



NDA 22281/S-017

CORRECTED SUPPLEMENT APPROVAL

Innovative Science Solutions, Inc. (Lumanity)
on behalf of Riley Consumer Care, LLC d/b/a Carlin Consumer Health, LLC
Attention: Steven M. Weisman, PhD
Global President, Clinical and Regulatory
67 Park Place East
Morristown, NJ 07960-7143

Dear Dr. Weisman:

Please refer to your supplemental new drug application (sNDA) dated and received on December 20, 2022, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zegerid OTC (omeprazole 20 mg/sodium bicarbonate 1100 mg) capsules.

We also refer to our approval letter dated April 24, 2023, which contained the following error: missing enclosures (e.g., approved labeling).

This corrected action letter incorporates the correction of the error. The effective action date will remain April 24, 2023, the date of the original letter.

This "Prior Approval" supplemental new drug application provides for the following changes for Zegerid OTC:

- graphical elements of the principal display panel were revised
- for the 14-count container label, [REDACTED] ^{(b) (4)} was removed from the warning "you need to take this product for more than 14 days unless directed by your doctor" in subsection "Stop use and ask a doctor if" of the 14-count container label

APPROVAL & LABELING

We have completed our review of this application, as amended. 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
14-count carton (bottle)	March 27, 2023
28-count carton (bottle)	March 27, 2023
42-count carton (bottle)	March 27, 2023
14-count immediate container (bottle)	March 27, 2023

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 22281/S-017.**” Approval of this submission by FDA is not required before the labeling is used.

If you are interested in marketing other package configurations in the future (e.g., individual containers containing greater than 14-count, total package sizes greater than 42-count), we expect submission of a prior approval supplement that includes data to demonstrate consumer comprehension of use.

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.

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>

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 Cynthia Kim, PharmD, BCPS, Senior Regulatory Project Manager, at (301) 796-0879.

Sincerely,

{See appended electronic signature page}

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

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
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