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APPLICATION NUMBER:

021187Orig1s021s022

PHARMACOLOGY REVIEW(S)

Memo to the file

Date: 1/14/2013

NDA #: 21187 S-022 Supporting Document number 815, eCTD Sequence number 0013

Date of submission: 12/20/2012

Sponsor: Organon USA Inc. A subsidiary of Merck & Co., Inc.

Drug Product: NuvaRing (etonogestrel/ethinyl estradiol) vaginal ring

Indication: Prevention of pregnancy

Subject: Prior Approval Supplement for Physician Labeling Rule (PLR) Format

Reviewer: Krishan L. Raheja, D.V.M., Ph.D.

Through P/T Expert Reviewer: Alex Jordan, Ph.D.

Regulatory action: This PLR conversion supplement for NuvaRing is fine from the P/T perspective.

Reference ID: 3248437

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/s/

KRISHAN L RAHEJA
01/22/2013

ALEXANDER W JORDAN 01/22/2013