CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 021330/S-007

Name: Commit® (nicotine polacrilex) Lozenge

Sponsor: GlaxoSmithKline Consumer Healthcare

Approval Date: May 23, 2008

This supplemental new drug application provided for a new cappuccino flavored Commit® (nicotine polacrilex) Lozenge.

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 021330/S-007

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 021330/S-007

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-330/S-007

GlaxoSmithKline Consumer Healthcare
Attention: Iris H. Shelton
Assistant Director, Regulatory Affairs
1500 Littleton Road
Parsippany, NJ 07054-3884

Dear Ms. Shelton:

Please refer to your supplemental new drug application dated January 24, 2008 received January 24, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Commit (2 mg and 4 mg, nicotine polacrilex) lozenge.

We also acknowledge receipt of your submissions dated April 17, 2008, providing confirmatory six month stability data, and May 22, 2008, providing a revised 48-count POPPAC container label.

This supplemental new drug application provides for the nonprescription marketing of a new Cappuccino flavor of the 2 mg and 4 mg lozenge with associated packaging and labeling.

We have completed our review of this supplement, as amended. This supplement is 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 (immediate container and carton labels for the 72-count 2 mg and 4 mg Cappuccino lozenge and the immediate container labels for the 48-count 2 mg and 4 mg Cappuccino lozenge submitted on January 24, 2008, and the carton labels for the 48-count 2 mg and 4 mg Cappuccino lozenge submitted on May 22, 2008). This 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 this submission "**FPL for approved supplement NDA 21-330/S-007".** Approval of this submission 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.

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}

Andrea Leonard-Segal, M.D.
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/

Andrea Segal

5/23/2008 10:58:09 AM

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 021330/S-007

LABELING

In case of overdose, get medical help or contact a Poison Control Center right away.

Retain outer carton for full product uses, directions and warnings. Discard POPPAC after use.

Tamper Evident Feature: Do not use if clear neckband printed "SEALED FOR SAFETY" is missing or broken.

Distributed By:
GlaxoSmithKline Consumer Healthcare, L.P.
Moon Township, PA 15108
Made in the U.S.A.

62076XA

24 LOZENGES

To open vial, push in child resistant band on the POPPAC™ with thumb.

Flip up the top of the POPPAC™ and remove lozenge.

A small amount of powder on opening of POPPAC™ is normal.

POPPAC™

Commit®

nicotine polacrilex lozenge, 2mg

STOP SMOKING AID

CAPPUCCINO FLAVOR

Directions:

Not for Individual Sale

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

Place the lozenge in your mouth and allow the lozenge to slowly dissolve. Minimize swallowing. Do not chew or swallow lozenge. Occasionally move the lozenge from one side of your mouth to the other until completely dissolved (about 20 - 30 minutes). Do not eat or drink 15 minutes before using or while the lozenge is in your mouth.

Do not use more than 5 lozenges in 6 hours. Do not use more than 20 lozenges per day.

Keep out of reach of children and pets. Nicotine lozenges may have enough nicotine to make children and pets sick. If you need to remove the lozenge, wrap it in paper and throw away in the trash.

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In case of overdose, get medical help or contact a Poison Control Center right away.

Retain outer carton for full product uses, directions and warnings. Discard POPPAC after use.

Tamper Evident Feature: Do not use if clear neckband printed "SEALED FOR SAFETY" is missing or broken.

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62077XA

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POPPAC™

Commit®

nicotine polacrilex lozenge, 4mg

STOP SMOKING AID

CAPPUCCINO FLAVOR

Directions: ***Not for Individual Sale***

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

Place the lozenge in your mouth and allow the lozenge to slowly dissolve. Minimize swallowing. Do not chew or swallow lozenge. Occasionally move the lozenge from one side of your mouth to the other until completely dissolved (about 20 - 30 minutes). Do not eat or drink 15 minutes before using or while the lozenge is in your mouth.

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Internet access required. Offer good only in US. Void in CA & where prohibited. Must be 18 or over. Internet access & valid email acct. required. Find Code inside. Beginning 06/01/2006 @ 12:01 am PT, collect Codes redeemable at www.commitlozenge.com for Points which can be redeemed for coupons and/or rebates. Promotion ends 08/30/2011 @ 11:59 pm PT. Subject to Terms & Conditions on website.

