DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 204152

ANDA APPROVAL

Perrigo R&D Company
515 Eastern Avenue
Allegan, MI 49010
Attention: James Chambers
Senior Manager-Global Regulatory Affairs

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated March 29, 2012, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), for Omeprazole Magnesium Delayed-release Tablets, 20.6 mg (20 mg base).

Reference is also made to the Complete Response letter issued by this office on December 31, 2014, and to your amendments dated June 29 and July 20, 2015.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for over-the-counter (OTC) use as recommended in the submitted labeling. **Accordingly the ANDA is approved**, effective on the date of this letter. The Division of Bioequivalence has determined your Omeprazole Magnesium Delayed-release Tablets, 20.6 mg, to be bioequivalent to the reference listed drug (RLD), Prilosec OTC Delayed-release Tablets, 20.6 mg, of AstraZeneca Pharmaceutical Company (AstraZeneca).

Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA. The “interim” dissolution specifications are as follows:

Dissolution Testing should be conducted in:

Buffer stage:

Medium:	Tablets are pre-exposed to 300 mL of 0.1 N HCl for 2 hours and then 700 mL of 0.086 M Na_2HPO_4 is added to the medium containing the tablets to give 1000 ml with pH 6.8.
Apparatus:	USP Apparatus II (paddle)
Speed:	100 rpm

(b) (4)

(b) (4)

Specifications:

NMT (b) (4) (Q) of Omeprazole in the dosage form is dissolved in 120 min

NLT (b) (4) (Q) of Omeprazole in the dosage form is dissolved in 30 min

The "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data for the first three production size batches. Data should be submitted as a Special Supplement – Changes Being Effected when there are no revisions to the "interim" specifications or when the final specifications are tighter than the "interim" specifications. In all other instances, the information should be submitted in the form of a Prior Approval Supplement.

The RLD upon which you have based your ANDA, AstraZeneca's Prilosec OTC Delayed-release Tablets, is subject to periods of patent protection. The following patents and expiration dates are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"):

U.S. Patent Number	Expiration Date
5,817,338 (the '338 patent)	October 6, 2015
5,900,424 (the '424 patent)	May 4, 2016
6,403,616 (the '616 patent)	November 15, 2019
6,428,810 (the '810 patent)	November 3, 2019

With respect to each of these patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Omeprazole Magnesium Delayed-release Tablets, 20.6 mg, under this ANDA. You have notified the agency that Perrigo R&D Company (Perrigo) complied with the requirements of section 505(j)(2)(B) of the FD&C Act, and that no action for infringement was brought against Perrigo within the statutory 45-day period.

With respect to 180-day generic drug exclusivity, we note that Perrigo was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification. Therefore, with this approval, Perrigo is eligible for 180 days of generic drug exclusivity for Omeprazole Magnesium Delayed-release Tablets, 20.6 mg. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the FD&C Act, will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

Under section 506A of the FD&C 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.

You have been requested to provide information after the ANDA has been approved. Any information submitted to meet the conditions requested in this letter is considered a "Post Approval Commitment Response." To alert the Office of Generic Drug staff to the fact that you are providing post approval commitment information, please designate your submission in your cover letter as "POST APPROVAL COMMITMENT RESPONSE."

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1 of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts. All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

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.

Sincerely yours,

William P. Rickman -S

Digitally signed by William P. Rickman -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300043242, cn=William P. Rickman -S
Date: 2015.07.30 10:26:43 -04'00'

For Carol A. Holquist, RPh
Acting Deputy Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research