CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

021187Orig1s034

Trade Name: **NuvaRing**

Generic Name: **etonogestrel/ethinyl estradiol**

Sponsor: **Organon USA Inc.**

Approval Date: 12/04/2017

Indications: NuvaRing is an estrogen/progestin combination hormonal contraceptive (CHC) indicated for use by women to prevent pregnancy.

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

021187Orig1s034

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

021187Orig1s034

APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 021187/S-034

SUPPLEMENT APPROVAL

Organon USA Inc
Attention: Shawn Moylan
Regulatory Liaison, Global Regulatory Affairs
351 North Sumneytown Pike
P.O.Box 1000, UG2C-50
North Wales, PA 19454

Dear Mr. Moylan:

Please refer to your Supplemental New Drug Application (sNDA) dated and received June 9, 2017, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for NuvaRing® (etonogestrel/ethinyl estradiol) Vaginal Insert.

This "Changes Being Effected in 30 days" supplemental new drug application provides for a change to the sachet to add a (b) (4) label on the foil pouch sachet.

APPROVAL & LABELING

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your June 9, 2017, submission containing final printed carton and container labels.

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 Rey Cantave, Regulatory Business Process Manager, at (240) 402 - 4035.

Sincerely,

{See appended electronic signature page}

David Lewis, PhD
Acting Branch Chief
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure:
Carton and Container Labeling

(b) (4)

Back (glues to front of sachet)

Front

Inside Left

Contents: Each ring releases 0.120 mg/day of etonogestrel and 0.015 mg/day of ethinyl estradiol over a 3-week period of use. Each ring contains 11.7 mg etonogestrel and 2.7 mg ethinyl estradiol as active ingredients and ethylene vinylacetate copolymer and magnesium stearate as excipients.

Dosage and Administration: Use as prescribed. See package insert.

Storage: Prior to dispensing to the patient, store refrigerated 2-8°C (36-46°F).
After dispensing to the patient, NuvaRing can be stored for up to 4 months at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature].
Avoid storing NuvaRing in direct sunlight or at temperatures above 30°C (86°F).

Inside Right

NUVARING®
(etonogestrel/ethinyl estradiol vaginal ring)
delivers 0.120 mg/0.015 mg per day