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Drug Facts (continued)

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

- **nicotine lozenge is a medicine and must be used a certain way to get the best results**
- place the lozenge in your mouth and allow the lozenge to slowly dissolve (about 20 – 30 minutes). Minimize swallowing. **Do not chew or swallow lozenge.**
- you may feel a warm or tingling sensation
- occasionally move the lozenge from one side of your mouth to the other until completely dissolved (about 20 – 30 minutes)
- do not eat or drink 15 minutes before using or while the lozenge is in your mouth
- to improve your chances of quitting, use at least 9 lozenges per day for the first 6 weeks
- do not use more than one lozenge at a time or continuously use one lozenge after another since this may cause you hiccups, heartburn, nausea or other side effects
- **do not use more than 5 lozenges in 6 hours. Do not use more than 20 lozenges per day.**
- stop using the nicotine lozenge at the end of 12 weeks. If you still feel the need to use nicotine lozenges, talk to your doctor.

Other information

- **each lozenge contains:** sodium, 18mg
- store at 20 - 25°C (68 - 77°F)
- keep POPPAC tightly closed and protect from light

Inactive ingredients

acesulfame potassium, butylhydroxy toluene, calcium polycarbophil, flavor, magnesium stearate, maltodextrin, mannitol, potassium bicarbonate, sodium alginate, sodium carbonate, xanthan gum

Questions or comments?

call toll-free **1-888-569-1743** (English/Spanish) weekdays (9:00am - 4:30pm ET)

NEW CAPPUCCINO FLAVOR

FROM THE MARKETERS OF Nicorette®

Commit®

nicotine polacrilex lozenge, 2mg

STOP SMOKING AID

Includes User's Guide

CAPPUCCINO FLAVOR

2 mg

FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE MORE THAN 30 MINUTES AFTER WAKING UP.

If you smoke your first cigarette **WITHIN 30 MINUTES** of waking up, use Commit® 4mg Lozenge

48 LOZENGES

(2 Poppac™ Containers of 24)

2mg EACH

PLACE ANTI-THEFT STICKER HERE

THEFT SURVEILLANCE TAG AREA

- **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**

TAMPER EVIDENT FEATURE: Do not use if clear neckband printed "SEALED FOR SAFETY" is missing or broken. Retain outer carton for full product uses, directions and warnings.

TO INCREASE YOUR SUCCESS IN QUITTING:

1. You must be motivated to quit.
2. **Use Enough -** Use **at least 9 lozenges** of Commit® per day during the first six weeks.
3. **Use Long Enough -** Use Commit® for the full 12 weeks.
4. **Use With a Support Program** as directed in the enclosed User's Guide.

Commit® POPPAC™

To open vial, push in child resistant band on the POPPAC™ with thumb.

Flip up the top of the POPPAC™ and remove lozenge. A small amount of powder on opening of the POPPAC™ is normal.

go to www.commitlozenge.com for online support program

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Moon Township, PA 15108, Made in the U.S.A.

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Drug Facts

Active ingredient (in each lozenge) — **Purpose**

Nicotine polacrilex, 2mg ..... 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 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 prescription medicine for depression or asthma. Your prescription dose may need to be adjusted.

Stop use and ask a doctor if

- mouth problems occur
- persistent indigestion or severe sore throat occurs
- 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. Nicotine lozenges may have enough nicotine to make children and pets sick. If you need to remove the lozenge, wrap it 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 lozenge
- **if you smoke your first cigarette within 30 minutes of waking up,** use 4mg nicotine lozenge
- **if you smoke your first cigarette more than 30 minutes after waking up,** use 2mg nicotine lozenge according to the following 12 week schedule: ▶

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Internet access required. Offer good only in US. Void in CA & where prohibited. Must be 18 or over. Internet access & valid email acct. required. Find Code inside. Beginning 06/01/2008 @ 12:01 am PT, collect Codes redeemable at www.commitlozenge.com for Points which can be redeemed for coupons and/or rebates. Promotion ends 08/30/2011 @ 11:59 pm PT. Subject to Terms & Conditions on website.

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Drug Facts (continued)

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

- **nicotine lozenge is a medicine and must be used a certain way to get the best results**
- place the lozenge in your mouth and allow the lozenge to slowly dissolve (about 20 – 30 minutes). Minimize swallowing. **Do not chew or swallow lozenge.**
- you may feel a warm or tingling sensation
- occasionally move the lozenge from one side of your mouth to the other until completely dissolved (about 20 – 30 minutes)
- do not eat or drink 15 minutes before using or while the lozenge is in your mouth
- to improve your chances of quitting, use at least 9 lozenges per day for the first 6 weeks
- do not use more than one lozenge at a time or continuously use one lozenge after another since this may cause you hiccups, heartburn, nausea or other side effects
- **do not use more than 5 lozenges in 6 hours. Do not use more than 20 lozenges per day.**
- stop using the nicotine lozenge at the end of 12 weeks. If you still feel the need to use nicotine lozenges, talk to your doctor.

