DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 022056/S-21

SUPPLEMENT APPROVAL

Covis Pharma B.V.
C/o Cardinal Health
Attention: Marjorie Zettler, PhD, MPH
Senior Scientist
Cardinal Health Regulatory Science
7400 W. 110th St., Suite 300
Overland Park, KS 66210

Dear Dr. Zettler:

Please refer to your Supplemental New Drug Application (sNDA) dated February 10, 2017, received submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for PRILOSEC (omeprazole magnesium) for delayed-release oral suspension.

This Prior Approval supplemental new drug application proposes to remove PRILOSEC (omeprazole magnesium) delayed-release capsules, NDA 019810, from the Prescribing information, Medication Guide and Instructions for Use. NDA 019810 has been withdrawn as per the Federal Register notice of October 3, 2017.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revisions listed below:

- Reduced white space and removed bolding in Recent Major Changes section of Highlights
- Updated revision dates to the current date

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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 from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your June 21, 2018, submission containing final printed carton and container labels.

REPORTING REQUIREMENTS

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

If you have any questions, call CAPT Mimi Phan, Regulatory Project Manager, at 301-796-5408.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director for Safety
Division of Gastroenterology and Inborn Errors Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling
Instructions For Use Labeling
Medication Guide 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/

JOYCE A KORVICK
08/21/2018