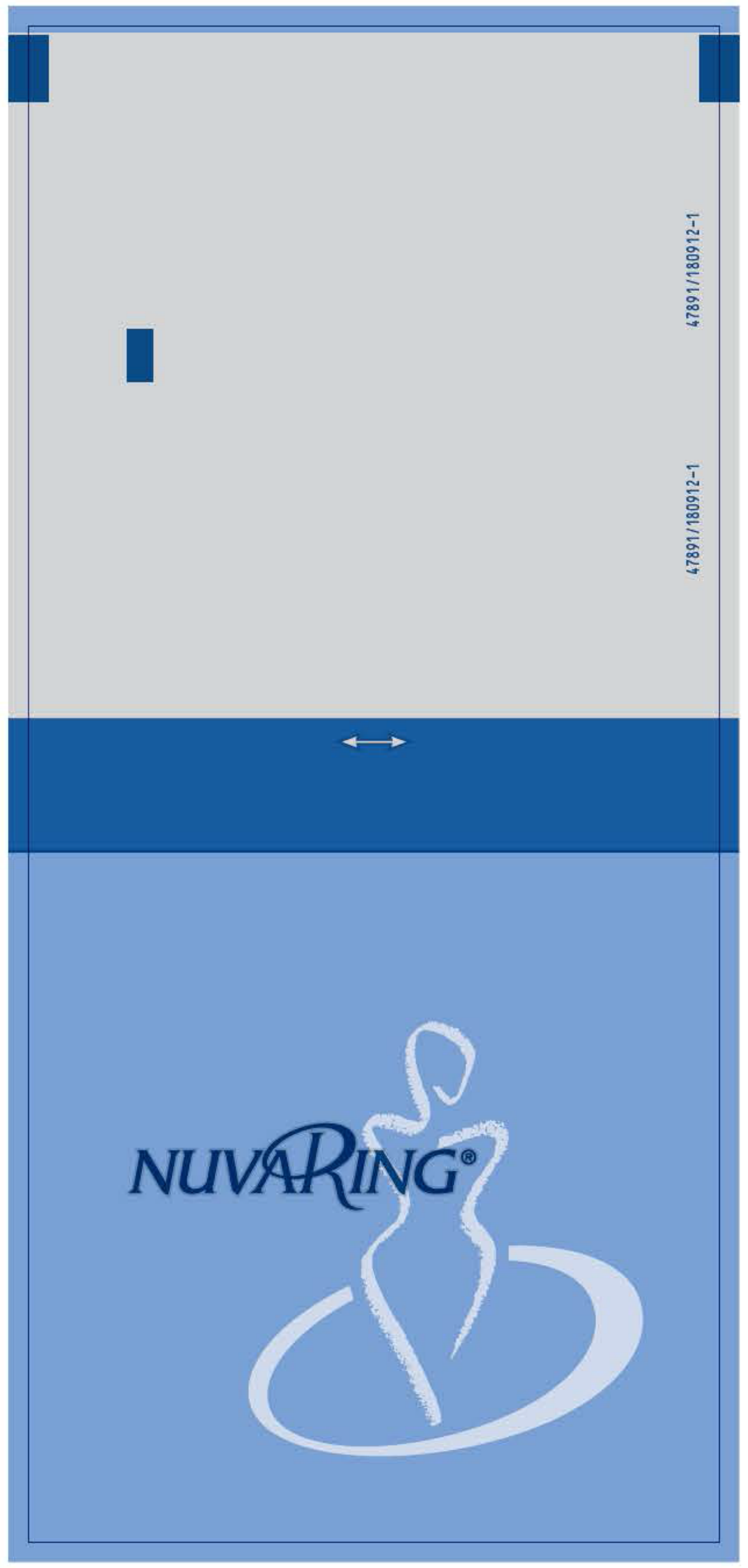
For Vaginal Use
Do not use if seal on pouch is broken.

Keep the foil pouch for proper disposal of the ring after use.

Manufactured for: Merck Sharp & Dohme Corp., a subsidiary of **MERCK & CO., INC.**, Whitehouse Station, NJ 08889, USA
Manufactured by: N.V. Organon, Oss, The Netherlands, a subsidiary of **Merck & Co., Inc.**, Whitehouse Station, NJ 08889, USA
Product of The Netherlands

(b) (4)

(b) (4)
[redacted]



(b) (4)
[redacted]

David Lewis

Digitally signed by David Lewis
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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

021187Orig1s034

CHEMISTRY REVIEW(S)

Office of Lifecycle Drug Products
Division of Post-Marketing Activities I
Review of Chemistry, Manufacturing, and Controls

1. **NDA Supplement Number: NDA 21187/ S-034**

2. **Submission(s) Being Reviewed**:

Submission	Type	Submission Date	CDER Stamp Date	Internal date	PDUFA Goal Date	Review Date
21187/ S34	CBE-30	9-Jun-2017	9-Jun-2017	24-Nov-2017	9-Dec-2017	17-Nov-2017

3. **Provides For:**
This supplement provides for a change to the sachet to add a (b) (4) label on the foil pouch sachet.

4. **Review** #: 1

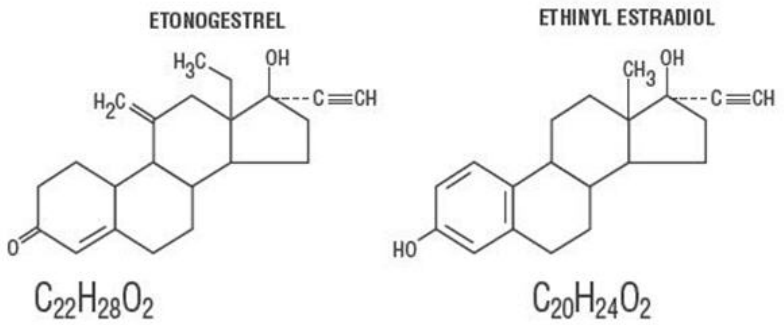
5. **Clinical Division**: Bone, Reproductive, and Urology Drugs

6. **Name and Address of Applicant**:
Organon USA Inc., a subsidiary of Merck & Co., Inc.
2000 Gallopping Hill Road
Kenilworth, NJ 07033

7. **Drug Product**:

Drug Name	Dosage Form	Strength	Route of Administration	Rx or OTC	Special Product
NUVARING- etonogestrel and ethinyl estradiol insert, extended release	Insert	0.120 mg eto/ 0.015 mg EE	vaginal	Rx.	N/A.