Other information

- **each lozenge contains:** sodium, 18mg
- store at 20 - 25°C (68 - 77°F)
- keep POPPAC tightly closed and protect from light

Inactive ingredients

acesulfame potassium, butylhydroxy toluene, calcium polycarbophil, flavor, magnesium stearate, maltodextrin, mannitol, potassium bicarbonate, sodium alginate, sodium carbonate, xanthan gum

Questions or comments?

call toll-free **1-888-569-1743** (English/Spanish) weekdays (9:00am - 4:30pm ET)

NEW CAPPUCCINO FLAVOR

FROM THE MARKETERS OF Nicorette®

Commit®

nicotine polacrilex lozenge, 4mg

STOP SMOKING AID

Includes User's Guide

CAPPUCCINO FLAVOR

4 mg

FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE WITHIN 30 MINUTES OF WAKING UP.

If you smoke your first cigarette **MORE THAN 30 MINUTES** after waking up, use Commit® 2mg Lozenge

48 LOZENGES
(2 Poppac™ Containers of 24)
4mg EACH

PLACE ANTI-THEFT STICKER HERE

THEFT SURVEILLANCE TAG AREA

- **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**

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1. You must be motivated to quit.
2. **Use Enough** - Use **at least 9 lozenges** of Commit® per day during the first six weeks.
3. **Use Long Enough** – Use Commit® for the full 12 weeks.
4. **Use With a Support Program** as directed in the enclosed User's Guide.

Commit® POPPAC™

To open vial, push in child resistant band on the POPPAC™ with thumb.

Flip up the top of the POPPAC™ and remove lozenge. A small amount of powder on opening of the POPPAC™ is normal.

go to www.commitlozenge.com for online support program

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Moon Township, PA 15108, Made in the U.S.A.

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Drug Facts

Active ingredient (in each lozenge) — Purpose

Nicotine polacrilex, 4mg.....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 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 prescription medicine for depression or asthma. Your prescription dose may need to be adjusted.

Stop use and ask a doctor if
- mouth problems occur
- persistent indigestion or severe sore throat occurs
- 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. Nicotine lozenges may have enough nicotine to make children and pets sick. If you need to remove the lozenge, wrap it 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 lozenge
- **if you smoke your first cigarette more than 30 minutes after waking up,** use 2mg nicotine lozenge
- **if you smoke your first cigarette within 30 minutes of waking up,** use 4mg nicotine lozenge according to the following 12 week schedule: ▶

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Internet access required. Offer good only in US. Void in CA & where prohibited. Must be 18 or over. Internet access & valid email acct. required. Find Code inside. Beginning 06/01/2008 @ 12:01 am PT, collect Codes redeemable at www.commitlozenge.com for Points which can be redeemed for coupons and/or rebates. Promotion ends 08/30/2011 @ 11:59 pm PT. Subject to Terms & Conditions on website.

Lot

Exp

Drug Facts (continued)

- **if you smoke your first cigarette more than 30 minutes after waking up,** use 2mg nicotine lozenge according to the following 12 week schedule:

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

- **nicotine lozenge is a medicine and must be used a certain way to get the best results**
- **place** the lozenge in your mouth and allow the lozenge to slowly dissolve (about 20 - 30 minutes). Minimize swallowing. **Do not chew or swallow lozenge.**
- you may feel a warm or tingling sensation
- occasionally move the lozenge from one side of your mouth to the other until completely dissolved (about 20 - 30 minutes)
- do not eat or drink 15 minutes before using or while the lozenge is in your mouth
- to improve your chances of quitting, use at least 9 lozenges per day for the first 6 weeks
- do not use more than one lozenge at a time or continuously use one lozenge after another since this may cause you hiccups, heartburn, nausea or other side effects
- **do not use more than 5 lozenges in 6 hours. Do not use more than 20 lozenges per day.**
- stop using the nicotine lozenge at the end of 12 weeks. If you still feel the need to use nicotine lozenges, talk to your doctor.

