before chewing the nicotine gum, or while chewing a piece
- to improve your chances of quitting, use at least 9 pieces per day for the first 6 weeks
- if you experience strong or frequent cravings, you may use a second piece within the hour. However, do not continuously use one piece after another since this may cause you hiccups, heartburn, nausea or other side effects.
- do not use more than 24 pieces a day
- it is important to complete treatment. Stop using the nicotine gum at the end of 12 weeks. If you still feel the need to use nicotine gum, talk to your doctor.

Other information
- **each piece contains:** calcium 94mg, sodium 11mg • store at 20 - 25°C (68 - 77°F) • protect from light

Inactive ingredients acesulfame potassium, carnauba wax, edible ink, flavor, gum base, hypromellose, magnesium oxide, menthol, peppermint oil, polysorbate 80, sodium bicarbonate, sodium carbonate, starch, sucralose, titanium dioxide, xylitol

Questions or comments?
call toll-free 1-800-419-4766 (English/Spanish) weekdays (9:00 am - 4:30 pm ET)

Distributed by
GlaxoSmithKline Consumer Healthcare, L.P.
Moon Township, PA 15108
Made in Sweden

www.nicorette.com 30524PA

This product is protected in sealed blisters.
Do not use if individual blisters or printed backings are broken, open, or torn.

SAVE $10.00 on Nicorette® White Ice™ Mint gum 100ct or larger

Experience a NEW Flavor from Nicorette® White Ice™ Mint

Redeemable at food, drug and mass merchandise stores. CONSUMER: Limit 1 coupon per purchase of indicated product(s). You pay any sales tax. You are not eligible for this offer if reimbursement for the product will be sought from any federal or state healthcare program, including Medicare or Medicaid, or any similar federal or state programs, including any state pharmaceutical assistance program, or under any private insurance, HMO, or other third-party payment arrangement. **RETAILER:** GSK will reimburse you the face value of this coupon plus 12¢ Handling Fee if submitted in compliance with our Redemption Policy. Copy available upon request. Cash value 1/100 of 1¢. Coupon is void if altered, transferred, exchanged, sold, copied or if prohibited by law. Good only in USA and at APOs, FPOs. **Send coupons to:** GlaxoSmithKline Consumer Healthcare, P.O. Box 880658, El Paso, Texas 88588-0658. ©2008 GlaxoSmithKline Read and follow label directions.

Go to Nicorette.com ***NOW*** for product availability!

548762

5 00766 51461 7 (8101)3 54876 0710

LOT
EXP

TO INCREASE YOUR SUCCESS IN QUITTING:

1. You must be motivated to quit.
2. **Use Enough** - Chew **at least 9 pieces** of Nicorette per day during the first six weeks.
3. **Use Long Enough** - Use Nicorette for the full 12 weeks.
4. **Use with a support program** as directed in the enclosed User's Guide.

To remove the gum, tear off single unit. | Peel off backing, starting at corner with loose edge. | Push gum through foil.

For more information and for a FREE individualized stop smoking program, please visit www.Nicorette.com for more details.
Free Audio CD upon request.

- not for sale to those under 18 years of age
- proof of age required
- not for sale in vending machines or from any source where proof of age cannot be verified

0305241601

Nicorette
nicotine polacrilex gum, 2mg stop smoking aid

20 PIECES, 2mg EACH

NEW FLAVOR See Back for $10.00 Coupon

2mg
FOR THOSE WHO SMOKE LESS THAN 25 CIGARETTES A DAY
If you smoke 25 or more cigarettes a day: use Nicorette 4mg

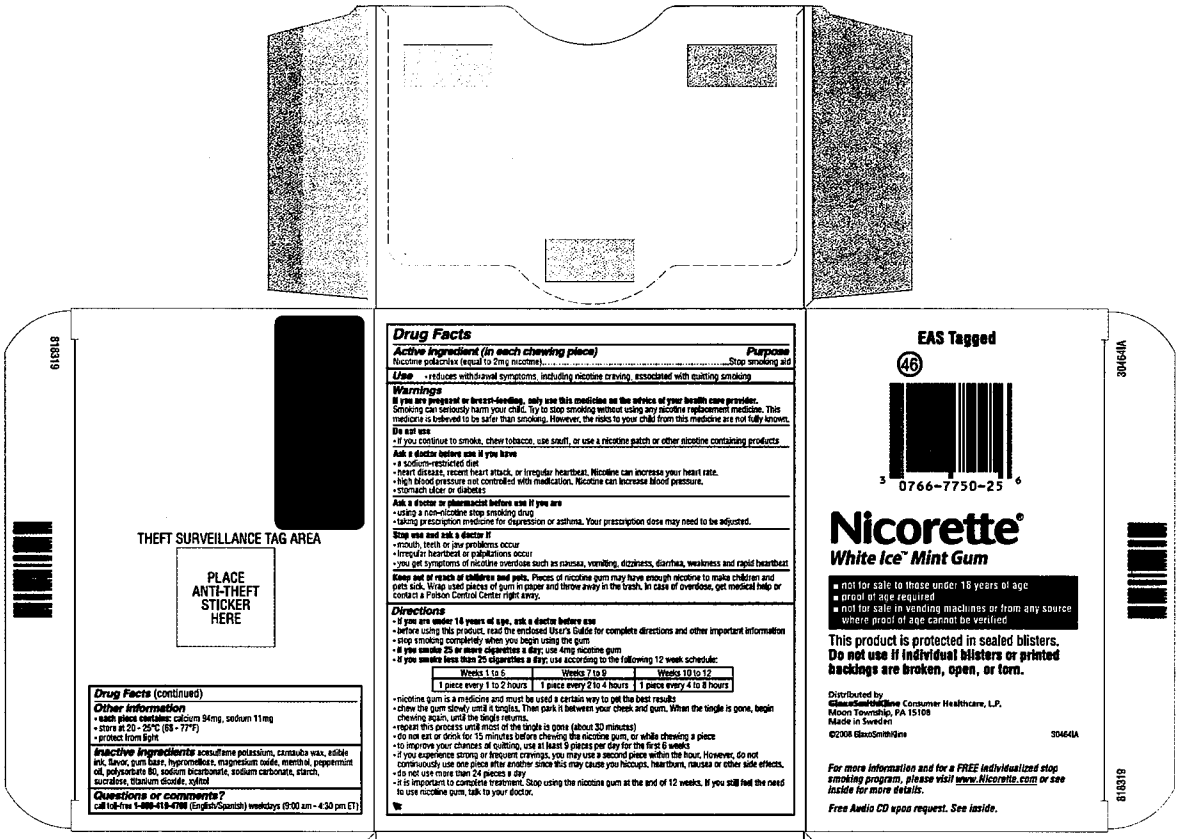
Coated for Intense Flavor

White Ice™ Mint Gum

0305241601


OPEN HERE
TO INCREASE YOUR SUCCESS IN QUITTING:
1. You must be motivated to quit.
2. Use Enough - Chew at least 9 pieces of Nicorette per day during the first six weeks.
3. Use Long Enough - Use Nicorette for the full 12 weeks.
4. Use with a support program as directed in the enclosed User's Guide.
100 PIECES, 4mg EACH
QUIT REWARDS
Earn over $170 in coupons and rewards
NEW FLAVOR
QUIT REWARDS
Nicorette®
polacrilex gum, 4mg • stop smoking aid
4mg
FOR THOSE WHO SMOKE 25 OR MORE CIGARETTES A DAY
If you smoke less than 25 cigarettes a day: use Nicorette 2mg
Coated for Intense Flavor
White Ice™ Mint Gum
100 PIECES, 4mg EACH
Nicorette®
White Ice™ Mint Gum
QUIT REWARDS
Drug Facts
Active Ingredient (in each chewing piece)
Purpose
Nicotine polacrilex (equal to 4mg nicotine)
Stop smoking aid
Use
• reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking
Warnings
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.
Do not use
• if you continue to smoke, chew tobacco, use snuff, or use a nicotine patch or other nicotine containing products
Ask a doctor before use if you have
• a sodium-restricted diet
• heart disease, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate.
• high blood pressure not controlled with medication. Nicotine can increase blood pressure.
• stomach ulcer or diabetes
Ask a doctor or pharmacist before use if you are
• using a non-nicotine stop smoking drug
• taking prescription medicine for depression or asthma. Your prescription dose may need to be adjusted.
Stop use and ask a doctor if
• mouth, teeth or jaw problems occur
• irregular heartbeat or palpitations occur
• high blood pressure not controlled with medication. Nicotine can increase blood pressure.
• you get symptoms of nicotine overdose such as nausea, vomiting, dizziness, diarrhea, weakness and rapid heartbeat
Keep out of reach of children and pets. Pieces of nicotine gum may have enough nicotine to make children and pets sick. Wrap used pieces of gum in paper and throw away in the trash. In case of overdose, get medical help or contact a Poison Control Center right away.
Directions
• If you are under 18 years of age, ask a doctor before use
• before using this product, read the enclosed User's Guide for complete directions and other important information
• stop smoking completely when you begin using the gum
• If you smoke less than 25 cigarettes a day, use 2mg nicotine gum
• If you smoke 25 or more cigarettes a day, use according to the following 12 week schedule:
Weeks 1 to 6: 1 piece every 1 to 2 hours
Weeks 7 to 9: 1 piece every 2 to 4 hours
Weeks 10 to 12: 1 piece every 4 to 8 hours
• nicotine gum is a medicine and must be used a certain way to get the best results
• chew the gum slowly until the tingles. Then park it between your cheek and gum. When the tingle is gone, begin chewing again, until the tingle returns.
• repeat this process until most of the tingle is gone (about 30 minutes)
• to improve your chances of quitting, use at least 9 pieces per day for the first 6 weeks
• do not eat or drink for 15 minutes before chewing the nicotine gum. or while chewing a piece
• do not use more than 24 pieces a day
continuously use one piece after another since this may cause you hiccups, heartburn, nausea or other side effects.
• if you experience strong or frequent cravings, you may use a second piece within the hour. However, do not
• it is important to complete treatment. Stop using the nicotine gum at the end of 12 weeks. If you still feel the need to use nicotine gum, talk to your doctor.
Other Information
• each piece contains:
calcium 3mg, sodium 13mg
• protect from light
• store at 20 - 25°C (68 - 77°F)
Inactive Ingredients acesulfame potassium, candelilla wax, D&C yellow #10 Al. lake, edible ink, flavor, gum base, hypromellose, magnesium oxide, menthol, peppermint oil, polycrystalline SiO2, sodium carbonate, starch, sucralose, titanium dioxide, xylitol
Questions or comments?
call toll-free 1-800-413-4784 (English/Spanish) weekdays (9:00 am - 4:30 pm ET)
PLACE ANTI-THEFT STICKER HERE
THEFT SURVEILLANCE TAG AREA
EAS Tagged
45
0766-7760-00
3
2
Nicorette®
White Ice™ Mint Gum
• not for sale to those under 18 years of age
• proof of age required
• not for sale in vending machines or from any source where proof of age cannot be verified
This product is protected in sealed blisters. Do not use if individual blisters or printed backings are broken, open, or torn.
Distributed by
GlaxoSmithKline Consumer Healthcare, L.P.
Moon Township, PA 15108
Made in Sweden
©2008 GlaxoSmithKline
3046SIA
For more information and for a FREE information/prize, please visit www.Nicorette.com or see inside for more details.
Free audio CD upon request. See inside.
Includes Carrying Case
818318
818318
818318
818318
3046SIA

