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RESEARCH**

APPLICATION NUMBER:

206323Orig1s000

PROPRIETARY NAME REVIEW(S)

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Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

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Date of This Review: February 17, 2015

Application Type and Number: NDA 206323

Product Name and Strength: Rinotuss 12 (Codeine Phosphate and Chlorpheniramine Maleate) extended release tablets

Product Type: Multiple Ingredients

Rx or OTC: Rx

Applicant/Sponsor Name: Spriaso Inc.

Submission Date: November 25, 2014

Panorama #: 2014-44065

DMEPA Primary Reviewer: Sherly Abraham, R.Ph

DMEPA Team Leader: Kendra Worthy, Pharm.D.

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/s/

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