Other information

- **each lozenge contains:** sodium, 18mg
- store at 20 - 25°C (68 - 77°F)
- keep POPPAC tightly closed and protect from light

Inactive ingredients acesulfame potassium, butylhydroxy toluene, calcium polycarbophil, flavor, magnesium stearate, maltodextrin, mannitol, potassium bicarbonate, sodium alginate, sodium carbonate, xanthan gum

Questions or comments? call toll-free 1-888-569-1743 (English/Spanish) weekdays (9:00 am - 4:30 pm ET)

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NEW CAPPUCCINO FLAVOR

FROM THE MARKETERS OF Nicorette®

Commit®

nicotine polacrilex lozenge, 2mg

STOP SMOKING AID

Includes User's Guide

CAPPUCCINO FLAVOR

2 mg

FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE MORE THAN 30 MINUTES AFTER WAKING UP.
If you smoke your first cigarette **WITHIN 30 MINUTES** of waking up, use Commit® 4mg Lozenge

72 LOZENGES
(3 Poppac™ Containers of 24)
2mg EACH

PLACE ANTI-THEFT STICKER HERE

THEFT SURVEILLANCE TAG AREA

- **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**

TAMPER EVIDENT FEATURE: Do not use if clear neckband printed "SEALED FOR SAFETY" is missing or broken.
Retain outer carton for full product uses, directions and warnings.

TO INCREASE YOUR SUCCESS IN QUITTING:

1. You must be motivated to quit.
2. **Use Enough -** Use **at least 9 lozenges** of Commit® per day during the first six weeks.
3. **Use Long Enough -** Use Commit® for the full 12 weeks.
4. **Use With a Support Program** as directed in the enclosed User's Guide.

Commit® POPPAC™

To open vial, push in child resistant band on the POPPAC™ with thumb.

Flip up the top of the POPPAC™ and remove lozenge. A small amount of powder on opening of the POPPAC™ is normal.

go to www.commitlozenge.com for online support program

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Drug Facts

Active ingredient (in each lozenge) — **Purpose**
Nicotine polacrilex, 2mg ..... 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 product

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 prescription medicine for depression or asthma. Your prescription dose may need to be adjusted.

Stop use and ask a doctor if
- mouth problems occur
- persistent indigestion or severe sore throat occurs
- 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. Nicotine lozenges may have enough nicotine to make children and pets sick. If you need to remove the lozenge, wrap it 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 lozenge
- **if you smoke your first cigarette within 30 minutes of waking up,** use 4mg nicotine lozenge ▶

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Drug Facts (continued)

- if you smoke your first cigarette within 30 minutes of waking up, use 4mg nicotine lozenge according to the following 12 week schedule:

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

- nicotine lozenge is a medicine and must be used a certain way to get the best results
- place the lozenge in your mouth and allow the lozenge to slowly dissolve (about 20 - 30 minutes). Minimize swallowing. Do not chew or swallow lozenge.
- you may feel a warm or tingling sensation
- occasionally move the lozenge from one side of your mouth to the other until completely dissolved (about 20 - 30 minutes)
- do not eat or drink 15 minutes before using or while the lozenge is in your mouth
- to improve your chances of quitting, use at least 9 lozenges per day for the first 6 weeks
- do not use more than one lozenge at a time or continuously use one lozenge after another since this may cause you hiccups, heartburn, nausea or other side effects
- **do not use more than 5 lozenges in 6 hours. Do not use more than 20 lozenges per day.**
- stop using the nicotine lozenge at the end of 12 weeks. If you still feel the need to use nicotine lozenges, talk to your doctor.

Other information

- each lozenge contains: sodium, 18mg
- store at 20 - 25°C (68 - 77°F)
- keep POPPAC tightly closed and protect from light

Inactive ingredients acesulfame potassium, butylhydroxy toluene, calcium polycarbophil, flavor, magnesium stearate, maltodextrin, mannitol, potassium bicarbonate, sodium alginate, sodium carbonate, xanthan gum

Questions or comments? call toll-free 1-888-569-1743 (English/Spanish) weekdays (9:00 am - 4:30 pm ET)

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4 mg

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Commit® POPPAC™

go to www.commitlozenge.com for online support program

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Drug Facts

Active ingredient (in each lozenge) — **Purpose**
Nicotine polacrilex, 4mg — Stop smoking aid

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

Warnings

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- 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.
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- 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 problems occur
- persistent indigestion or severe sore throat occurs
- 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. Nicotine lozenges may have enough nicotine to make children and pets sick. If you need to remove the lozenge, wrap it 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 lozenge
- if you smoke your first cigarette more than 30 minutes after waking up, use 2mg nicotine lozenge ▶

0305190901

Glue area - No Varnish

0305190901

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 021330/S-007

LABELING REVIEWS

Labeling Supplement Review

NDA #: 21-330	**Sponsor**: GlaxoSmithKline Consumer Healthcare
Drug Product: Nicotine Polacrilex Lozenges, 2 mg and 4 mg	**# of Stock Keeping Units in Submission**: 2
Submission Date: May 22, 2008	**Review Date**: May 22, 2008
Type of Submission: SCF-007	**Reviewer**: Mary S. Robinson