Nicorette White Ice Mint 4mg / 20ct Carton



818319

THEFT SURVEILLANCE TAG AREA

PLACE ANTI-THEFT STICKER HERE

Drug Facts (continued)

Other information
- **each piece contains:** calcium 94mg, sodium 11mg
- store at 20 - 25°C (68 - 77°F)
- protect from light

Inactive ingredients acesulfame potassium, carnauba wax, edible ink, flavor, gum base, hypromellose, magnesium oxide, menthol, peppermint oil, polysorbate 80, sodium bicarbonate, sodium carbonate, starch, sucralose, titanium dioxide, xylitol

Questions or comments?
call toll-free **1-866-419-4766** (English/Spanish) weekdays (9:00 am - 4:30 pm ET)

Drug Facts

Active ingredient (in each chewing piece) — **Purpose**
Nicotine polacrilex (equal to 2mg nicotine) — Stop smoking aid

Use
- reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking

Warnings

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.

Do not use
- if you continue to smoke, chew tobacco, use snuff, or use a nicotine patch or other nicotine containing products

Ask a doctor before use if you have
- a sodium-restricted diet
- heart disease, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate.
- high blood pressure not controlled with medication. Nicotine can increase blood pressure.
- stomach ulcer or diabetes

Ask a doctor or pharmacist before use if you are
- using a non-nicotine stop smoking drug
- taking a prescription medicine for depression or asthma. Your prescription dose may need to be adjusted.

Stop use and ask a doctor if
- mouth, teeth or jaw problems occur
- irregular heartbeat or palpitations occur
- you get symptoms of nicotine overdose such as nausea, vomiting, dizziness, diarrhea, weakness and rapid heartbeat

Keep out of reach of children and pets. Pieces of nicotine gum may have enough nicotine to make children and pets sick. Wrap used pieces of gum in paper and throw away in the trash. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions
- **if you are under 18 years of age, ask a doctor before use**
- before using this product, read the enclosed User's Guide for complete directions and other important information
- stop smoking completely when you begin using the gum
- **if you smoke 25 or more cigarettes a day;** use 4mg nicotine gum
- **if you smoke less than 25 cigarettes a day;** use according to the following 12 week schedule:

Weeks 1 to 6	Weeks 7 to 9	Weeks 10 to 12
1 piece every 1 to 2 hours	1 piece every 2 to 4 hours	1 piece every 4 to 8 hours

- nicotine gum is a medicine and must be used a certain way to get the best results
- chew the gum slowly until it tingles. Then park it between your cheek and gum. When the tingle is gone, begin chewing again, until the tingle returns.
- repeat this process until most of the tingle is gone (about 30 minutes)
- do not eat or drink for 15 minutes before chewing the nicotine gum, or while chewing a piece
- to improve your chances at quitting, use at least 9 pieces per day for the first 6 weeks
- if you experience strong or frequent cravings, you may use a second piece within the hour. However, do not continuously use one piece after another since this may cause you hiccups, heartburn, nausea or other side effects.
- do not use more than 24 pieces a day
- it is important to complete treatment. Stop using the nicotine gum at the end of 12 weeks. If you still feel the need to use nicotine gum, talk to your doctor.

EAS Tagged

46

3 0766-7750-25 6

Nicorette®

White Ice™ Mint Gum

- not for sale to those under 18 years of age
- proof of age required
- not for sale in vending machines or from any source where proof of age cannot be verified

This product is protected in sealed blisters. Do not use if individual blisters or printed backings are broken, open, or torn.

Distributed by
GlaxoSmithKline Consumer Healthcare, L.P.
Moon Township, PA 15108
Made in Sweden

©2008 GlaxoSmithKline — 30464IA

For more information and for a FREE individualized stop smoking program, please visit www.Nicorette.com or see inside for more details.

Free Audio CD upon request. See inside.

30464IA

818319

818319

OPEN HERE

Nicorette®
White Ice™ Mint Gum

160 PIECES, 2mg EACH

Coated for Intense Flavor

White Ice™ Mint Gum

FOR THOSE WHO SMOKE LESS THAN 25 CIGARETTES A DAY

2 mg

NEW FLAVOR

QUIT REWARDS

160 PIECES, 2mg EACH

EAS Tagged

(44)

3 0766-7750-00 3

Nicorette®

White Ice™ Mint Gum

- not for sale to those under 18 years of age
- proof of age required
- not for sale in vending machines or from any source where proof of age cannot be verified

This product is protected in sealed blisters. **Do not use if individual blisters or printed backings are broken, open, or torn.**

Distributed by
GlaxoSmithKline Consumer Healthcare, L.P.
Moon Township, PA 15108
Made in Sweden

 304621A

For more information and for a FREE individualized stop smoking program, please visit www.Nicorette.com or see inside for more details.

Free Audio CD upon request. See inside. Includes Carrying Case

304621A

818317

818317

Drug Facts

Active ingredient (in each chewing piece)	***Purpose***
Nicotine polacrilex (equal to 2mg nicotine)	Stop smoking aid

Use • reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking

Warnings

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.

Do not use
- if you continue to smoke, chew tobacco, use snuff, or use a nicotine patch or other nicotine containing products

Ask a doctor before use if you have
- a sodium-restricted diet
- heart disease, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate.
- high blood pressure not controlled with medication. Nicotine can increase blood pressure.
- stomach ulcer or diabetes

Ask a doctor or pharmacist before use if you are
- using a non-nicotine stop smoking drug
- taking prescription medicine for depression or asthma. Your prescription dose may need to be adjusted.

Stop use and ask a doctor if
- mouth, teeth or jaw problems occur
- irregular heartbeat or palpitations occur
- you get symptoms of nicotine overdose such as nausea, vomiting, dizziness, diarrhea, weakness and rapid heartbeat

Keep out of reach of children and pets. Pieces of nicotine gum may have enough nicotine to make children and pets sick. Wrap used pieces of gum in paper and throw away in the trash. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- **if you are under 18 years of age, ask a doctor before use**
- before using this product, read the enclosed User's Guide for complete directions and other important information
- stop smoking completely when you begin using the gum
- **if you smoke 25 or more cigarettes a day**; use 4mg nicotine gum
- **if you smoke less than 25 cigarettes a day**; use according to the following 12 week schedule:

Weeks 1 to 6	Weeks 7 to 9	Weeks 10 to 12
1 piece every 1 to 2 hours	1 piece every 2 to 4 hours	1 piece every 4 to 8 hours

- nicotine gum is a medicine and must be used a certain way to get the best results
- chew the gum slowly until it tingles. Then park it between your cheek and gum. When the tingle is gone, begin chewing again, until the tingle returns.
- repeat this process until most of the tingle is gone (about 30 minutes)
- do not eat or drink for 15 minutes before chewing the nicotine gum, or while chewing a piece
- to improve your chances of quitting, use at least 9 pieces per day for the first 6 weeks
- if you experience strong or frequent cravings, you may use a second piece within the hour. However, do not continuously use one piece after another since this may cause you hiccups, heartburn, nausea or other side effects.
- do not use more than 24 pieces a day
- it is important to complete treatment. Stop using the nicotine gum at the end of 12 weeks. If you still feel the need to use nicotine gum, talk to your doctor.

818317

THEFT SURVEILLANCE TAG AREA

PLACE ANTI-THEFT STICKER HERE

Drug Facts (continued)

Other information
- **each piece contains:** calcium 94mg, sodium 11mg
- store at 20 - 25°C (68 - 77°F)
- protect from light

Inactive ingredients acesulfame potassium, carnauba wax, edible ink, flavor, gum base, hypromellose, magnesium oxide, menthol, peppermint oil, polysorbate 80, sodium bicarbonate, sodium carbonate, starch, sucralose, titanium dioxide, xylitol

Questions or comments?
call toll-free 1-800-419-4766 (English/Spanish) weekdays (9:00 am - 4:30 pm ET)

QUIT REWARDS

Internet access required. Program valid only in the U.S. Must be a legal U.S. resident, 18 years of age or older. Void where prohibited. Enroll online between August 1, 2007 (12:01 a.m. PT) and December 6, 2010 (11:59:59 p.m. PT). Collect codes found inside specially marked cartons of Nicorette gum until February 28, 2011 (11:59:59 p.m. PT). Redeem for coupons and/or gifts until February 28, 2011 (11:59:59 p.m. PT). Subject to complete Terms & Conditions at www.nicorette.com.

