ANDA 75-794 November 26, 2001

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

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated January 28, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Acetaminophen, Aspirin, and Caffeine Tablets USP, 250 mg/250 mg/65 mg, respectively.

Reference is also made to our Tentative Approval letter dated July 12, 2001, and to your amendment dated November 5, 2001.

The listed drug product referenced in your application, Excedrin Migraine Tablets of Bristol Myers Products, Inc., is subject to periods of patent protection which expire on July 24, 2007, (U.S. Patent No. 4,943,565 [the '565 patent]) and July 14, 2017, (U.S. Patent No. 5,972,916 [the '916 patent]). Your application contains Paragraph IV Certifications to each of these patents under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of this drug product will not infringe on these patents or that the patents are otherwise invalid. Section 505(j)(5)(B)(iii) of the Act provides that approval of this abbreviated new drug application shall be made effective immediately, unless an action is brought against L. Perrigo Company (Perrigo) for infringement of one or more of the patents. This action should be brought before the expiration of forty-five days from the date the notice provided by Perrigo under paragraph (2)(B)(I) is received by the patent and new drug application (NDA) holder. You have notified the agency that Perrigo has complied with the requirements of Section 505(j)(2)(B) of the Act and that no legal action regarding the '565 patent was brought against Perrigo within the statutory forty-five day period. However, you have also informed the agency that litigation was initiated in the United States District Court for the Western District of Michigan involving your challenge to the '916 patent (Bristol-Myers Squibb Company

v. Perrigo Company and L. Perrigo Company, Civil Action No. 1:00 CV 404). In your November 5, 2001 amendment you informed the agency that the '916 patent litigation was dismissed by the court without a judgement on October 31, 2001. You also stated that Perrigo entered into a license agreement with the Bristol Myers Squibb Company granting Perrigo certain rights, including the right to market products containing the combination of aspirin, acetaminophen, and caffeine with a label claim for the treatment of migraine.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted over-the-counter (OTC) labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Acetaminophen, Aspirin, and Caffeine Tablets USP, 250 mg/250 mg/65 mg, respectively, to be bioequivalent to the listed drug (Excedrin Migraine Tablets of Bristol Myers Products, Inc.). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

With respect to 180-day generic drug exclusivity, we note that Perrigo was the first ANDA applicant to submit a substantially complete ANDA containing Paragraph IV Certifications to the '565 and '916 patents. Therefore, upon this approval Perrigo is deemed eligible for 180-days of generic drug market exclusivity. Such exclusivity will commence beginning on the date Perrigo begins commercial marketing of this drug product, or in the absence of marketing, from the date of a decision of a court finding the '916 patent to be invalid, unenforceable, or not infringed, whichever event occurs earlier {Section 505(j)(5)(B)(iv)].

With respect to the "first commercial marketing" trigger for the commencement of exclusivity, please refer to 21 CFR 314.107(c)(4). The agency expects that you will begin commercial marketing of this drug product in a prompt manner. Please submit correspondence to your application stating the date you commence commercial marketing of this product, or the date of a decision of a court holding the relevant patent invalid, unenforceable, or not infringed.

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

Post-marketing reporting requirements for this abbreviated application 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
Director
Office of Generic Drugs
Center for Drug Evaluation and Research