CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

ANDA 076777/S025

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

Sponsor: L. Perrigo Company

Approval Date: October 31, 2011

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APPLICATION NUMBER:

ANDA 076777/S025

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APPLICATION NUMBER:

ANDA 076777/S025

APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Rockville MD 20855

ANDA 076777/S-025

L. Perrigo Company
Attention: Gregory Shawaryn
515 Eastern Avenue
Allegan, MI 49010

Dear Sir:

This is in reference to your supplemental new drug application dated September 21, 2011, submitted pursuant to 21 CFR 314.70(c) (6) [Supplement – Changes Being Effected] regarding your abbreviated new drug application for Nicotine Polacrilex Gum USP, 2 mg (Mint, Coated).

This supplemental new drug application provides the addition of a 10 count package of Nicotine Polacrilex Gum USP, 2 mg (Mint, Coated).

We have completed the review of your application and it is approved.

We note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of

Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

PROMOTIONAL MATERIALS

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the following address or by facsimile at 301-847-8444:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

In addition, as required under 21 CFR 314.81(b)(3)(i), you must submit your updated final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA-2253, directly to the above address. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

We remind you that you must comply with the requirements for an approved abbreviated new drug application described in 21 CFR 314.80-81.

The materials submitted are being retained in our files.

Sincerely,

{See appended electronic signature page}

William Peter Rickman
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

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/s/

LILLIE D GOLSON
10/31/2011
for Wm. Peter Rickman

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 076777/S025

LABELING

FINAL PRINTED LABELING
Nicotine Polacrilex Gum, 2 mg
(Cool Mint Coated)
10-count carton

(b) (4)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 076777/S025

LABELING REVIEW

Labeling Review Branch
Division of Labeling and Program Support
Office of Generic Drugs

Labeling Supplement Review

Application Number: 076777/S-025

Name of Drug: Nicotine Polacrilex Gum USP, 2 mg (Mint, Coated)

Applicant: L. Perrigo Company

Material Reviewed: (specify labeling pieces)
Submission Date(s):
September 21, 2011: CBE (Carton Labeling)

Background and Summary

1. This supplemental application provides for the addition of a smaller 10 count package of Nicotine Polacrilex Gum USP, 2 mg (Mint, Coated).

   On March 18, 2011, Perrigo submitted a supplement under ANDA 076775/S-018, providing for the addition of a 10 count package for the 2 mg strength of Nicotine Polacrilex Gum USP (Regular). Historically, the Agency had concerns that a smaller package would be promotional and may contribute to abuse and misuse as a result of a potentially lower price. A consult was requested by OGD to the Division of Nonprescription Clinical Evaluation (DNCE) on Perrigo's proposal (for ANDA 076775, 2 mg). DNCE concluded that there is no clear evidence that either the nicotine gum or lozenge forms are drug products which are likely to be abused by any age group, including adolescents (the full consult review can be found in DARRTS, review date 5/27/2011). ANDA 076775/S-018 was approved for the 10 count package on August 30, 2011.

2. Model Labeling: Nicorette® Gum (Nicotine Polacrilex, USP), 2 mg, NDA 018612.S-056, approved May 17, 2011. This supplement provides for the change in format of the consumer information leaflet from a booklet to a leaflet based document.

   The latest approved RLD labeling is NDA 019612/S-057 approved September 27, 2011. However, the approved changes apply only to the Cinnamon flavor. Thus, the changes do not apply to this ANDA.

3. Patent/Exclusivity: None

Review

Perrigo provides for the addition of a 10 count package of Nicotine Polacrilex Gum USP, 2 mg (Mint, Coated). The container label is identical to the currently approved label with the exception of

the net contents of 10 and the inclusion of the footnote associated with the new net content: *This package size may not be a full day's supply; it is intended to start or continue a quit attempt." This statement was recommended by DNCE to be included on the labeling of 10 count packaging cartons.

The submitted labeling is acceptable for approval.

Recommendation

Recommend approval.

{see appended electronic signature}

Lisa Kwok
Labeling Reviewer

Supervisory Comment/Concurrence:

{see appended electronic signature}

Lillie Golson
Team Leader

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

/s/

LISA H KWOK
10/31/2011

LILLIE D GOLSON
10/31/2011

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 076777/S025

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

September 21, 2011

Special Supplement-
Changes Being Effected
Labeling Supplement

Keith Webber, Ph.D., Acting Director
Office of Generic Drugs
Document Control Room
7620 Standish Place
Rockville, MD 20855

Via ESG (Gateway)

RE: ANDA 76-777
Nicotine Polacrilex Gum USP, 2 mg (Mint, Coated)

Dear Dr. Webber:

Reference is made to the telephone conversation held on January 5, 2011, between Lillie Golson of OGD and Barinder Sandhu of Perrigo, on the possibility of commercially marketing a packaging size of less than 20 pieces of gum. As a follow-up to that discussion, Perrigo is proposing the addition of a 10-count package (configured with already approved packaging components) for distribution. Included in Attachment 1 is an example of Final Printed Labeling for the proposed 10-count. This representative label is identical to our currently approved labels with the exception of the net contents of 10 and the inclusion of the footnote associated with the new net contents, "*This package size may not be a full day's supply; it is intended to start or continue a quit attempt." Further this count size and footnote have been previously approved on August 30, 2011 in related Nicotine Polacrilex Gum ANDA's 76-775 and 76-789.