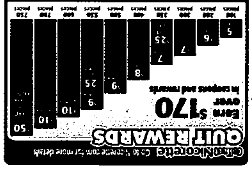
Nicorette®

White Ice™ Mint Gum

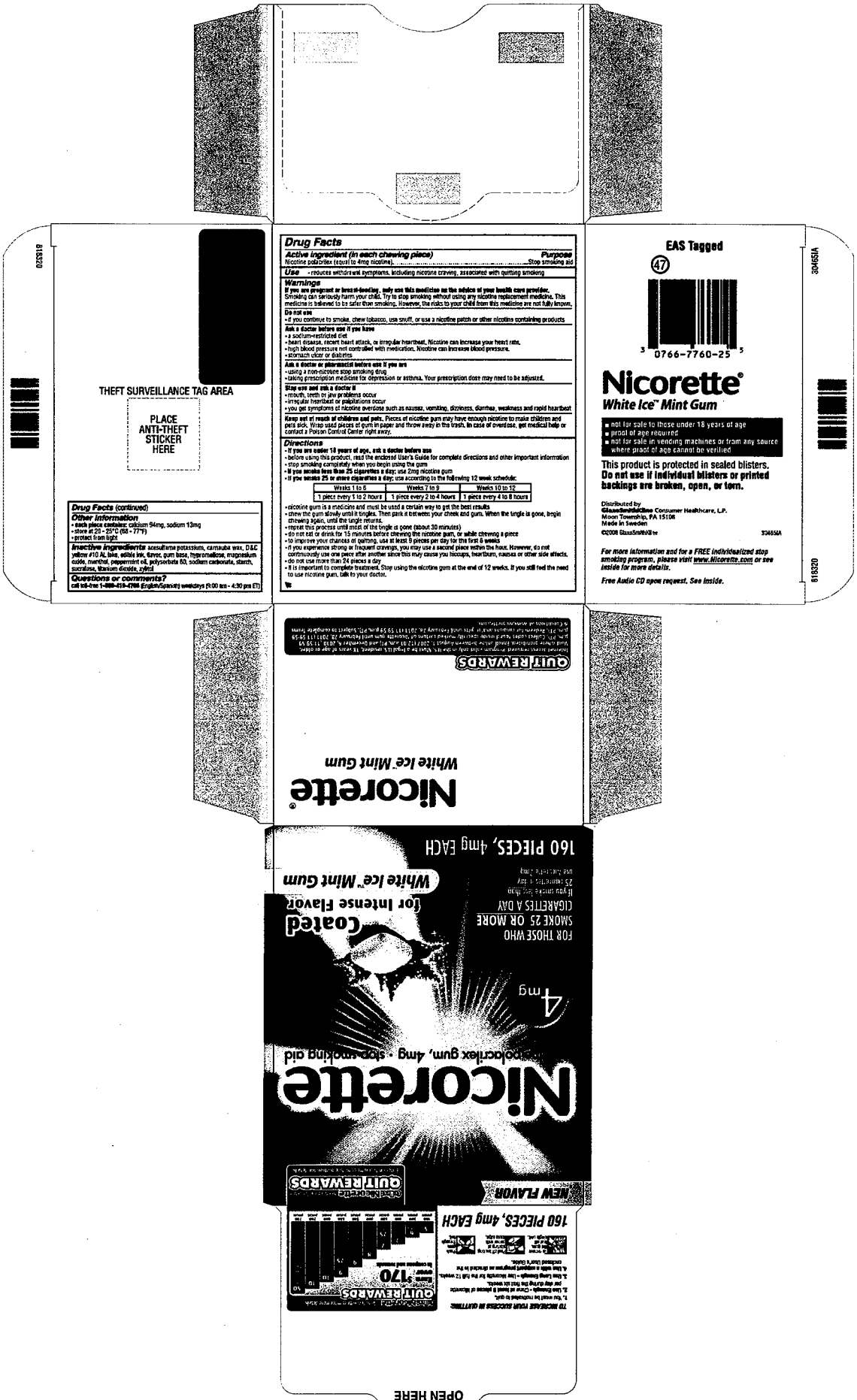
TO INCREASE YOUR SUCCESS IN QUITTING:
1. You must be motivated to quit.
2. **Use Enough** - Chew at least 9 pieces of Nicorette per day during the first six weeks.
3. **Use Long Enough** - Use Nicorette for the full 12 weeks.
4. **Use with a support program** as directed in the enclosed User's Guide.

To remove the gum, tear off single unit. Peel off backing, starting at corner with loose edge. Push gum through foil.

100 PIECES, 2mg EACH



OPEN HERE



818320

THEFT SURVEILLANCE TAG AREA

PLACE ANTI-THEFT STICKER HERE

Drug Facts (continued)

Other information
- each piece contains: calcium 94mg, sodium 13mg
- store at 20 - 25°C (68 - 77°F)
- protect from light

Inactive ingredients acesulfame potassium, carnauba wax, D&C yellow #10 AL lake, edible ink, flavor, gum base, hypromellose, magnesium oxide, menthol, peppermint oil, polysorbate 80, sodium carbonate, starch, sucralose, titanium dioxide, xylitol

Questions or comments?
call toll-free 1-888-515-1788 (English/Spanish) weekdays (9:00 am - 4:30 pm ET)

Drug Facts

Active ingredient (in each chewing piece) — **Purpose**
Nicotine polacrilex (equal to 4mg nicotine) ..... Stop smoking aid

Use
- reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking

Warnings
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.

Do not use
- if you continue to smoke, chew tobacco, use snuff, or use a nicotine patch or other nicotine containing products

Ask a doctor before use if you have
- a sodium-restricted diet
- heart disease, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate.
- high blood pressure not controlled with medication. Nicotine can increase blood pressure.
- stomach ulcer or diabetes

Ask a doctor or pharmacist before use if you are
- using a non-nicotine stop smoking drug
- taking prescription medicine for depression or asthma. Your prescription dose may need to be adjusted.

Stop use and ask a doctor if
- mouth, teeth or jaw problems occur
- irregular heartbeat or palpitations occur
- you get symptoms of nicotine overdose such as nausea, vomiting, dizziness, diarrhea, weakness and rapid heartbeat

Keep out of reach of children and pets. Pieces of nicotine gum may have enough nicotine to make children and pets sick. Wrap used pieces of gum in paper and throw away in the trash. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions
- **If you are under 18 years of age, ask a doctor before use**
- before using this product, read the enclosed User's Guide for complete directions and other important information
- stop smoking completely when you begin using the gum
- **If you smoke less than 25 cigarettes a day:** use 2mg nicotine gum
- **If you smoke 25 or more cigarettes a day:** use according to the following 12 week schedule:

Weeks 1 to 6	Weeks 7 to 9	Weeks 10 to 12
1 piece every 1 to 2 hours	1 piece every 2 to 4 hours	1 piece every 4 to 8 hours

- nicotine gum is a medicine and must be used a certain way to get the best results
- chew the gum slowly until it tingles. Then park it between your cheek and gum. When the tingle is gone, begin chewing again, until the tingle returns.
- repeat this process until most of the tingle is gone (about 30 minutes)
- do not eat or drink for 15 minutes before chewing the nicotine gum, or while chewing a piece
- to improve your chances of quitting, use at least 9 pieces per day for the first 6 weeks
- if you experience strong or frequent cravings, you may use a second piece within the hour. However, do not continuously use one piece after another since this may cause you hiccups, heartburn, nausea or other side effects.
- do not use more than 24 pieces a day
- it is important to complete treatment. Stop using the nicotine gum at the end of 12 weeks. If you still feel the need to use nicotine gum, talk to your doctor.

EAS Tagged

47

3 0766-7760-25 5

Nicorette®

White Ice™ Mint Gum

- not for sale to those under 18 years of age
- proof of age required
- not for sale in vending machines or from any source where proof of age cannot be verified

This product is protected in sealed blisters.
Do not use if individual blisters or printed backings are broken, open, or torn.

Distributed by
GlaxoSmithKline Consumer Healthcare, L.P.
Moon Township, PA 15108
Made in Sweden
©2008 GlaxoSmithKline 304656A

For more information and for a FREE individualized stop smoking program, please visit www.Nicorette.com or see inside for more details.

Free Audio CD upon request. See inside.

304656A

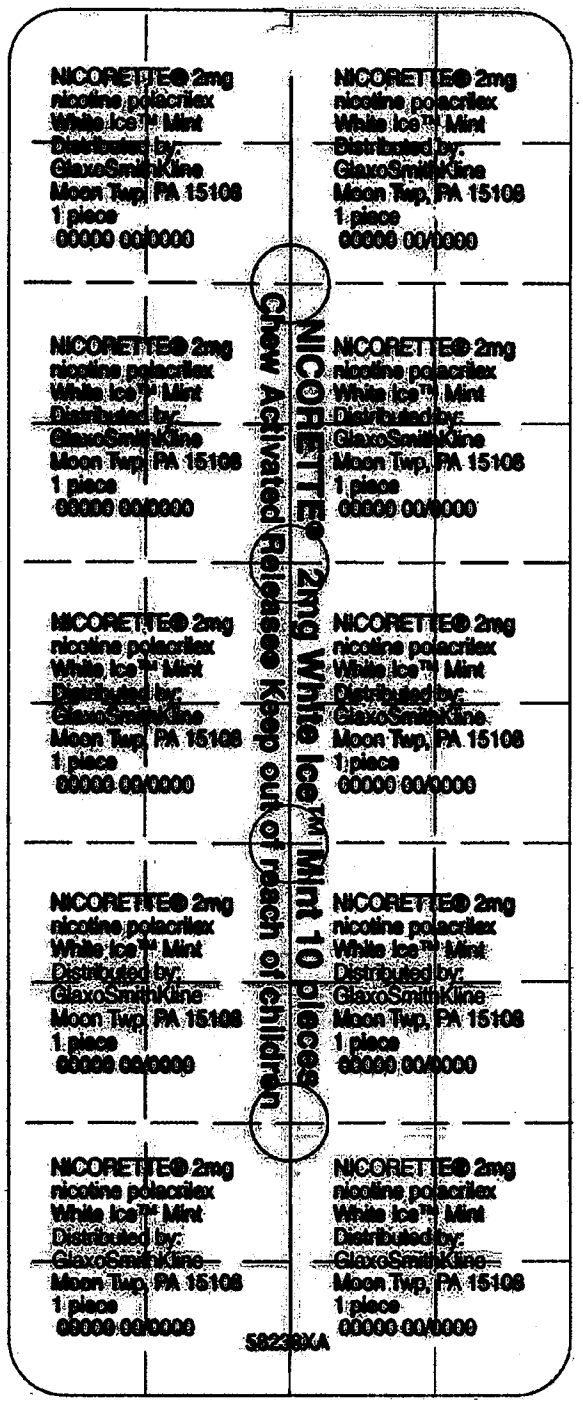
818320

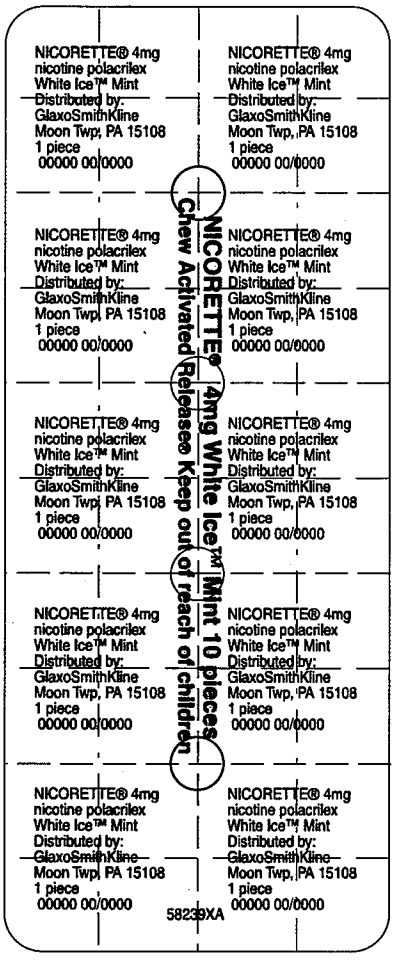
OPEN HERE

818320

Nicorette®
White Ice™ Mint Gum

160 PIECES, 4mg EACH


NICORETTE® 2mg
nicotine polacrilex
White Ice™ Mint
Distributed by:
GlaxoSmithKline
Moon Twp, PA 15108
1 piece
00000 00/0000
NICORETTE® 2mg White Ice™ Mint 10 pieces
Chew Activated Release Keep out of reach of children
582283XA


