

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
ANDA 76-777

Name: Nicotine Polacrilex Gum USP, 2 mg (base)
Mint Flavor

Sponsor: L. Perrigo Company

Approval Date: September 16, 2004

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 76-777

CONTENTS

Reviews / Information Included in this Review
--

Approval Letter	X
Tentative Approval Letter(s)	
Approved Labeling	X
Labeling Review(s)	X
Medical Review(s)	
Chemistry Reviews	X
Bioequivalence Reviews	X
Statistical Review(s)	
Microbiology Review(s)	
Administrative Documents	X
Correspondence	X

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 76-777

APPROVAL LETTER

ANDA 76-775 [2 mg (base), Regular]
76-776 [2 mg (base), Orange]
76-777 [2 mg (base), Mint]
76-778 [4 mg (base), Orange]
79-779 [4 mg (base), Mint]
76-789 [4 mg (base), Regular]

SEP 16 2004

L. Perrigo Company
Attention: Brian R. Schuster
515 Eastern Avenue
Allegan, MI 49010

Dear Sir:

This is in reference to your abbreviated new drug applications (ANDAs) dated June 30, 2003, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Nicotine Polacrilex Gum USP, 2 mg (base) (Regular, Orange, and Mint Flavored), and 4 mg (base) (Regular, Orange, and Mint Flavored).


Reference is also made to your amendments to each application dated January 20, February 6, March 16, March 29, May 20, June 17, June 28, August 13, and August 17, 2004.

We have completed the review of these abbreviated applications and have concluded that the drugs are safe and effective for over-the-counter (OTC) use as recommended in the submitted labeling. Accordingly, the applications are approved. The Division of Bioequivalence has determined your Nicotine Polacrilex Gum USP, 2 mg (base) (Regular, Orange, and Mint Flavored), and 4 mg (base) (Regular, Orange, and Mint Flavored), to be bioequivalent to the corresponding strength and flavor of the listed drug, Nicorette Gum, of GlaxoSmithKline. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your applications.

Under Section 506A of the Act, certain changes in the conditions described in these abbreviated applications require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for these abbreviated applications are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Sincerely yours,



Gary Buehler 9/16/04

Director

Office of Generic Drugs

Center for Drug Evaluation and Research

cc: ANDA 76-775 (2 mg, Regular)
ANDA 76-776 (2 mg, Orange)
ANDA 76-777 (2 mg, Mint)
ANDA 76-778 (4 mg, Orange)
ANDA 79-779 (4 mg, Mint)
ANDA 76-789 (4 mg, Regular)
Division Files
Field Copy
HFD-610/R. West
HFD-330
HFD-205
HFD-610/Orange Book Staff

Approved Electronic Labeling Located at:

HFD-640/D.Skanchy/8/27/04
HFD-640/S.Rosencrance/8/27/04
HFD-617/T.Hinchliffe/8/27/04
HFD-613/M.Dillahunt/8/27/04
HFD-613/L.Golson/8/27/04