Background
This review is based on an amendment to the January 24, 2008 supplement for Commit™ 2 mg and 4 mg nicotine polacrilex lozenges. That submission provided for a flavor change only for the nicotine polacrilex lozenges. This submission contains revised labeling for the new cappuccino flavored Commit™ 2 mg and 4 mg 48- count cartons. Per discussion with the Agency on May 21, 2008, the sponsor is amending the 48-count 2mg and 4mg Commit cappuccino flavor carton (2 POPPAC Containers of 24) under "Other information.

Full color printed labeling of the 2 mg and 4 mg Commit™ nicotine polacrilex cappuccino lozenge for the 48- count cartons is included in this submission (attached). The proposed carton labeling was approved October 25, 2005, except for those changes related to the "cappuccino flavor" of the lozenge. The proposed revisions to the label are noted and initialed by Iris H. Shelton, Assistant Directory, Regulatory Affairs, GlaxoSmithKline Consumer Healthcare, L.P.

Graphic specifications for the labeling and User's Guide were not included in this submission. Unless otherwise noted, the reviewer's comments and recommendations refer to the labeling for both the 2 mg and 4 mg nicotine polacrilex drug products.

Stock Keeping Unit: (describe unit)
Cartons for the 2 mg 48-count carton and 4 mg 48-count carton.

Reviewer's Comments.
The sponsor has made the following changes:

Cartons (2mg 48-count carton and 4 mg 48-count cartons)

1. Under "Other information", 48-count carton, the phrase '(b) (4) (b) (4)" is a typographical error and is removed to be consistent with the 72-count carton.

This change is acceptable.

2. Under "Other information", 48-count carton, 4th bullet, the phrase "keep vial closed and protect from light" is revised to read "keep POPPAC tightly closed and protect from light" to be consistent with the 72 count carton.

This change is acceptable

Recommendations:

Inform the sponsor that this labeling supplement amendment can be approved. The changes to the 48-count carton made for consistency with the 72-count carton can be submitted in the FPL. Remind the sponsor that the word "new" needs to be removed from the labeling after 6 months OTC marketing.

Following this page, 6 pages withheld in full - draft labeling (b)(4)

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/s/

Mary Robinson
5/22/2008 02:49:42 PM
INTERDISCIPLINARY

Debbie Lumpkins
5/22/2008 02:51:02 PM
INTERDISCIPLINARY

Labeling Supplement Review

NDA #: 21-330	**Sponsor**: GlaxoSmithKline Consumer Healthcare
Drug Product: Nicotine Polacrilex Lozenges, 2 mg and 4 mg	**# of Stock Keeping Units in Submission**: 2
Submission Date: January 24, 2008	**Review Date**: April 1, 2008
Type of Submission: SCF-007	**Reviewer**: Mary S. Robinson

Background

This review is based on a supplement submitted January 24, 2008 for Commit™ 2 mg and 4 mg nicotine polacrilex lozenges. This submission contains labeling for the new cappuccino flavored Commit™ 2 mg and 4 mg 48- and 72-count cartons, and the 24-count POPPAC. This submission provides for a flavor change only. The sponsor indicates that the manufacturing processes and process controls are like those in the previously approved original application (approved October 31, 2001), spearmint (SCF_002, approved February 13,2004) and cherry flavors (SCF-004, approved November 22, 2005). Also there have been no changes to the manufacture of the drug substance, nicotine polacrilex lozenge approved October 31, 2002. The new flavor lozenges meet the current spearmint, mint and cherry lozenge specifications. See NDA 21330/SCF-007, CMC review dated May 16, 2008.

Full color printed labeling of the 2 mg and 4 mg Commit™ nicotine polacrilex cappuccino lozenge for the 48- and 72-count cartons and the 24-count POPPAC are included in this submission (attached). The proposed carton and POPPAC labeling were approved October 25, 2005, except for those changes related to the "cappuccino flavor" of the lozenge.

On May 16, 2008, the Agency requested clarification on certain parts of the submitted labeling. The sponsor submitted a response in electronic format on May 19, 2008 with attached copies of the approved labeling for the Commit mint flavored lozenge. This information is considered under Reviewer's Comments, below.

Graphic specifications for the labeling and User's Guide were not included in this submission. Unless otherwise noted, the reviewer's comments and recommendations refer to the labeling for both the 2 mg and 4 mg nicotine polacrilex drug products.