NICORETTE® 4mg
nicotine polacrilex
White Ice™ Mint
Distributed by:
GlaxoSmithKline
Moon Twp, PA 15108
1 piece
00000 00/0000
NICORETTE® 4mg White Ice™ Mint 10 pieces
Chew Activated Release® Keep out of reach of children
58239XA

Nicorette®

nicotine polacrilex gum

2mg and 4mg User's Guide

HOW TO USE NICORETTE TO HELP YOU QUIT SMOKING.

(See insert)

KEYS TO SUCCESS.

1) You must really want to quit smoking for **Nicorette®** to help you.
2) You can greatly increase your chances for success by using at least 9 to 12 pieces every day when you start using **Nicorette**. See page 12.
3) You should continue to use **Nicorette** as explained in this User's Guide for 12 full weeks.
4) **Nicorette** works best when used together with a support program — See page 3 for details.
5) If you have trouble using **Nicorette,** ask your doctor or pharmacist or call GlaxoSmithKline at 1-800-419-4766 weekdays (10:00 am - 4:30 pm EST.)
6) To request a free audio CD containing tips to help make quitting easier, call the toll free number listed above. (ONE CD PER CUSTOMER)

SO YOU DECIDED TO QUIT.

Congratulations. Your decision to stop smoking is an important one. That's why you've made the right choice in choosing **Nicorette** gum.

Your own chances of quitting smoking depend on how much you want to quit, how strongly you are addicted to tobacco, and how closely you follow a quitting program like the one that comes with **Nicorette**.

QUITTING SMOKING IS HARD!

If you've tried to quit before and haven't succeeded, don't be discouraged! Quitting isn't easy. It takes time, and most people try a few times before they are successful. The important thing is to try again until you succeed. This User's Guide will give you support as you become a non-smoker. It will answer common questions about **Nicorette** and give tips to help you stop smoking, and should be referred to often.

WHERE TO GET HELP. You are more likely to stop smoking by using **Nicorette** with a support program that helps you break your smoking habit. There may be support groups in your area for people trying to quit. Call your local chapter of the American Lung Association, American Cancer Society or American Heart Association for further information. Toll free phone numbers are printed on the Wallet Card on the back cover of this User's Guide.

If you find you cannot stop smoking or if you start smoking again after using **Nicorette**, remember breaking this addiction doesn't happen overnight. You may want to talk to a health care professional who can help you improve your chances of quitting the next time you try **Nicorette** or another method.

LET'S GET ORGANIZED. Your reason for quitting may be a combination of concerns about health, the effect of smoking on your appearance, and pressure from your family

and friends to stop smoking. Or maybe you're concerned about the dangerous effect of second-hand smoke on the people you care about. All of these are good reasons. You probably have others. Decide your most important reasons, and write them down on the wallet card inside the back cover of this User's Guide. Carry this card with you. In difficult moments, when you want to smoke, the card will remind you why you are quitting.

WHAT YOU'RE UP AGAINST.

Smoking is addictive in two ways. Your need for nicotine has become both physical and mental. You must overcome both addictions to stop smoking. So while **Nicorette** will lessen your body's physical addiction to nicotine, you've got to want to quit smoking to overcome the mental dependence on cigarettes. Once you've decided that you're going to quit, it's time to get started. But first, there are some important warnings you should consider.

SOME IMPORTANT WARNINGS. This product is only for those who want to stop smoking.

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.

Do not use

- if you continue to smoke, chew tobacco, use snuff, or use a nicotine patch or other nicotine containing products.

Ask a doctor before use if you have

- a sodium-restricted diet
- heart disease, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate.
- high blood pressure not controlled with medication. Nicotine can increase your blood pressure.
- stomach ulcer or diabetes

Ask a doctor or pharmacist before use if you are

- using a non-nicotine stop smoking drug
- taking a prescription medicine for depression or asthma. Your prescription dose may need to be adjusted.

Stop use and ask a doctor if

- mouth, teeth or jaw problems occur
- irregular heartbeat or palpitations occur
- you get symptoms of nicotine overdose such as nausea, vomiting, dizziness, diarrhea, weakness and rapid heartbeat

Keep out of reach of children and pets. Pieces of nicotine gum may have enough nicotine to make children and pets sick. Wrap used pieces of gum in paper and throw away in the trash. In case of overdose, get medical help or contact a Poison Control Center right away.

LET'S GET STARTED. Becoming a non-smoker starts today. First, check that you bought the right starting dose. **If you smoke 25 or more cigarettes a day,** use 4 mg nicotine gum. **If you smoke less than 25 cigarettes a day,** use 2 mg

nicotine gum. Next, read through the entire User's Guide carefully. Then, set your personalized quitting schedule. Take out a calendar that you can use to track your progress, and identify four dates, using the stickers in the center of this User's Guide:

STEP 1. (Weeks 1-6). Your quit date (and the day you'll start using Nicorette gum). Choose your quit date (it should be soon). This is the day you will quit smoking cigarettes entirely and begin using **Nicorette** to satisfy your cravings for nicotine. For the first six weeks, you'll use a piece of **Nicorette** every hour or two. Be sure to follow the directions starting on pages 10 and 12. Place the Step 1 stickers on this date.

STEP 2. (Weeks 7 to 9). The day you'll start reducing your use of Nicorette. After six weeks, you'll begin gradually reducing your **Nicorette** usage to one piece every two to four hours. Place the Step 2 sticker on this date (the first day of week seven).

STEP 3. (Weeks 10-12). The day you'll further reduce your use of Nicorette.

Nine weeks after you begin using **Nicorette**, you will further reduce your nicotine intake by using one piece every four to eight hours. Place the Step 3 sticker on this date (the first day of week ten). For the next three weeks, you'll use a piece of **Nicorette** every four to eight hours.

End of treatment: The day you'll complete Nicorette therapy.

Nicorette should not be used for longer than twelve weeks. Identify the date thirteen weeks after the date you chose in Step 1, and place the "EX-SMOKER" sticker on your calendar.

PLAN AHEAD. Because smoking is an addiction, it is not easy to stop. After you've given up cigarettes, you will still have a strong urge to smoke. Plan ahead NOW for these times, so you're not defeated in a moment of weakness. The following tips may help:

- Keep the phone numbers of supportive friends and family members handy.
- Keep a record of your quitting process. Track the number of **Nicorette** pieces you use each day, and whether you feel a craving for cigarettes. In the event that

you slip, immediately stop smoking and resume your quit attempt with the **Nicorette** program.

- Put together an Emergency Kit that includes items that will help take your mind off occasional urges to smoke. Include cinnamon gum or lemon drops to suck on, a relaxing cassette tape, and something for your hands to play with, like a smooth rock, rubber band, or small metal balls.
- Set aside some small rewards, like a new magazine or a gift certificate from your favorite store, which you'll "give" yourself after passing difficult hurdles.
- Think now about the times when you most often want a cigarette, and then plan what else you might do instead of smoking. For instance, you might plan to take your coffee break in a new location, or take a walk right after dinner, so you won't be tempted to smoke.

HOW NICORETTE GUM WORKS. **Nicorette's** sugar-free chewing pieces provide nicotine to your system – they work as a temporary aid to help you quit smoking by reducing nicotine withdrawal symptoms. **Nicorette** provides a lower level of nicotine to your blood than cigarettes, and allows you to gradually do away with your body's need for nicotine. Because **Nicorette** does not contain the tar or carbon monoxide of cigarette smoke, it does not have the same health dangers as tobacco. However, it still delivers nicotine, the addictive part of cigarette smoke. Nicotine can cause side effects such as headache, nausea, upset stomach, and dizziness.

HOW TO USE NICORETTE GUM. **If you are under 18 years of age, ask a doctor before use.** Before you can use **Nicorette** correctly, you have to practice! That sounds silly, but it isn't. **Nicorette isn't like ordinary chewing gum.** It's a medicine, and must be chewed a certain way to work right. Chewed like ordinary gum, **Nicorette** won't work well and

can cause side effects. An overdose can occur if you chew more than one piece of **Nicorette** at the same time, or if you chew many pieces one after another. Read all the following instructions before using **Nicorette**. Refer to them often to make sure you're using **Nicorette** gum correctly. If you chew too fast, or do not chew correctly, you may get hiccups, heartburn, or other stomach problems. Don't eat or drink for 15 minutes before using **Nicorette**, or while chewing a piece. The effectiveness of **Nicorette** may be reduced by some foods and drinks, such as coffee, juices, wine or soft drinks.

1) Stop smoking completely before you start using **Nicorette.**
2) To reduce craving and other withdrawal symptoms, use **Nicorette** according to the dosage schedule on page 12.
3) Chew each **Nicorette** piece very slowly several times.
4) Stop chewing when you notice a peppery taste, or a slight tingling in your mouth. (This usually happens after about 15 chews, but may vary from person to person.)

5) "PARK" the **Nicorette** piece between your cheek and gum, and leave it there.

6) When the peppery taste or tingle is almost gone (in about a minute), start to chew a few times slowly again. When the taste or tingle returns, stop again.

7) Park the **Nicorette** piece again (in a different place in your mouth).

8) Repeat steps 3 to 7 (chew, chew, park) until most of the nicotine is gone from the **Nicorette** piece (usually happens in about half an hour; the peppery taste or tingle won't return.)

