NDA 021903/S-011

SUPPLEMENT APPROVAL

Recordati Rare Diseases, Inc.
c/o: Intertek Surveying Services
Attention: Jennifer Tillman, (Authorized US Agent)
16441 Space Center Boulevard
Suite D-100
Houston, TX 77058

Dear Ms. Tillman:

Please refer to your supplemental new drug application (sNDA) dated and received February 8, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for NeoProfen (ibuprofen lysine) 10 mg/mL for Injection and your authorized generic product marketed by Prasco.

This Prior Approval supplemental new drug application provides for revisions to the carton and container labeling as follows:

1. The total strength per volume was added to the label.

2. The IV abbreviation was replaced with the word "Intravenous"

3. The statement "single use vial" was replaced with the words "single dose vial".

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.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling 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*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved NDA 021903/S-11**." Approval of this submission by FDA is not required before the labeling is used.

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, please call:

Lori Anne Wachter, RN, BSN, RAC
Regulatory Project Manager for Safety
301 796-3975

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, PharmD.
Deputy Director for Safety
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton and Container Labeling

CC: Steven Peltier
100 Corporate Drive
Lebanon, NJ 08833

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/

MARY R SOUTHWORTH
08/14/2019 02:12:37 PM