Stock Keeping Unit: (describe unit)
Cartons for the 2 mg 72-count, and 4 mg 72 count cartons. 2 mg 48-count carton and 4 mg 48-count carton.

Reviewer's Comments.

The sponsor has made the following changes:

POPPAC:

Principal Display Panel. The words "Cappuccino Flavor" are placed on a brown background above "Directions".

This change is acceptable.

B. Cartons (2mg 48-count carton and 4 mg 48-count carton and 2 mg 72-count, and 4 mg 72-count cartons)

Principal Display Panel.

1. The background color is change to brown to symbolize the "Cappuccino" flavor.

This change is acceptable.

2. **Lower left corner.** Under the phrase "Includes User's Guide" the font color of the flavor's name is brown

This change is acceptable.

3. **Upper left corner**. The"POPPAC trademark is deleted. The words "New Cappuccino Flavor" are added.

This change is acceptable. However, the sponsor should be reminded that the word "New" needs to be removed from the labeling after the first 6 months.

4. **Upper right corner.** (b) (4) "Nicorette".

This change is acceptable.

Carton Side (May 19, 2008 submitted sponsor changes)

5. Under "Other information", 48-count carton, the phrase " (b) (4) (b) (4)' is a typographical error and will be deleted to be consistent with the 72-count carton.

(b) (4) *this change is acceptable.*

6. Under "Other information", 48-count carton, 4th bullet, the phrase "keep vial closed and protect from light" is revised to read "keep POPPAC tightly closed and protect from light" to be consistent with the 72 count carton.

This change is acceptable

Carton Side

7. (b) (4)

This change is acceptable

Recommendations:

Inform the sponsor that this labeling supplement can be approved. The changes to the 48-count carton (see 5 and 6 above) for consistency with the 72-count carton can be submitted in the FPL. Also remind the sponsor that the word "new" needs to be removed from the labeling after 6 months OTC marketing.

Following this page, 11 pages withheld in full - draft labeling (b)(4)

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/s/

Mary Robinson
5/20/2008 07:01:08 PM
INTERDISCIPLINARY

Debbie Lumpkins
5/21/2008 08:15:45 AM
INTERDISCIPLINARY

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 021330/S-007

CHEMISTRY REVIEWS

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

NDA #: 21-330 **CHEM.REVIEW #:** 1 **REVIEW DATE:** 16-MAY-2008

SUBMISSION/TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
NDA 21-330/SCF-007	24-JAN-2008	24-JAN-2008	05-FEB-2008
NDA 21-330/SCF-007(BC)	17-APR-2008	17-APR-2008	17-APR-2008

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

Iris H. Shelton
Assistant Director, Regulatory Affairs
(973) 889-2167

DRUG PRODUCT NAME

Proprietary:	Commit® Lozenges
Nonproprietary/USAN:	nicotine polacrilex
Code Names/#'s:	
Chemical Type/	3
Therapeutic Class:	S

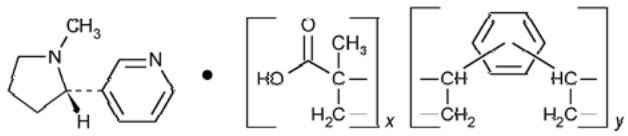
PHARMACOLOGICAL CATEGORY/INDICATION: Reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking.

DOSAGE FORM: Lozenges
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]

SUPPORTING DOCUMENTS:

DMF (b) (4), Type IV, for (b) (4) as Manufactured in (b) (4), (b) (4)", held by (b) (4). Letter of Authorization dated 27-FEB-2007. DMF is adequate.

The following DMFs are referenced for all Commit® Lozenges:

DMF (b) (4) Type III, for " (b) (4) as Manufactured in (b) (4)", held by (b) (4). Letter of Authorization dated 19-FEB-2007. DMF is adequate; not reviewed.

DMF (b) (4) Type IV, for " (b) (4)", held by (b) (4) (b) (4). Letter of Authorization dated 12-FEB-2007. DMF is adequate; not reviewed.

DMF (b) (4) Type II, for " (b) (4) as Manufactured in (b) (4)", held by (b) (4) (b) (4) Letter of Authorization dated 13-FEB-2007. DMF is adequate; not reviewed.