9) Wrap the used **Nicorette** piece in paper and throw away in the trash.

The following chart lists the recommended usage schedule for Nicorette:		
Weeks 1 to 6	**Weeks 7 to 9**	**Weeks 10 to 12**
1 piece every 1 to 2 hours	1 piece every 2 to 4 hours	1 piece every 4 to 8 hours
DO NOT USE MORE THAN 24 PIECES PER DAY.		

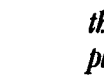
To improve your chances of quitting, use at least 9 pieces of **Nicorette** a day. If you experience strong or frequent cravings, you may use a second piece within the hour. However, do not continuously use one

A Personal
Invitation to Join
brought to you by
Nicorette®
FREE
INDIVIDUALIZED STOP
SMOKING PROGRAM
COMMITTED
QUITTERS®™
VISIT COMMITTEDQUITTERS.COM

ENROLL
NOW!

To Enroll Call Now

or enroll online at



Having a Plan Will Help You Quit

Nicorette® INDIVIDUALIZED STOP SMOKING PROGRAM COMMITTED QUITTERS™

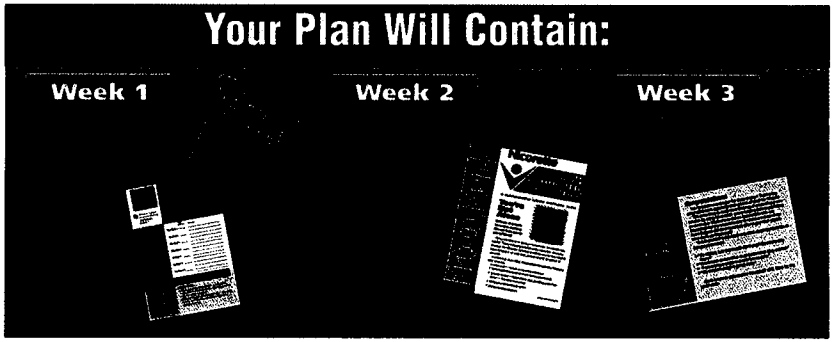
is a FREE custom-tailored plan to help you break your psychological addiction to smoking — while NICORETTE® fights the physical addiction. To get your plan, call toll free 1-800-770-0708 or visit us on the Web at www.committedquitters.com.

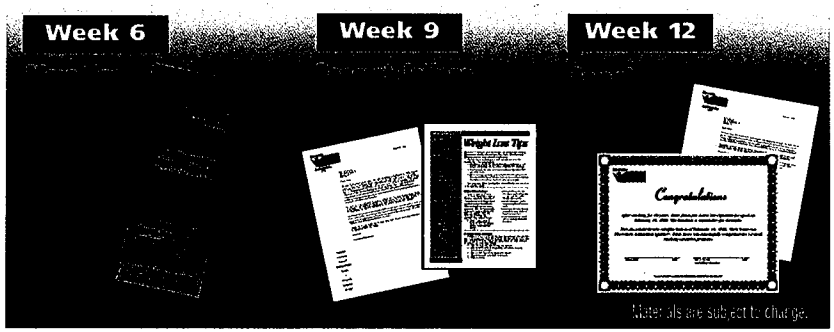
CALL:

Provide your **Committed Quitters®** personal code (the personal code is located within the **Committed Quitters®** portion of this User's Guide). You will be asked a few questions by a plan specialist to understand YOU and YOUR specific needs.

CALL:

In a few days, you will receive your custom-tailored stop smoking plan. You will continue to receive personal, custom-tailored support — six times during the next twelve weeks.


Your Plan Will Contain:
Week 1
Week 2
Week 3


Week 6
Week 9
Week 12
Congratulations
Materials are subject to change.

First Week:

1. Control your physical cravings for nicotine.
Use enough – You can greatly increase your chances for success by using at least 9 to 12 pieces every day when you start using Nicorette.

2. Get rid of all signs that you ever smoked —
ashtrays, matches and, of course, cigarettes.

3. Stay active.
Keep busy to take your mind off smoking.

4. Think positive!
The first week is the toughest. Remind yourself that it will get easier.

Use the sample of the Stop Smoking Plan (see next page) *to get you through the first week until your materials arrive.*

WEEK ONE

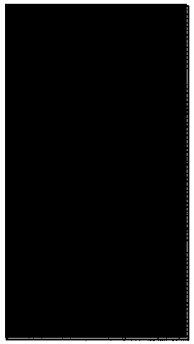
CALENDAR

Day	Pieces Chewed	Planning: Plan ahead. Note events here that will tempt you to smoke, and how you will deal with them.
1.		
2.		
3.		
4.		
5.		
6.		
7.		

*Carry this calendar with you.

If you have gone back to smoking, call 1-800-770-0708 to order relapse information.

TIPS



*The **Committed Quitters**® program is a plan specifically individualized for you.*

Call Between 7 am and 12 Midnight EST or enroll online 24 hours a day. (ONE PLAN PER CUSTOMER)

Read and follow label directions

FOLD LINE

piece after another, since this may cause you hiccups, heartburn, nausea or other side effects.

HOW TO REDUCE YOUR NICORETTE USAGE. The goal of using **Nicorette** is to slowly reduce your dependence on nicotine. The schedule for using **Nicorette** will help you reduce your nicotine craving gradually as you reduce and then stop your use of **Nicorette**. Here are some tips to help you cut back during each step and then stop using **Nicorette**:

- After a while, start chewing each **Nicorette** piece for only 10 to 15 minutes, instead of half an hour. Then, gradually begin to reduce the number of pieces used.
- Or, try chewing each piece for longer than half an hour, but reduce the number of pieces you use each day.
- Substitute ordinary chewing gum for some of the **Nicorette** pieces you would normally use. Increase the number of pieces of ordinary gum as you cut back on the **Nicorette** pieces.

- Check how well you've reduced your daily usage of **Nicorette** in Weeks 10 to 12. You should only be using about 3 to 5 pieces a day. Get ready to stop.

STOP USING NICORETTE AT THE END OF WEEK 12. The following tips may help you with stopping **Nicorette** Gum at the end of 12 weeks.

- Set a stop date.
- Use the same number of pieces of confectionery gum or mints as you were using **Nicorette** per day.

At the times when you have an urge to use **Nicorette**, use a strong flavored gum or mint such as cinnamon or peppermint.

- Reduce the number of pieces of gum or mints you use by one piece per day until you do not need to use any gum or mints.

Talk to your doctor if you:

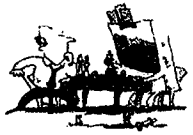
- still feel the need to use **Nicorette** at the end of week 12
- start using **Nicorette** again after stopping
- start smoking again

TIPS TO MAKE QUITTING EASIER.

Within the first few weeks of giving up smoking, you may be tempted to smoke for pleasure, particularly after completing a difficult task, or at a party or bar. Here are some tips to help get you through the important first stages of becoming a non-smoker:

On Your Quit Date:

- Ask your family, friends and co-workers to support you in your efforts to stop smoking.
- Throw away all your cigarettes, matches, lighters, ashtrays, etc.
- Keep busy on your quit day. Exercise. Go to a movie. Take a walk. Get together with friends.



- Figure out how much money you'll save by not smoking. Most ex-smokers can save more than $1,000 a year.
- Write down what you will do with the money you save.

- Know your high risk situations and plan ahead how you will deal with them.
- Keep **Nicorette** gum near your bed, so you'll be prepared for any nicotine cravings when you wake up in the morning.
- Visit your dentist and have your teeth cleaned to get rid of the tobacco stains.

Right after Quitting:

- During the first few days after you've stopped smoking, spend as much time as possible at places where smoking is not allowed.
- Drink large quantities of water and fruit juices.
- Try to avoid alcohol, coffee and other beverages you associate with smoking.
- Remember that temporary urges to smoke will pass, even if you don't smoke a cigarette.
- Keep your hands busy with something like a pencil or a paper clip.
- Find other activities which help you relax without cigarettes.
- Swim, jog, take a walk, play basketball.

- Don't worry too much about gaining weight. Watch what you eat, take time for daily exercise, and change your eating habits if you need to.
- Laughter helps. Watch or read something funny.

WHAT TO EXPECT. Your body is now coming back into balance. During the first few days after you stop smoking, you might feel edgy and nervous and have trouble concentrating. You might get headaches, feel dizzy and a little out of sorts, feel sweaty or have stomach upsets. You might even have trouble sleeping at first. These are typical withdrawal symptoms that will go away with time. Your smoker's cough will get worse before it gets better. But don't worry, that's a good sign. Coughing helps clear the tar deposits out of your lungs.

After A Week Or Two.
By now you should be feeling more confident that you can handle those smoking urges. Many of your withdrawal symptoms have left by now, and you should be noticing some positive signs: less coughing, better breathing and an improved sense of taste and smell, to name a few.

After A Month.
You probably have the urge to smoke much less often now. But urges may still occur, and when they do, they are likely to be powerful ones that come out of nowhere. Don't let them catch you off guard. Plan ahead for these difficult times.

Concentrate on the ways non-smokers are more attractive than smokers. Their skin is less likely to wrinkle. Their teeth are whiter, cleaner. Their breath is fresher. Their hair and clothes smell better. That cough that seems to make even a laugh sound more like a rattle is a thing of the past. Their children and others around them are healthier, too.

What To Do About Relapse.
What should you do if you slip and start smoking again? The answer is simple. A lapse of one or two or even a few cigarettes has not spoiled your efforts! Discard your cigarettes, forgive yourself and try again. If you start smoking again, keep your box of **Nicorette** for your next quit attempt.

If you have taken up regular smoking again, don't be discouraged. Research shows that the best thing you can do is to try again. The important thing is to learn from your last attempt.

- Admit that you've slipped, but don't treat yourself as a failure.
- Try to identify the "trigger" that caused you to slip, and prepare a better plan for dealing with this problem next time.
- Talk positively to yourself – tell yourself that you have learned something from this experience.
- Make sure you used **Nicorette** gum correctly over the full 12 weeks to reduce your craving for nicotine.
- Remember that it takes practice to do

anything, and quitting smoking is no exception.

WHEN THE STRUGGLE IS OVER.

Once you've stopped smoking, take a second and pat yourself on your back. Now do it again. You deserve it. Remember now why you decided to stop smoking in the first place. Look at your list of reasons. Read them again. And smile. Now think about all the money you are saving and what you'll do with it. All the non-smoking places you can go, and what you might do there. All those years you may have added to your life, and what you'll do with them. Remember that temptation may not be gone forever. However, the hard part is behind you so look forward with a positive attitude, and enjoy your new life as a non-smoker.

