DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 77-007

JAN 31 2006

Perrigo R&D Company
Attention: Valerie Gallagher
Manager, Regulatory Affairs
515 Eastern Avenue
Allegan, MI 49010

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 29, 2003, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Nicotine Polacrilex Lozenges, 2 mg and 4 mg.

Reference is also made to your amendments dated July 9, and November 18, 2004; and April 21, July 28, October 20, December 12, December 13, December 14, 2005, January 26, and January 27 2006.

We have completed the review of this ANDA and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Nicotine Polacrilex Lozenges, 2 mg and 4 mg, to be bioequivalent and therefore, therapeutically equivalent to the listed drug, Commit of GlaxoSmithKline. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

The reference listed drug (RLD) upon which you have based your ANDA, Commit of GlaxoSmithKline, is subject to a period of patent protection. As noted in the Agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book", U.S. Patent No. 5,110,605 (the '605 patent) is scheduled to expire on August 21, 2010.

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '605 patent is invalid and will not be infringed by your manufacture, use, or sale of Nicotine Polacrilex Lozenges, 2 mg and 4 mg, under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that

approval of an ANDA shall be made effective immediately, unless an action is brought against Perrigo R&D Company (Perrigo) for infringement of the patent that was the subject of the paragraph IV certification. This action must be brought against Perrigo prior to the expiration of 45 days from the date the notice you provided under paragraph (2)(B)(i) was received by the NDA/patent holder(s). You have notified the Agency that Perrigo complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement of the '605 patent was brought against Perrigo within the statutory 45-day period, which action would have resulted in a 30-month stay under section 505(j)(5)(B)(iii).[1]

With regard to 180-day generic drug exclusivity and Nicotine Polacrilex Lozenges, 2 mg and 4 mg, Perrigo was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '605 patent. Therefore, with this approval, Perrigo is eligible for 180-days of market exclusivity for Nicotine Polacrilex Lozenges, 2 mg and 4 mg. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act,[2] will begin to run from the date Perrigo begins commercial marketing of the drug product. Please submit correspondence to this ANDA informing the Agency of the date the exclusivity begins to run.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Postmarketing reporting requirements for this ANDA 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.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in

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[1] Because information on the '605 patent was submitted to FDA before August 18, 2003, this reference to section 505(j)(5)(B)(iii) is to that section of the Act as in effect prior to December 8, 2003, when the Medicare Prescription Drug, Improvement and Modernization Act (MMA) (Public Law 108-173) was enacted. See MMA § 1101(c)(3).

[2] As amended by the MMA in 2003. See MMA § 1102(b)(1).

draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

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

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications (HFD-42) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research