REMARKS/COMMENTS:

This Supplement for Prior Approval provides for a new flavor for Commit® (nicotine polacrilex) Lozenges, 2mg and 4mg, "Cappucino". Commit® Cappuccino Lozenges, 2mg and 4mg, are considered to be a line extension of the currently marketed Commit® Lozenges (original, mint and cherry flavor) which are available in the same strengths and contain the same active ingredient, Nicotine Polacrilex. The only ingredient change from the previously approved formulations is the flavor agent, all other ingredients remaining identical to those currently approved (NDA 21-330, S-002 and S-004). Minor quantitative differences in the amounts of excipients have been made to adjust for a different amount of flavor agent in the drug product formulation. There are no changes to the manufacturing and control of drug substance, or to drug product manufacturing, packaging components or analytical procedures (including validation). The product specifications will be the same as currently approved except for the product description as it relates to the new flavor.

Three full production batches for the 2mg and 4mg strengths were placed on stability. Six months of stability data for these batches were provided in the amendment. Since this formulation is nearly identical, except for type and quantity of the flavor component, to previously approved mint and cherry formulations, the data provided (in conjunction with data on similar products in similar package configurations), support a shelf life of 24 months when stored

below 30°C. The (b) (4) vial packaging is identical to that used for the mint and cherry lozenges.

Dissolution studies were conducted consistent with SUPAC guidelines, demonstrating that the new flavor does not impact nicotine release. GSK proposed (letter dated 09-MAY-2003), and FDA agreed (letter dated 02-JUN-2003), that establishment of bioequivalence for new flavor variants was acceptable using in vitro dissolution comparisons with the original, approved Nicotine Polacrilex Lozenges. GSK has provided comparative dissolution data as the basis of this application. Testing confirmed that the changes in formulation from the original to cappuccino lozenges do not affect the in-vitro dissolution performance of the products.

CONCLUSIONS & RECOMMENDATIONS: **APPROVAL**

The information submitted in the supplement adequately supports the proposed changes. Approval is recommended.

(see attached electronic signature page)

Joel S. Hathaway, Ph.D.
Reviewing Chemist

cc: Orig. NDA 21-330
ONDQA/DPE/Chem/JSHathaway
ONDQA/DPE/ChemBranchChf/HPatel
ONP/DNP/Division File
ONDQA/DPE/ChemPAL/LZhou
ONDQA/DPE/ProjMgr/RMcKnight

filename: C:\Documents and Settings\hathaways\My Documents\MSWordDocs\NDA Reviews\SuppNDAs\21330\N21330r.scf.007.doc

Approval

Following this page, 18 pages withheld in full - (b)(4)

B. Environmental Assessment or Claim of Categorical Exclusion

The firm claims categorical exclusion from the preparation of an environmental assessment for this Supplemental New Drug Application in accordance with 21 CFR 25.31(a).

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/s/

Steve Hathaway
5/19/2008 08:28:43 AM
CHEMIST
New flavor for lozenges, plus related packaging
for your concurrence

Hasmukh Patel
5/19/2008 08:49:34 AM
CHEMIST

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 021330/S-007

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

From: Iris.H.Shelton@gsk.com
Sent: Monday, May 19, 2008 5:42 PM
To: Lewis, Mary
Cc: Abraham, Elaine G; Christl, Leah A
Subject: Re: NDA 21-330; Commit Cappuccino Lozenge; Letter date 1/24/08; need for clarification

Attachments: 61818XB COM MT 4mg 24ct Lbl.pdf; 30348XA COM MT 2mg 48 Ctn.pdf; 30349XA COM MT 4mg 48 Ctn.pdf; 61799XB COM MT 2mg 24ct Lbl.pdf

Hi Mary,
Provided is clarification on the labeling issues you addressed. See comments below in red.
Please contact me if you require any additional information.
Regards,
Iris

"Lewis, Mary" <Mary.1.Lewis@fda hhs.gov>

18-May-2008 21:31

To Iris H.Shelton@gsk.com
cc "Abraham, Elaine G" <elaine.abraham@fda.hhs.gov>, "Christl, Leah A" <Leah.Christl@fda hhs.gov>
Subject NDA 21-330; Commit Cappuccino Lozenge; Letter date 1/24/08; need for clarification

Hi Iris,

I am not going to be in the office Monday due to a family matter that has come up. If you have responses to the Cappuccion issues that I sent you Friday (see below) please send them to Elaine Abraham and Leah Christl. One of them will cover for me and forward it to the reviewer. At this moment I'm no sure who will be covering since it's Sunday evening.

Otherwise, I will look for a response from you on Tuesday when I plan to be in the office, minus a couple hours for a meeting. Thank you.

Mary

-----Original Message-----
From: Lewis, Mary
Sent: Friday, May 16, 2008 4:22 PM
To: 'Iris.H.Shelton@gsk.com'
Subject: NDA 21-330; Commit Cappuccino Lozenge; Letter date 1/24/08; need for clarification
Importance: High

Hi Iris,

One of my labeling reviewers needs clarification on the labeling. In your cover letter you state the cappuccino flavored lozenge is identical to the spearmint lozenge with regard to other excipients and manufacturing processes.