QUESTIONS & ANSWERS.

1. How will I feel when I stop smoking and start using Nicorette?

You'll need to prepare yourself for some nicotine withdrawal symptoms. These begin almost immediately after you stop

smoking, and are usually at their worst during the first three or four days. Understand that any of the following is possible:

- craving for cigarettes
- anxiety, irritability, restlessness, mood changes, nervousness
- drowsiness
- trouble concentrating
- increased appetite and weight gain
- headaches, muscular pain, constipation, fatigue.

Nicorette can help provide relief from withdrawal symptoms such as irritability and nervousness, as well as the craving for nicotine you used to satisfy by having a cigarette.

2. Is Nicorette just substituting one form of nicotine for another?

Nicorette does contain nicotine. The purpose of **Nicorette** is to provide you with enough nicotine to help control the physical withdrawal symptoms so you can deal with the mental aspects of quitting. During the 12 week program, you will gradually

reduce your nicotine intake by switching to fewer pieces each day. Remember, don't use **Nicorette** together with nicotine patches or other nicotine containing products.

3. Can I be hurt by using Nicorette?
For most adults, the amount of nicotine in the gum is less than from smoking. Some people will be sensitive to even this amount of nicotine and should not use this product without advice from their doctor (see page 5).

Because **Nicorette** is a gum-based product, chewing it can cause dental fillings to loosen and aggravate other mouth, tooth and jaw problems. **Nicorette** can also cause hiccups, heartburn and other stomach problems especially if chewed too quickly or not chewed correctly.

4. Will I gain weight?
Many people do tend to gain a few pounds the first 8-10 weeks after they stop smoking. This is a very small price to pay for the enormous gains that you will make in your overall health and attractiveness. If you

continue to gain weight after the first two months, try to analyze what you're doing differently. Reduce your fat intake, choose healthy snacks, and increase your physical activity to burn off the extra calories.

5. Is Nicorette more expensive than smoking?

The total cost of **Nicorette** for the twelve week program is about equal to what a person who smokes one and a half packs of cigarettes a day would spend on cigarettes for the same period of time. Also, use of **Nicorette** is only a short-term cost, while the cost of smoking is a long-term cost, because of the health problems smoking causes.

6. What if I slip up?

Discard your cigarettes, forgive yourself and then get back on track. Don't consider yourself a failure or punish yourself. In fact, people who have already tried to quit are more likely to be successful the next time.

GOOD LUCK!

Recommended dosage schedule for Nicorette:

STEP 1	STEP 2	STEP 3
weeks 1 to 6	**weeks 7 to 9**	**weeks 10 to 12**
1 piece every	1 piece every	1 piece every
1 to 2 hours	2 to 4 hours	4 to 8 hours

60425XB

WALLET CARD

My most important reasons to quit smoking are:

_____

_____

_____

_____

_____

WHERE TO CALL FOR HELP:

American Lung Association
1-800-LUNG-USA

American Cancer Society
1-800-227-2345

American Heart Association
1-800-242-8721

WALLET CARD

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

18-612/S-050 & 20-066/S-031

CHEMISTRY REVIEW(S)

OFFICE ON NEW DRUG QUALITY ASSESSMENT
DIVISION OF POST-MARKETING EVALUATION, BRANCH VIII
Review of Chemistry, Manufacturing, and Controls
for the Division of Non-prescription Products, HFD-560

NDA #: 18-612
20-066 **CHEM.REVIEW #:** 1 **REVIEW DATE:** 04-JUN-2008

SUBMISSION/TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
NDA 18-612/SCF-050	13-FEB-2008	13-FEB-2008	04-MAR-2008
NDA 20-066/SCF-031	13-FEB-2008	13-FEB-2008	04-MAR-2008
NDA 18-612/SCF-050 (BC)	21-MAR-2008	21-MAR-2008	21-MAR-2008
NDA 20-066/SCF-031 (BC)	21-MAR-2008	21-MAR-2008	21-MAR-2008

NAME & ADDRESS OF APPLICANT: GlaxoSmithKline
1500 Littleton Road
Parsippany, NJ 0704

Marissa M. Fletcher, Ph.D.
Manager, Regulatory Affairs
(973) 889-4443

DRUG PRODUCT NAME

Proprietary: Nicorette® Gum
Nonproprietary/USAN: Nicotine Polacrilex
Code Names/#'s: (b) (4)
Chemical Type/
Therapeutic Class:

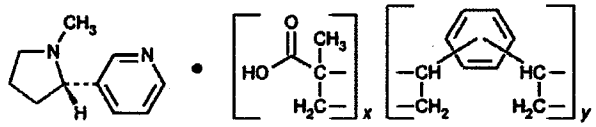
PHARMACOLOGICAL CATEGORY/INDICATION: Reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking.

DOSAGE FORM: Gum, chewing, buccal
STRENGTHS: 2mg; 4mg
ROUTE OF ADMINISTRATION: Oral
DISPENSED: ___ **Rx** _X_ **OTC**

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

Nicotine: 3-(1-Methyl-2-pyrrolidinyl)pyridine; or **β**-Pyridyl-**α**-*N*-methyl pyrrolidine
CAS No.: [54-11-5]
Molecular Formula: $C_{10}H_{14}N_2$
Molecular Weight: 162.23

Nicotine Polacrilex is a nicotine complex with a weak carboxylic cation-exchange resin prepared from methacrylic acid and divinylbenzene. It contains not less than 95.0% and not more than 115.0% of the labeled amount of nicotine, calculated on the anhydrous basis.



CAS No.: [96055-45-7]

RELATED DOCUMENTS:

NDA 18-612/SCF-028, NDA 20-066/SCF-016; approved 25-SEP-2000
NDA 18-612/SCF-037, NDA 20-066/SCF-019; approved 18-JUN-2004
NDA 18-612/SCF-042, NDA 20-066/SCF-023; approved 02-DEC-2005
NDA 18-612/SCF-049, NDA 20-066/SCF-030; approved 26-JUN-2007

SUPPORTING DOCUMENTS:

DMF 3835, Type II, for Nicotine Polacrilex Gums, held by McNeil Consumer Healthcare, a Johnson & Johnson Co., Letter of Authorization dated 14-MAR-2008. [On December 21, 2006, former DMF holder Pfizer sold its consumer healthcare business (the manufacturer of Nicorette® Gum) to Johnson & Johnson.]

DMF 5757, Type II, for Nicotine Polacrilex Resin 20%, held by McNeil Consumer Healthcare, a Johnson & Johnson Co., Letter of Authorization dated 15-FEB-2008. [On December 21, 2006, former DMF holder Pfizer sold its consumer healthcare business (the manufacturer of Nicorette® Gum) to Johnson & Johnson.]

DMF 3831, Type II, Nicotine Polacrilex Gums Manufactured at Esjerg, Denmark, held by McNeil Consumer Healthcare, a Johnson & Johnson Co., Letter of Authorization dated 24-JUL-2006. [On December 21, 2006, former DMF holder Pfizer sold its consumer healthcare business (the manufacturer of Nicorette® Gum) to Johnson & Johnson.]

REMARKS/COMMENTS:

This "Supplement for Prior Approval" provides for a new flavor for Nicorette® Gums, 2mg (NDA 18-612) and 4mg (NDA 20-066). **Specifically, Nicorette® White Ice™ Mint 2mg and** 4mg Coated Gum is a line-extension to approved Nicorette® coated gum variants. The subject drug product will be manufactured by McNeil at their Helsingborg, Sweden facility. This facility

is already an FDA-approved site for the manufacture of currently marketed Nicorette® gum products.

Note that all of the Nicorette® coated gum products, including the subject drug product, have an (b) (4) (b) (4) The main differences between currently marketed Nicorette® coated gum products and the subject drug product are the flavor and (b) (4) These modifications in the formulation are considered minor and are not expected to affect drug product stability, quality, or drug release. An *in vitro* study was performed to compare the release profile of the subject drug product with a reference formulation, Nicorette® Fruit Chill. The similarity factor obtained in the release comparison was 69. According to the criterion for this test, Nicorette® White Ice Mint is considered similar to the currently approved Nicorette Fruit Chill formulation.

With the exception of the new ingredients ((b) (4) Flavor and starch), all of the ingredients **in Nicorette® (nicotine polacrilex) White Ice™ Mint 2mg and 4mg Coated Gums are identical to** those used in Nicorette® (nicotine polacrilex) **Cinnamon Surge™ 2mg and 4mg Coated Gums.** (b) (4) (b) (4) In light of this, no data were presented on the residual solvent profile of this product. For an overview of **the residual solvent profile of Nicorette® (nicotine polacrilex) White Ice™ Mint 2mg and 4mg** Coated Gums, refer to NDA 18-612/SCF-049 and NDA 20-066/SCF-030 for Nicorette® **(nicotine polacrilex) Cinnamon Surge™ 2mg** and 4mg Coated Gum, approved 02-JUL-2007.

The specifications and test methods used to release and evaluate the product on stability are equivalent to already approved specifications and test methods for currently marketed Nicorette® coated gums.

The inactive ingredients contained in Nicorette® (nicotine polacrilex) White Ice™ Mint 2mg and 4mg Coated Gum consist of polacrilex resin (b) (4) gum base, xylitol, sodium bicarbonate (2mg only), sodium carbonate, magnesium oxide, hypromellose, polysorbate 80, starch, acesulfame potassium, sucralose, menthol, peppermint oil, (b) (4) Flavor, titanium dioxide, D&C Yellow No. 10 aluminum lake (4mg only) and carnauba wax. With the exception of the flavor, all of the excipients are approved pharmaceutical grade materials (USP or USP- NF) and all have a history of in-use safety in similar products of this type. In light of this, no data are presented for any of these ingredients. The flavor ingredient, (b) (4) Flavor, contains components which are designated as substances that are generally recognized as safe (GRAS), or are approved for use by a regulation of the United States Food and Drug Administration. Exposure to these inactive ingredients from use of Nicorette® (nicotine **polacrilex) White Ice™ Mint 2mg and 4mg Coated Gum is comparable to exposures from**

similar products that are currently marketed, and therefore this product presents no significant toxicological risk.

Three pilot-scale batches of each strength of the subject drug products have been placed on stability. Satisfactory 6-month stability data, provided in the amendment's Module 3, Section 3.2.P.8, together with 24 months of data from Nicorette® Fruit Chill, support a 24-month expiry date for the proposed drug product.