*No CMC issues 9/15/04
RCR*

\CDSNAS\OGDS11\FIRMSNZ\PERRIGO\LTRS&REV\76775.AP.doc
F/T by TOH/8/27/04

APPROVAL

*Robert West
9/16/2004*

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 76-777

APPROVED LABELING

<p>Nicotine Polacrilex Gum USP, 2 mg (nicotine) MINT MADE IN DENMARK DISTRIBUTED BY PERRIGO ALLEGAN, MI 49010 USA LOT 1 piece EXP</p>	<p>Nicotine Polacrilex Gum USP, 2 mg (nicotine) MINT MADE IN DENMARK DISTRIBUTED BY PERRIGO ALLEGAN, MI 49010 USA LOT 1 piece EXP</p>	<p>Nicotine Polacrilex Gum USP, 2 mg (nicotine) MINT MADE IN DENMARK DISTRIBUTED BY PERRIGO ALLEGAN, MI 49010 USA LOT 1 piece EXP</p>
<p>Nicotine Polacrilex Gum USP, 2 mg (nicotine) MINT MADE IN DENMARK DISTRIBUTED BY PERRIGO ALLEGAN, MI 49010 USA LOT 1 piece EXP</p>	<p>Nicotine Polacrilex Gum USP, 2 mg (nicotine) MINT MADE IN DENMARK DISTRIBUTED BY PERRIGO ALLEGAN, MI 49010 USA LOT 1 piece EXP</p>	<p>Nicotine Polacrilex Gum USP, 2 mg (nicotine) MINT MADE IN DENMARK DISTRIBUTED BY PERRIGO ALLEGAN, MI 49010 USA LOT 1 piece EXP</p>
<p>Nicotine Polacrilex Gum USP, 2 mg (nicotine) MINT MADE IN DENMARK DISTRIBUTED BY PERRIGO ALLEGAN, MI 49010 USA LOT 1 piece EXP</p>	<p>Nicotine Polacrilex Gum USP, 2 mg (nicotine) MINT MADE IN DENMARK DISTRIBUTED BY PERRIGO ALLEGAN, MI 49010 USA LOT 1 piece EXP</p>	<p>Nicotine Polacrilex Gum USP, 2 mg (nicotine) MINT MADE IN DENMARK DISTRIBUTED BY PERRIGO ALLEGAN, MI 49010 USA LOT 1 piece EXP</p>
<p>Nicotine Polacrilex Gum USP, 2 mg (nicotine) MINT MADE IN DENMARK DISTRIBUTED BY PERRIGO ALLEGAN, MI 49010 USA LOT 1 piece EXP</p>	<p>Nicotine Polacrilex Gum USP, 2 mg (nicotine) MINT MADE IN DENMARK DISTRIBUTED BY PERRIGO ALLEGAN, MI 49010 USA LOT 1 piece EXP</p>	<p>Nicotine Polacrilex Gum USP, 2 mg (nicotine) MINT MADE IN DENMARK DISTRIBUTED BY PERRIGO ALLEGAN, MI 49010 USA LOT 1 piece EXP</p>

APPROVED
SEP 16 2004
20600 FAX

APPROVED
SEP 16 2004

Drug Facts (continued)

- store at 20 to 25°C (68 to 77°F) [see USP Controlled Room Temperature]
- protect from light

Inactive ingredients acesulfame potassium, calcium carbonate, carnauba wax, D&C yellow #10, flavors, gum base, sodium bicarbonate, sodium carbonate, sorbitol, talc

Questions? If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional.

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

BLISTER PACKAGED FOR YOUR PROTECTION. DO NOT USE IF INDIVIDUAL SEALS ARE BROKEN.

MADE IN DENMARK

DISTRIBUTED BY



ALLEGAN, MI 49010 U.S.A.



0 00000 00000 0
 NOT FOR RESALE
 PRODUCTION QUALITY
 SAMPLE IN IT

To remove the gum, tear off single unit.



Peel backing starting at corner with loose edge.



Push gum through foil.



PROVED
 6 2004
 REFILL
 MINT
 Stop Smoking Aid
 Nicotine Polacrilex Gum, 2 mg (nicotine)

Nicotine Polacrilex Gum, 2 mg (nicotine)

Theft surveillance tag area

20667 FA C3

Drug Facts

Active ingredient (in each chewing piece) Purpose
 Nicotine polacrilex, 2 mg (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. ▶

Drug Facts (continued)

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

Drug Facts (continued)

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 medication 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 or 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 Nicotine Polacrilex Gum, 4 mg ▶

Drug Facts (continued)

■ 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 tingling 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 chewing piece contains: calcium 97 mg and sodium 11 mg

Nicotine Polacrilex Gum, 2 mg (nicotine)

Stop Smoking Aid

108 PIECES, 2 mg EACH

FOR THOSE WHO SMOKE LESS THAN 25 CIGARETTES A DAY: use Nicotine Polacrilex Gum, 4 mg

STARTER KIT
Includes stop smoking plan with User's Guide and audio tape

SEP 16 2004

APPROVED

Stop Smoking Aid

MINT

Nicotine Polacrilex Gum, 2 mg (nicotine)



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

Drug Facts

Active ingredient (in each chewing piece) Purpose
Nicotine polacrilex, 2 mg (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. 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 medication 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 or 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.

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 Nicotine Polacrilex Gum, 4 mg
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 tingling 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 chewing piece contains: calcium 97 mg and sodium 11 mg
store at 20 to 25°C (68 to 77°F) [see USP Controlled Room Temperature]
protect from light

Inactive ingredients acesulfame potassium, calcium carbonate, carnauba wax, D&C yellow #10, flavors, gum base, sodium bicarbonate, sodium carbonate, sorbitol, talc

Questions? If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional.

© 2004 F.C.S.

Nicotine Polacrilex Gum, 2 mg (nicotine)

Stop Smoking Aid

MINT

BLISTER PACKAGED FOR YOUR PROTECTION. DO NOT USE IF INDIVIDUAL SEALS ARE BROKEN.