1. Please clarify why there are more **inactive ingredients** for the cappuccino than for the spearmint lozenge.

There are more ingredients on the spearmint lozenge labels based on differences in the flavoring (b) (4) in the 2 products.

2. Is there a mint POPPAC label and carton label that includes all approved changes so that the reviewer can compare to the cappuccino POPPAC label and carton label?

Attached are copies of the labels.

3. Please clarify: The 48 count cappuccino (2 POPPAC Containers of 24) 2 mg, "other information" is different than the 72 count cappuccino (3 POPPAC containers of 24) 2 mg "Other information".

a. The 48 count has "(b) (4) and the 72 count label does not include this information

This was a typographical error in (b) (4) (b) (4) This statement has been removed.

b. The 48 count has "keep vial closed and protect from light", and the 72 count has "keep POPPAC tightly closed and protect from light".

Components have been revised to read "keep POPPAC tightly closed and protect from light."

4. We see a 24 count and a 27 count for cherry and Mint POPPACs. Please tell us when the 27 count was approved. What is the reason for the two different counts?

Following approval of the 24 count mint, we submitted a 28 count vial (S005, approved 9/1/06). Marketing did not proceed with this count rather introduced a 27 bonus pack of the mint. Count size was based on bracketing of the stabilty data for the 24 and 27 counts mint. The 27 cherry was a brief bonus count. Consistent with SUPAC guidelines this increase in count size was submitted via annual report.

5. We see cappuccino has a 24 count package. (b) (4)

Currently there are no plans for a (b) (4).

Thank you.

Mary

Mary M. Lewis, RN, BSN
Regulatory Project Manager
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products

Center for Drug Evaluation and Research
Phone: 301-796-0941
Fax: 301-796-9899
Email: Mary.1.Lewis@fda.hhs.gov

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/s/

Mary Lewis
5/20/2008 01:28:37 PM
CSO

From: Lewis, Mary
Sent: Friday, May 16, 2008 4:22 PM
To: 'Iris.H.Shelton@gsk.com'
Subject: NDA 21-330; Commit Cappuccino Lozenge; Letter date 1/24/08; need for clarification

Importance: High
Hi Iris,

One of my labeling reviewers needs clarification on the labeling. In your cover letter you state the cappuccino flavored lozenge is identical to the spearmint lozenge with regard to other excipients and manufacturing processes.

1. Please clarify why there are more **inactive ingredients** for the cappuccino than for the spearmint lozenge.

2. Is there a mint POPPAC label and carton label that includes all approved changes so that the reviewer can compare to the cappuccino POPPAC label and carton label?

3. Please clarify: The 48 count cappuccino (2 POPPAC Containers of 24) 2 mg, "other information" is different than the 72 count cappuccino (3 POPPAC containers of 24) 2 mg "Other information".

a. The 48 count has "(b) (4) and the 72 count label does not include this information.

b. The 48 count has "keep vial closed and protect from light", and the 72 count has "keep POPPAC tightly closed and protect from light".

4. We see a 24 count and a 27 count for cherry and Mint POPPACs. Please tell us when the 27 count was approved. What is the reason for the two different counts?

5. We see cappuccino has a 24 count package. (b) (4)

Thank you.

Mary

Mary M. Lewis, RN, BSN
Regulatory Project Manager
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research
Phone: 301-796-0941
Fax: 301-796-9899
Email: Mary.1.Lewis@fda.hhs.gov

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/s/

Mary Lewis
5/16/2008 04:45:38 PM
CSO

Mary Lewis
5/16/2008 04:46:19 PM
CSO

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-330/S-007 **PRIOR APPROVAL SUPPLEMENT**

GlaxoSmithKline Consumer Healthcare
Attention: Iris H. Shelton
Assistant Director, Regulatory Affairs
1500 Littleton Road
Parsippany, NJ 07054

Dear Ms Shelton:

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

Name of Drug Product: Commit (2 mg and 4 mg, nicotine polacrilex) lozenge

NDA Number: 21-330

Supplement number: 007

Date of supplement: January 24, 2008

Date of receipt: January 24, 2008

This supplemental application proposes a new cappuccino flavor in (b) (4) vial packaging 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 March 24, 2008 in accordance with 21 CFR 314.101(a). If the application is filed, the goal date will be May 24, 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

3/3/2008 01:34:40 PM