CONCLUSIONS & RECOMMENDATIONS: **APPROVAL**

The information submitted in the supplement and referenced DMFs adequately support the proposed changes. Approval is recommended.

(see attached electronic signature page)

J. S. Hathaway, Ph.D.
Reviewing Chemist

cc: Orig. NDA 18-612
Orig. NDA 20-066
ONP/DNP/Division File
ONDQA/DPE/Chem/JSHathaway
ONDQA/DPE/ChemPAL/LZhou
ONDQA/DPE/ChemBranchChf/HPatel
ONDQA/DPE/ProjMgr/RMcKnight

filename: C:\Documents and Settings\hathaways\My Documents\MSWordDocs\NDA Reviews\SuppNDAs\18612\N18612r.scf.050.doc

Approval

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

/s/

Steve Hathaway
6/4/2008 11:23:48 AM
CHEMIST
New flavoring, (b) (4) ingredientsfor 2mg and 4mg gums
For your concurrence

Liang Zhou
6/4/2008 11:38:31 AM
CHEMIST
For BC, Dr. H Patel Becky, It is OTC managed

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

18-612/S-050 & 20-066/S-031

OTHER REVIEW(S)

Drug Labeling Review

NDA # 18612 and 20-066	**Sponsor**: GlaxoSmithKline
Drug Product: Nicorette® gum 2 mg and 4 mg (White Ice Mint Gum coated)	**# of Stock Keeping Units in Submission:** 3 for each NDA submission
Submission Date: February 13 and 14, 2008	**Review Date:** June 6, 2008
Type of Submission: SCF-050 and SCF-031	**Reviewer**: Mary S. Robinson

Stock Keeping Unit: Nicorette (nicotine polacrilex) 4 mg White Ice Mint coated gum 20, 100, and 160 count cartons.

Background
This review is based on GlaxoSmithKline's February 13, 2008 and February 14, 2008 submission of NDA 18612/SCF-050 (2mg) and NDA 20066/SCF-031 (4 mg) gums, respectively, for Nicorette® new White Ice Mint coated gum. This submission contains full color draft printed labeling for Nicorette 2 mg and 4 mg White Ice Mint coated gum 20, 100, and 160 count cartons, annotated White Ice Mint 2 mg and 4 mg 20, 100 and 160 count cartons, White Ice Mint Carrying Case, blister card, and User's Guide. This product is a line extension to already approved Nicorette coated gum flavor variants. The sponsor states that the submitted labeling is consistent with previously approved labeling for the coated gums, with the exception of the inactive ingredients relating to the flavor and (b) (4)

On June 11, 2008 the sponsor amended (by eMail) the February 13 and 14, 2008 submissions in response to an agency inquiry about the nature of the reserved promotional text area on the cartons. The sponsor agreed to resubmit the labeling with the added promotional text. The new submission contained full color printed labeling for the 2 mg and 4 mg 20-, 100-, and 160-count cartons.

Unless otherwise noted, the reviewer's comments and recommendations refer to the labeling submitted for 2 mg and 4 mg 20-, 100-, and 160-count cartons

Reviewer's Comments
1. The 100-, and 160-count cartons include promotion text for the Quit Rewards promotional.

This is acceptable.

2. The 20 count carton includes a coupon instead of the Quit Rewards promotion.

This is acceptable.

3. The carton and "Drug Facts" labeling for the 20-, 100-, and 160-count cartons are identical to the previously approved labeling with the exception of the inactive ingredients relating to the flavor and (b) (4) in the "inactive ingredients" section. The annotated font specifications are acceptable. These labeling are acceptable. However, for consistency with the approved labeling for Nicorette coated gum flavor variants, the sponsor needs to capitalize the statement of identity phrase "STOP SMOKING AID" on the principal display panel at the time of next printing or within 180 days, whichever is sooner.

4. The carrying case label, blister card and Users' Guide Information contain no changes from the previous approved labeling. These labeling do not need to be re-approved.

Reviewer's Recommendations

1. Inform the sponsor that this supplement can be approved. Request the sponsor to submit final printed labeling, identical to the draft carton labels (20-, 100- and 160-counts) submitted on June 11, 2008, when available.

2. The carrying case label, blister card and Users' Guide Information are identical to the previous approved labeling, do not need to request to sponsor to submit final printed labeling identical to the labeling submitted on February 13 and 14, 2008.

3. Remind the sponsor to remove "NEW Flavor" on the principal display of the cartons, 6 months after introduction to the market place.

4. Request the sponsor to capitalize the statement of identity phrase "STOP SMOKING AID" on the principal display panel of for the 20-, 100-, and 160-, count cartons, at the time of next printing or within 180 days, whichever come first. This revision can be submitted in the sponsor's next annual report.

C:\data\DATA Nicotine\Nicorette White Ice Mint Gum NDA20066_S031andS050jun 6 2008DFS.doc

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

/s/

Mary Robinson
6/12/2008 03:47:03 PM
INTERDISCIPLINARY

Marina Chang
6/12/2008 03:57:53 PM
INTERDISCIPLINARY
NDA 18-612/SCF-050: This review is superseded by the labeling review that was DFS'ed on 6/11/08 and signed off on 6/12/08 morning.

Drug Labeling Review

NDA # 18-612	**Sponsor:** GlaxoSmithKline
Drug Product: Nicorette® gum 2 mg (White Ice Mint Gum coated)	**# of Stock Keeping Units in Submission:** 3
Submission Date: February 13, 2008/	**Review Date:** June 4, 2008
Type of Submission: SCF-050	**Reviewer:** Mary S. Robinson

Stock Keeping Unit: Nicorette (nicotine polacrilex) 2 mg White Ice Mint coated gum 20, 100, and 160 count cartons.

Background
This review is based on GlaxoSmithKline's February 13, 2008 submission of NDA 18612/SCF-050 for Nicorette® 2 mg new White Ice Mint coated gum. This submission contains full color draft printed labeling for Nicorette 2 mg White Ice Mint coated gum 20, 100, and 160 count cartons, annotated White Ice Mint 2 mg 20, 100 and 160 count cartons, White Ice Mint Carrying Case, blister card, and User's Guide. This product is a line extension to already approved Nicorette coated gum flavor variants. The sponsor states that the submitted labeling is consistent with previously approved labeling for the coated gums, with the exception of the inactive ingredients relating to the flavor and (b) (4)

On June 11, 2008 the sponsor amended (by eMail) the February 13, 2008 submission in response to an agency inquiry about the nature of the reserved promotional text area on the cartons. The sponsor agreed to resubmit the labeling with the added promotional text. The new submission contained full color printed labeling for the 2 mg 20-, 100-, and 160-count cartons.

Unless otherwise noted, the reviewer's comments and recommendations refer to the labeling submitted for 2 mg 20-, 100-, and 160-count cartons

Reviewer's Comments
1. The 100-, and 160-count cartons include promotion text for the Quit Rewards promotional.

This is acceptable.

2. The 20 count carton includes a coupon instead of the Quit Rewards promotion.

This is acceptable.

Reviewer's Recommendations
The submitted labeling is acceptable. The sponsor maybe informed that this supplement can be approved.

However, at printing, for consistency with the approved labeling for Nicorette coated gum flavor variants, the sponsor needs to capitalize the statement of identity phrase "STOP SMOKING AID" on the principal display panel of the Nicorette 2 mg White Ice Mint coated gum 20-, 100-, and 160-, count cartons.

Also remind the sponsor to remove "NEW Flavor" after 6 months on the 2 mg 20-, 100-, and -160 count cartons

46 Pages of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

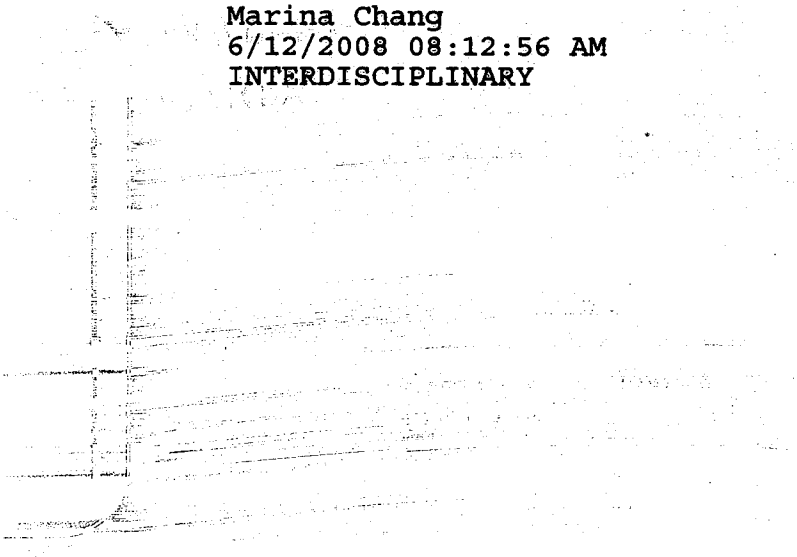
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Mary Robinson
6/11/2008 03:35:11 PM
INTERDISCIPLINARY

Marina Chang
6/12/2008 08:11:50 AM
INTERDISCIPLINARY

Marina Chang
6/12/2008 08:12:56 AM
INTERDISCIPLINARY



CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

18-612/S-050 & 20-066/S-031

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

GlaxoSmithKline

GlaxoSmithKline
1500 Littleton Road
Parsippany, NJ
07054-3884

Tel. 973 889 2100
Fax. 973 889 2390
www.gsk.com

March 21, 2008

NDA 20-066

Andrea Leonard-Segal, M.D.
Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Food and Drug Administration
Center for Drug Evaluation and Research
5901-B Ammendale Rd.
Beltsville, MD 20705-1266

Re: NDA 20-066/S-031
Nicorette® White Ice™ Mint 4mg Coated Gum
AMENDMENT #1: CMC – Drug Product and Drug Substance

Dear Dr. Leonard-Segal,

Reference is made to NDA 20-066, Serial No. 031 for Nicorette® White Ice Mint™ 4mg Coated Gum submitted on February 14, 2008.

The drug product manufacturer, McNeil, has amended their drug master file (DMF No. 3835) on February 25, 2008 and March 14, 2008 to tighten the nicotine related substances (NRS) specifications for the following tests based on review of 6-month stability data for Nicorette White Ice Mint 4mg Coated Gum:

(b) (4)

As a result of these updates, the proposed specifications for the subject drug product are now consistent with the currently approved Nicorette coated gum products (i.e., Freshmint, Fruit Chill and Cinnamon Surge).