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

Nicotine Polacrilex Gum, 2 mg (nicotine)

Stop Smoking Aid

MINT

Theft surveillance tag area



MADE IN DENMARK
DISTRIBUTED BY
3M PERRIGO
ALLEGAN, MI 49010 U.S.A.

Mint
Stop Smoking Aid
**Nicotine Polacrilex
Gum, 2 mg (nicotine)**

168 PIECES, 2 mg EACH

FOR THOSE WHO SMOKE LESS THAN 25 CIGARETTES A DAY
If you smoke 25 or more cigarettes a day: use Nicotine Polacrilex Gum, 4 mg

REFILL
MINT

Stop Smoking Aid

APPROVED
SEP 16 2004

**Nicotine Polacrilex
Gum, 2 mg (nicotine)**



TO INCREASE YOUR SUCCESS IN QUITTING:

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

**Nicotine
Polacrilex
Gum, 2 mg
(nicotine)**

Stop Smoking Aid
Mint

Theft surveillance
tag area



Drug Facts

Active ingredient (in each chewing piece) Nicotine polacrilex, 2 mg (nicotine).....**Purpose** 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 medication 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 or 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.

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 Nicotine Polacrilex Gum, 4 mg
- 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 tingling 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 chewing piece contains: calcium 97 mg and sodium 11 mg
- store at 20 to 25°C (68 to 77°F) [see USP Controlled Room Temperature]
- protect from light

Inactive ingredients acesulfame potassium, calcium carbonate, carnauba wax, D&C yellow #10, flavors, gum base, sodium bicarbonate, sodium carbonate, sorbitol, talc

Questions? If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional.

020644 FA C3

**Nicotine
Polacrilex
Gum, 2 mg
(nicotine)**

Stop Smoking Aid
Mint

**BLISTER PACKAGED FOR
YOUR PROTECTION.
DO NOT USE IF INDIVIDUAL
SEALS ARE BROKEN.**

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

MADE IN DENMARK
DISTRIBUTED BY
PERRIGO
ALLEGAN, MI 49010 U.S.A.

Nicotine Polacrilex Gum

2 mg and 4 mg User's Guide

**How to Use
Nicotine Polacrilex Gum
To Help You
Quit Smoking.**

- **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.**

Keys to Success.

1. You must really want to quit smoking for Nicotine Polacrilex Gum 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 Nicotine Polacrilex Gum. See page 9.
3. You should continue to use Nicotine Polacrilex Gum as explained in this User's Guide for 12 full weeks.
4. Nicotine Polacrilex Gum works best when used together with a support program – See page 3 for details.
5. If you have trouble using Nicotine Polacrilex Gum, ask your doctor, pharmacist or health care professional.

APPROVED
SEP 16 2004



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 Nicotine Polacrilex 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 Nicotine Polacrilex Gum.

2

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 Nicotine Polacrilex Gum 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 Nicotine Polacrilex Gum 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 Nicotine Polacrilex Gum, 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 Nicotine Polacrilex Gum 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.

3

You must overcome both addictions to stop smoking. So while Nicotine Polacrilex Gum 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
4

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

- 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 Nicotine Polacrilex Gum, 4 mg.

If you smoke less than 25 cigarettes a day, use Nicotine Polacrilex Gum, 2 mg. 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 Nicotine Polacrilex Gum). Choose your quit date (it should be soon). This is the day you will quit smoking cigarettes entirely and begin using Nicotine Polacrilex Gum to satisfy your craving for nicotine. For the first six weeks, you'll use a piece of Nicotine Polacrilex Gum every hour or two. Be sure to follow the directions starting on pages 7 and 9. Place the Step 1 sticker on this date.

STEP 2. (Weeks 7 to 9). The day you'll start reducing your use of Nicotine Polacrilex Gum.

After six weeks, you'll begin gradually reducing your Nicotine Polacrilex Gum 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 Nicotine Polacrilex Gum.

Nine weeks after you begin using Nicotine Polacrilex Gum, 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 Nicotine Polacrilex Gum every four to eight hours.

End of treatment: The day you'll complete Nicotine Polacrilex Gum therapy.

