NDA 22281/S-014

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, May 3, 2022, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zegerid OTC (omeprazole 20 mg/sodium bicarbonate 1100 mg) capsules.

This "Prior Approval" supplemental new drug application provides for:

- revision of the Drug Facts label to include a warning for Severe Cutaneous Adverse Reactions (SCARs) in accordance with FDA's CBE Supplement Request letter issued on March 7, 2022
- moving cardiac warnings in the DFL from "***Ask a doctor before use***" to "***Do not use***"
- a new 28-count outer carton presentation

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 immediate container (bottle)	October 31, 2022
14-Count outer carton (bottle)	October 31, 2022
28-Count outer carton (bottle)	October 31, 2022

42-Count outer carton (bottle)	October 31, 2022

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-014**." 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.

REPORTING REQUIREMENTS

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

[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

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

If you have any questions, call Cynthia Kim, PharmD, 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
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton and Container 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/

NUSHIN F TODD
11/01/2022 01:45:33 PM