NDA 22360/S-012

SUPPLEMENT APPROVAL

GlaxoSmithKline Consumer Healthcare
Attention: Mini Nair
Director, US Regulatory Affairs
184 Liberty Corner Road, Suite 200
Warren, NJ 07059

Dear Ms. Nair:

Please refer to your supplemental new drug application (sNDA) dated and received November 6, 2020, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nicorette (nicotine polacrilex) Mini Lozenges, 2 mg and 4 mg.

This "Prior Approval" supplemental new drug application provides for a new formulation, alternate manufacturing site, alternate packaging site, and associated labeling.

APPROVAL & LABELING

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

LABELING

Submit final printed labeling (FPL), as soon as they are available, but no more than 30 days after they are printed. The FPL must be in the "Drug Facts" format (21 CFR 201.66), where applicable, and identical to the following:

Submitted Labeling	Date Submitted
2 mg and 4 mg Nicorette Mini Lozenges	
20-ct Nicorette Mini Lozenge-Immediate Container (Vial) Back Label	November 6, 2020
27-ct Nicorette Mini Lozenge-Immediate Container (Vial) Back Label	November 6, 2020
Nicorette Mini Lozenge-User Guide Leaflet	November 6, 2020
2 mg Nicorette Mini Lozenges	
2 mg Nicorette Mini Lozenge-Immediate Container (Vial) Front Label	November 6, 2020
2 mg, 20-ct Nicorette Mini Lozenge-Outer Container (Blister Card)	November 6, 2020
2 mg, 81-ct Nicorette Mini Lozenge-Outer Container (Carton)	November 6, 2020

4 mg Nicorette Mini Lozenges	
4 mg Nicorette Mini Lozenge-Immediate Container (Vial) Front Label	November 6, 2020
4 mg, 20-ct Nicorette Mini Lozenge-Outer Container (Blister Card)	November 6, 2020
4 mg, 81-ct Nicorette Mini Lozenge-Outer Container (Carton)	November 6, 2020

The FPL should be submitted electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*.[1] For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 22360/S-012**." Approval of this submission by FDA is not required before the labeling is used.

We note the presence of the MyQuit Band on the Nicorette website: https://www.nicorette.com/products/nicorette-lozenge.html. However, the MyQuit Band has been discontinued in 2019. We recommend that you remove reference to the MyQuit Band from the Nicorette website. If you wish to continue to display the MyQuit Band, provide a disclaimer that informs consumers that the product is no longer being manufactured.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at FDA.gov.[2] Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

[1] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

[2] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

If you have any questions, call Cynthia Kim, Regulatory Project Manager, at 301-796-0879.

Sincerely,

{See appended electronic signature page}

Nushin Todd, MD, PhD
Acting Director
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton and Container Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

NUSHIN F TODD
03/05/2021 01:36:34 PM