DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205919

NDA APPROVAL

Rare Disease Therapeutics, Inc. US Agent for
Nova Laboratories Limited
Attention: Jennifer Spinella MT (ASCP), RAC
Vice President, Regulatory Affairs and Quality Assurance
9550 Cuyamaca Ste. 203
Santee, CA 92071

Dear Ms. Spinella:

Please refer to your New Drug Application (NDA) dated July 9, 2013 received July 10, 2013 submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Purixan® (mercaptopurine), oral suspension 20 mg/ml.

We acknowledge receipt of your amendments dated July 30, August 8, 14, 16, 26, 27, 2013, October 8, November 4 and 6, December 2, 11, 12, 27, 2013; January 16 and 31, February 26, March 14, 20 (2), 24, 26 (2), 27, 31, 2014, April 1 (2), 3, 11 (4), and 14, 2014.

This new drug application provides for the use of Purixan® (mercaptopurine), oral suspension 20 mg/ml for use in pediatric, children, and adult patients for maintenance therapy of acute lymphoblastic leukemia (ALL) as part of a combination regimen.

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 text.

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 (text for the package insert). 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*, available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your April 11, 2014 submission containing final printed carton and container labels.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because this drug product for this indication has an orphan drug designation, you are exempt from this requirement.

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitment:

PMC 2148-1 Submit a Prior Approval Supplement [redacted (b) (4)] Nova will provide data from "in use" stability studies. Also included in the submission will be [redacted (b) (4)] data and revised labelling to include patient instructions

The timetable you submitted on March 26, 2014 states that you will provide this information according to the following schedule:

Prior Approval Supplement Submission: August, 2014

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

Although the Purixan label differs from the label of the reference product Purinethol, no safety advantage of Purixan compared to Purinethol has been established and no comparative safety advertising claims should be made.

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 Kris Kolibab, Regulatory Project Manager, at (240) 402-0277.

Sincerely,

{See appended electronic signature page}

Edvardas Kaminskas, MD
Deputy Director
Division of Hematology Products
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

Enclosures:
Content of Labeling
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

EDVARDAS KAMINSKAS
04/28/2014