Since NDA 20-066/S-031 was submitted in electronic Common Technical Document (e-CTD) format, the above-mentioned updates to the drug product are provided as replacement sections in Module 3.

In addition, an amendment to the manufacturer's drug substance drug master file (DMF No. 5757) was submitted to the Agency on February 15, 2008. The updates made to this DMF are considered minor in nature and were included in McNeil's annual report submitted on February 19, 2008. Information regarding this update to the drug substance DMF is referenced in Module 3 of this amendment.

Also enclosed are updated letters of authorization and cross reference information from McNeil. Please note that the following administrative change was made to Module 1:

- replacement of cross reference letter provided in NDA 20-066/S-031 (submitted on February 14, 2008) to reflect the correct letter provided by McNeil for the subject drug product

An additional administrative change was made by the Sponsor, GlaxoSmithKline (GSK) to Module 2, Section 2.7.1 *(Summary of Biopharmaceutic Studies and Associated Analytical Methods)* to correct for a typographical error.

Please note that this submission is provided in CTD format in accordance with the draft guidance titled, "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications Using the CTD Specifications," dated April 2006, and is formatted according to the folder/file structure described in the ICH M2 EWG Electronic Common Technical Document Specification v3.2 dated February 4, 2004.

This submission has been confirmed to be virus-free using Symantec AntiVirus Corporate Edition, version 10.1.0.396, scan engine 71.4.0.15, updated 3/20/2008 rev. 9, and is approximately 2.8 MB in size.

If you have any questions regarding this supplement, please call me at 973-889-4443.

Sincerely,

Marissa M. Fletcher, Ph.D.
Manager, Regulatory Affairs
GlaxoSmithKline Consumer Healthcare, L.P.

GlaxoSmithKline
1500 Littleton Road
Parsippany, NJ
07054-3884

Tel. 973 889 2100
Fax. 973 889 2390
www.gsk.com

March 21, 2008

NDA 18-612

Andrea Leonard-Segal, M.D.
Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Food and Drug Administration
Center for Drug Evaluation and Research
5901-B Ammendale Rd.
Belstville, MD 20705-1266

Re: NDA 18-612/S-050
Nicorette® White Ice™ Mint 2mg Coated Gum
AMENDMENT #1: CMC – Drug Product and Drug Substance

Dear Dr. Leonard-Segal,

Reference is made to NDA 18-612, Serial No. 050 for Nicorette® White Ice Mint™ 2mg Coated Gum submitted on February 13, 2008.

The drug product manufacturer, McNeil, has amended their drug master file (DMF No. 3835) on February 25, 2008 and March 14, 2008 to update the finished product specifications for the subject drug product as described below:

1. Tightening of the nicotine related substances (NRS) specifications for the following tests based on review of 6-month stability data:

(b) (4)

2. Corrections to clerical errors observed in the NRS acceptance criteria for the following:

(b) (4)

As a result of these updates, the proposed specifications for the subject drug product are now consistent with the currently approved Nicorette coated gum products (i.e., Freshmint, Fruit Chill and Cinnamon Surge).

Since NDA 18-612/S-050 was submitted in electronic Common Technical Document (e-CTD) format, the above-mentioned updates to the drug product are provided as replacement sections in Module 3.

In addition, an Amendment to the manufacturer's drug substance drug master file (DMF No. 5757) was submitted to the Agency on February 15, 2008. The updates made to this DMF are considered minor in nature and were included in McNeil's annual report submitted on February 19, 2008. Information regarding this update to the drug substance DMF is referenced in Module 3 of this Amendment.

Also enclosed are updated letters of authorization and cross reference information from McNeil. Please note that the following administrative change was made to Module 1:

- replacement of cross reference letter provided in NDA 18-612/S-050 (submitted on February 13, 2008) to reflect the correct letter provided by McNeil for the subject drug product

This submission is provided in CTD format in accordance with the draft guidance titled, "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications Using the CTD Specifications," dated April 2006, and is formatted according to the folder/file structure described in the ICH M2 EWG Electronic Common Technical Document Specification v3.2 dated February 4, 2004.

This submission has been confirmed to be virus-free using Symantec AntiVirus Corporate Edition, version 10.1.0.396, scan engine 71.4.0.15, updated 3/20/2008 rev. 9, and is approximately 2.6 MB in size.

If you have any questions regarding this supplement, please call me at 973-889-4443.

Sincerely,

Marissa M. Fletcher, Ph.D.
Manager, Regulatory Affairs
GlaxoSmithKline Consumer Healthcare, L.P.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 18-612/S-050

PRIOR APPROVAL SUPPLEMENT

GlaxoSmithKline Consumer Healthcare
Attention: Marissa M. Fletcher, Ph.D.
Manager, Regulatory Affairs
1500 Littleton Road
Parsippany, NJ 07054-3884

Dear Dr. Fletcher:

We have received your supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product:	Nicorette (2 mg, nicotine polacrilex) gum
NDA Number:	18-612
Supplement number:	050
Date of supplement:	February 13, 2008
Date of receipt:	February 13, 2008

This supplemental application proposes a new White Ice Mint flavor variant and associated labeling changes.

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on April 13, 2008, in accordance with 21 CFR 314.101(a). If the application is filed, the goal date will be June 13, 2008.

Please cite the application number listed above at the top of the first page of all submissions to this application. Send all submissions, electronic or paper, including those sent by overnight mail or courier, to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

If you have any question, call Mary Lewis, Regulatory Project Manager, at (301) 796-0941.

Sincerely,

{See appended electronic signature page}

Leah Christl, Ph.D.
Acting Chief, Project Management Staff
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
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/

Leah Christl
3/14/2008 03:04:50 PM

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 20-066/S-031

PRIOR APPROVAL SUPPLEMENT

GlaxoSmithKline Consumer Healthcare
Attention: Marissa M. Fletcher, Ph.D.
Manager, Regulatory Affairs
1500 Littleton Road
Parsippany, NJ 07054-3884

Dear Dr. Fletcher:

We have received your supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product:	Nicorette (4 mg, nicotine polacrilex) gum
NDA Number:	20-066
Supplement number:	031
Date of supplement:	February 14, 2008
Date of receipt:	February 14, 2008

This supplemental application proposes a new White Ice Mint flavor variant and associated labeling changes.

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on April 14, 2008, in accordance with 21 CFR 314.101(a). If the application is filed, the goal date will be June 14, 2008.

Please cite the application number listed above at the top of the first page of all submissions to this application. Send all submissions, electronic or paper, including those sent by overnight mail or courier, to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

If you have any question, call Mary Lewis, Regulatory Project Manager, at (301) 796-0941.

Sincerely,

{See appended electronic signature page}

Leah Christl, Ph.D.
Acting Chief, Project Management Staff
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
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/

Leah Christl
3/14/2008 03:05:44 PM

February 14, 2008

NDA 20-066

Andrea Leonard-Segal, M.D.
Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Food and Drug Administration
Center for Drug Evaluation and Research
5901-B Ammendale Rd.
Belstville, MD 20705-1266

Re: Nicotine Polacrilex Gum, 4mg
Supplement – Prior Approval (CMC): New flavor coated gum variant
Nicorette® White Ice™ Mint 4mg Coated Gum
NDA 20-066/S-031

Dear Dr. Leonard-Segal,

In accordance with 21 CFR 314.70(c), GlaxoSmithKline Consumer Healthcare (GSK) hereby submits a Prior Approval Supplement for Nicorette® White Ice Mint™ 4mg Coated Gum.

The subject drug product is a new flavor line extension to currently approved Nicorette coated gum variants. Please note that McNeil has deemed certain information in the Chemistry, Manufacturing, and Controls section of this Supplement to be proprietary. Therefore, cross-references to McNeil's drug master files (DMF) are provided and included in this Supplement accordingly.

This submission is provided in electronic CTD (e-CTD)format in accordance with the draft guidance titled, "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications Using the CTD Specifications," dated April 2006, and is formatted according to the folder/file structure described in the ICH M2 EWG Electronic Common Technical Document Specification v3.2 dated February 4, 2004.

This submission has been confirmed to be virus-free using Symantec AntiVirus Corporate Edition, version 10.1.0.396, scan engine 71.4.0.15, updated 2/13/08, and is approximately 12MB in size.

If you have any questions regarding this supplement, please call me at 973-889-4443.

Sincerely,

Marissa M. Fletcher, Ph.D.
Manager, Regulatory Affairs
GlaxoSmithKline Consumer Healthcare, L.P.

February 13, 2008

NDA 18-612

Andrea Leonard-Segal, M.D.
Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Food and Drug Administration
Center for Drug Evaluation and Research
5901-B Ammendale Rd.
Belstville, MD 20705-1266

Re: Nicotine Polacrilex Gum, 2mg
Supplement – Prior Approval (CMC): New flavor coated gum variant
Nicorette® White Ice™ Mint 2mg Coated Gum
NDA 18-612/S-050

Dear Dr. Leonard-Segal,

In accordance with 21 CFR 314.70(c), GlaxoSmithKline Consumer Healthcare (GSK) hereby submits a Prior Approval Supplement for Nicorette® White Ice Mint™ 2mg Coated Gum.

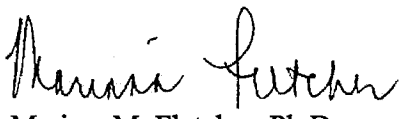
The subject drug product is a new flavor line extension to currently approved Nicorette coated gum variants. Please note that McNeil has deemed certain information in the Chemistry, Manufacturing, and Controls section of this Supplement to be proprietary. Therefore, cross-references to McNeil's drug master files (DMF) are provided and included in this Supplement accordingly.

This submission is provided in CTD format in accordance with the draft guidance titled, "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications Using the CTD Specifications," dated April 2006, and is formatted according to the folder/file structure described in the ICH M2 EWG Electronic Common Technical Document Specification v3.2 dated February 4, 2004.

This submission has been confirmed to be virus-free using Symantec AntiVirus Corporate Edition, version 10.1.0.396, scan engine 71.4.0.15, updated 2/12/2008, and is approximately 19.4 MB in size.

If you have any questions regarding this supplement, please call me at 973-889-4443.

Sincerely,



Marissa M. Fletcher, Ph.D.
Manager, Regulatory Affairs
GlaxoSmithKline Consumer Healthcare, L.P.