Nicotine Polacrilex Gum 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 Nicotine Polacrilex Gum 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 Nicotine Polacrilex Gum 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 Nicotine Polacrilex Gum Works. Nicotine Polacrilex Gum 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. Nicotine Polacrilex Gum 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 Nicotine Polacrilex Gum 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 Nicotine Polacrilex Gum. **If you are 18 years of age, ask a doctor before use.** Before you can use Nicotine Polacrilex Gum correctly, you have to practice! That sounds silly, but it isn't. **Nicotine Polacrilex Gum isn't like ordinary chewing gum.** It's a medicine, and must be chewed a certain way to work right. Chewed like ordinary gum, Nicotine Polacrilex Gum won't work well and can cause side effects. An overdose can occur if you chew more than one piece of Nicotine Polacrilex Gum at the same time, or if you chew many pieces one after another. Read all the following instructions before using Nicotine

Polacrilex Gum. Refer to them often to make sure you're using Nicotine Polacrilex 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 Nicotine Polacrilex Gum, or while chewing a piece. The effectiveness of Nicotine Polacrilex Gum may be reduced by some foods and drinks, such as coffee, juices, wine or soft drinks.

1. Stop smoking completely before you start using Nicotine Polacrilex Gum.
2. To reduce craving and other withdrawal symptoms, use Nicotine Polacrilex Gum according to the dosage schedule on page 9.
3. Chew each Nicotine Polacrilex Gum 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 Nicotine Polacrilex Gum 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 Nicotine Polacrilex Gum 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 Nicotine Polacrilex Gum piece (usually happens in about half an hour; the peppery taste or tingle won't return.)
9. Wrap the used Nicotine Polacrilex Gum piece in paper and throw away in the trash.

To improve your chances of quitting, use at least 9 pieces of Nicotine Polacrilex Gum a day. 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.

Place these stickers on your calendar:

Place these stickers on your calendar:



*At the Beginning of Week #1
(Quit Date)*



At the Beginning of Week #7



At the Beginning of Week #10



12 Weeks After Quit Date

The following chart lists the recommended usage schedule for Nicotine Polacrilex Gum:		
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.		

How To Reduce Your Nicotine Polacrilex Gum Usage.

The goal of using Nicotine Polacrilex Gum is to slowly reduce your dependence on nicotine. The schedule for using Nicotine Polacrilex Gum will help you reduce your nicotine craving gradually as you reduce and then stop your use of Nicotine Polacrilex Gum. Here are some tips to help you cut back during each step and then stop using Nicotine Polacrilex Gum:

- After a while, start chewing each Nicotine Polacrilex Gum 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 Nicotine Polacrilex Gum pieces you would normally use. Increase the number of pieces of ordinary gum as you cut back on the Nicotine Polacrilex Gum pieces.
- Check how well you've reduced your daily usage of Nicotine Polacrilex Gum in Weeks 10 to 12. You should only be using about 3 to 5 pieces a day. Get ready to stop.

STOP USING NICOTINE POLACRILEX GUM AT THE END OF WEEK 12.

The following tips may help you with stopping Nicotine Polacrilex 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 Nicotine Polacrilex Gum per day. At the times when you have an urge to use Nicotine Polacrilex Gum, 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 Nicotine Polacrilex Gum at the end of week 12
 - start using Nicotine Polacrilex Gum 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 Nicotine Polacrilex 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:

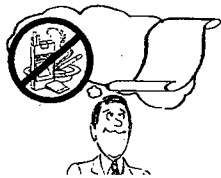
- During the first few days after you've stopped smoking, spend as much time as possible at places where smoking is not allowed.
- Drink large quantities of water and fruit juices.
- Try to avoid alcohol, coffee and other beverages you associate with smoking.
- Remember that temporary urges to smoke 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.

12

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 Nicotine Polacrilex Gum 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 Nicotine Polacrilex 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 life as a non-smoker.

Questions & Answers.

1. How will I feel when I stop smoking and start using Nicotine Polacrilex Gum?

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.

Nicotine Polacrilex Gum 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 Nicotine Polacrilex Gum just substituting one form of nicotine for another?

Nicotine Polacrilex Gum does contain nicotine. The purpose of Nicotine Polacrilex Gum 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 Nicotine Polacrilex Gum together with nicotine patches or other nicotine containing products.

3. Can I be hurt by using Nicotine Polacrilex Gum?

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 4). Because Nicotine Polacrilex Gum is a gum-based product, chewing it can cause dental

fillings to loosen and aggravate other mouth, tooth and jaw problems. Nicotine Polacrilex Gum 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 Nicotine Polacrilex Gum more expensive than smoking?