Historically, Perrigo has engaged in similar discussions with FDA seeking approval for a smaller packaging configuration. A letter dated June 21, 2005 was written to Mr. W. Peter Rickman, whereby Perrigo helped to mitigate FDA's concerns of commercially marketing a 20-count package by presenting several arguments and evidence in support of the 20-count (Attachment 2). FDA's primary concern was that the use of a 20-count package would be promotional, and may contribute to abuse and misuse as a result of a potentially lower price. These concerns were addressed by Perrigo and thus, the 20-count package continues to be commercially available.

Since approval and now being on the US market for 6 years with the 20-count package, there is no direct evidence that would support and/or help to warrant the concerns previously held by FDA regarding the lower packaging counts. Thus, marketing a lower packaging size will not introduce and/or encourage an inappropriate use and/or increase safety risks that are already inherent with the product, as outlined in the label. In fact, over the 7 years of domestic store

brand distribution of Nicotine Polacrilex Gum products, Perrigo has not been informed of an actual occurrence and/or observed any direct correlation of package size /or price on abuse /or underage use of Nicotine Polacrilex Gum.

In the absence of actual evidence based arguments and/or direct correlation of package size /or price on abuse /or underage use of Nicotine Polacrilex Gum, Perrigo believes there are several benefits that a 10-count packaging option can provide smokers who are trying to quit smoking.

We are requesting approval of the addition of the 10-count package based on the following benefits and also when considering that there is no direct evidence that a smaller packaging configuration will result in inappropriate use and/or safety issues:

- The availability of the 10 count package would lead to a comparable price point relative to a pack of cigarettes. This will reduce the one-time purchase price of Nicotine Polacrilex Gums so they are comparable in cost to one pack of cigarettes. A more affordable option for smokers that may want to reduce or quit smoking by providing a pack size available that is not potentially beyond their need or financial means.
- A consumer who uses Nicotine Polacrilex Gum products to quit smoking but who has forgotten to take their Nicotine Polacrilex Gum products with them on any given day is faced with the dilemma – to avoid a relapse by purchasing a small pack unit to help them through the day, or relapse.
- No consumer should be forced to decline to purchase the product (and resume smoking) simply because of the unnecessary cost and inconvenience associated with the larger packaging units. Thus, a smaller package size could help consumers with limited financial means to continue treatment until the next pay period; whereas, a larger package size may not be a viable option.
- The addition of the 10-count package would not change or impact the strong labeling warnings that are already stated on the label. Irrespective of the count size all safety information is included on the label to ensure that the consumer is informed on how to use the product safely and effectively.
- A smaller pack size helps consumer's traveling and who only need enough gum pieces to last several days while on their trip.
- Towards the end of the treatment period a consumer may only require a few gum pieces prior to the completion of the recommended course of treatment.

Additionally, the 10 count package will be subject of the approved Marketing and Surveillance Plan (Attachment 3). In particular:

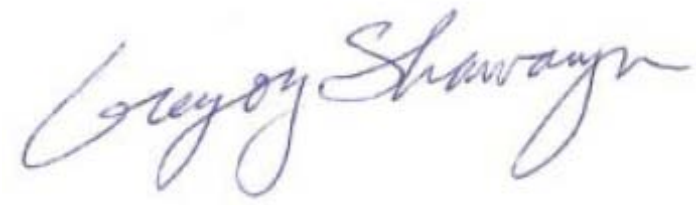
- The product will not be for sale to those under 18 years of age.
- Proof of age will be required.
- The product will not be for sale in vending machines or from any source where proof of age cannot be verified.
- The package design will not appeal to teenagers or children.
- All other provisions in the Plan will continue in place.

Please note that a similar submission is being made today to ANDA 76-779 (Nicotine Polacrilex Gum USP, 4 mg (Mint, Coated)).

If you have any questions or need any additional information, please feel free to contact me in the manner most convenient to you:

Telephone:	269-673-9181
Fax:	269-673-7655
E-mail:	gregory.shawaryn@perrigo.com

Respectfully submitted,



Gregory Shawaryn
Regulatory Affairs Project Manager