The total cost of Nicotine Polacrilex Gum 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 Nicotine Polacrilex Gum 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 Nicotine Polacrilex Gum:**

STEP 1	STEP 2	STEP 3
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

Made in Denmark

DISTRIBUTED BY **PERRIGO** ALLEGAN, MI 49010 U.S.A.
www.perrigo.com

17006 FA J2

WALLET CARD

**My most important reasons
to quit smoking are:**

WALLET CARD

WHERE TO CALL FOR HELP:

American Lung Association
1-800-586-4872

American Cancer Society
1-800-227-2345

American Heart Association
1-800-242-8721

APPROVED
How To Use Nicotine Polacrilex Gum

Side A



SEP 16 2004

Nicotine Polacrilex Gum, 2 mg and 4 mg

APPROVED
Usage Instructions

- ▶ 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.

DISTRIBUTED BY
PERRIGO
ALLEGAN, MI 49010 U.S.A.

Nicotine Polacrilex Gum

Tips To Help Make Quitting Easier

Side B



Attachment 6

AUDIOTAPE SCRIPT

Final Printed Labeling

**Nicotine Polacrilex Gum Audio Tape
Side A, Section 1**

August 13, 2004

SFX: Sound of various voices from happy crowd.

ANNCR: Congratulations on your decision to become a non-smoker. This is one of the most important decisions you'll ever make. And one of the best.

(VOICES: "Yeah! Right! Way to go!")

The Nicotine Polacrilex Gum User's Guide and this audio tape are designed to help make it as easy as possible to break the habit. But keep in mind that this program won't work unless you're really committed to becoming a non-smoker. Maybe you tried before and failed. If so, don't be discouraged. Remember, lots of people make several tries before they succeed. This time, Nicotine Polacrilex Gum will help relieve the physical symptoms of quitting, so you are better equipped to manage the mental part.

VOICE: ("Yeah -- you can do it!")

Even though Nicotine Polacrilex Gum is easy to use, it's not used like ordinary chewing gum. It's serious medicine! Like any medicine, you should use it only as directed. We'll get to the directions later, but you should also know that there are some people who shouldn't use Nicotine Polacrilex Gum or any product containing nicotine without checking with their doctor. Women who are pregnant or nursing, for example.

And anyone with a history of heart trouble, high blood pressure that can't be controlled with medication, takes insulin for diabetes or has a stomach ulcer should get medical advice first. Quitting smoking can also affect the way your body reacts to certain other medications you may be taking for asthma or depression -- so check with your doctor if any of these things apply to you.

Be sure to read the User's Guide that comes in this kit for other important information about using Nicotine Polacrilex Gum.

Even though Nicotine Polacrilex Gum contains nicotine, it doesn't contain any of the thousands of other harmful chemicals that are in cigarette smoke. And it's designed to get you off nicotine for good.

**Nicotine Polacrilex Gum Audio Tape
Side A, Section 2**

August 13, 2004

Support group. Adults. Group leader is authoritative but pleasant woman. Among students are Older Woman (OW), Young Woman (YW), Young Man (YM), and cynical Older Man with gruff voice (OM).

(SFX: Murmurs, conversation. Leader raps on desk for attention.)

LEADER: All right everybody; quiet now, we're ready to start. This support group is all about how to use Nicotine Polacrilex Gum to help you quit smoking.

OM: So who needs a support group? It's a chewing gum. You chew it. We might as well have to take a class on how to breathe.

LEADER: How to Breathe is Mr. Yamato's group, down the hall. You'll be in that one later. But this comes first because Nicotine Polacrilex Gum isn't ordinary chewing gum. You have to use it the right way or it won't work the way it's supposed to.

OM: Hey, chewing gum is kid stuff.

LEADER: But chewing Nicotine Polacrilex Gum isn't. It's only for people who are at least 18 and who really want to quit smoking. Younger people should talk to a doctor first.

Okay, so let's begin. First, has everybody read the Nicotine Polacrilex Gum User's Guide?

OW: I read it, yeah. It didn't take long and it made the whole quitting process a lot clearer to me.

LEADER: Right. There's nothing mysterious or complicated about it. But there's a right way to do it, and the only way you can expect to get the results you want is to use Nicotine Polacrilex Gum the way it's supposed to be used.

Now, who remembers the very first instruction?

OW: Buy Nicotine Polacrilex Gum.

LEADER: Actually, there's an even earlier step. Before using Nicotine Polacrilex Gum you have to stop smoking -- and I mean completely. That's important. And you mustn't chew tobacco or use snuff or nicotine patches either.

You start using Nicotine Polacrilex Gum on the day you stop smoking, and you never smoke and use Nicotine Polacrilex Gum together. That could give an overdose of nicotine, which is pretty powerful stuff. The results could make you sick.