8. Name and Structure of Drug Substances:

Etonogestrel and Ethinyl Estradiol T	

9. Indication: prevention of pregnancy

10. Supporting/RelatedDocuments: N/A

11. Consults: DMEPA: Recommend Approval. Review by Walter Fava.

12. Executive Summary:

The NuvaRing is provided in a foil sachet. The current sachet has labeled information printed directly on the foil sachet. This supplement proposes to move the labeled information to the front of the sachet and to add the labeling information via [redacted] (b) (4). The adhesive used to affix the label will not introduce any leachables to the ring as the sachet is constructed from a foil matrix.

No change is being made in any of the approved text. The DMEPA reviewer has evaluated this change and recommends approval.

13. Conclusions & Recommendations:

Approval

14. Comments/Deficiencies to be Conveyed to Applicant: None

15. Primary Reviewer:

Jean Salemme, Ph.D., CMC reviewer, Branch 2, Division of Post-Marketing Activities I, Office of Lifecycle Drug Products, Office of Pharmaceutical Quality (OPQ)

16. Secondary Reviewer:

David Lewis, Ph.D., Acting Branch Chief, Branch 2, Division of Post-Marketing Activities I, Office of Lifecycle Drug Products, Office of Pharmaceutical Quality (OPQ)

CMC Assessment

Background

The NuvaRing is provided in a foil sachet. Labeling on the container is printed directly on the sachet.

Proposed Changes

This supplement proposes to add move the labeling text to the front portion of the sachet pouch, and affix the labeling text via (b) (4):

(b) (4)

From the DMEPA review, by Walter Fava:

3 OVERALL ASSESSMENT OF THE MATERIALS REVIEWED

Our review of the revised sachet label notes the proposed revised sachet label relocates information from the back of the sachet, to the front of the sachet in a 'peel back' format using (b) (4) labeling.

Our review of the proposed changes to the sachet label finds the expiration dating information, 'For the Dispenser' has not been included with the (b) (4) labeling, but does appear on the outer carton where the dispenser is instructed to apply an adhesive expiration sticker provided in the carton on each sachet, since the expiration date should not exceed either 4 months from the date of removing from the refrigerator for dispensing or the pre-printed expiration date, whichever comes first. We find this acceptable.

As part of our evaluation we considered whether the proposed changes to the sachet label would require updates to the Prescriber Information (PI) or carton labeling; however, our evaluation did not identify any necessary changes at this time. We find the sachet label revision does not pose increased risk of medication errors.

1. APPENDIX A. PRODUCT INFORMATION/PRESCRIBING INFORMATION

2. Table 2 presents relevant product information for NuvaRing that Merck submitted on June 9, 2017.

3. Table 2. Relevant Product Information for NuvaRing	
4. Initial Approval Date	5. October 3, 2001
6. Active Ingredient	7. Etonogestrel/ethinyl estradiol
8. Indication	9. Prevention of pregnancy
10. Route of Administration	11. Vaginal
12. Dosage Form	13. Vaginal Ring
14. Strength	15. 0.120 mg/0.015 mg per day
16. Dose and Frequency	17. One ring inserted vaginally for three weeks, then remove for one week
18. How Supplied/Container Closure	19. Carton containing three individually foil recloseable sachet pouches
20. Storage	21. Prior to dispensing to the patient, store refrigerated 2°C to 8°C (36°F to 46°F). After dispensing to the patient, NuvaRing can be stored up to 4 months at 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature. Avoid storing NuvaRing in direct sunlight or at temperatures about 30°C (86°F).

Reviewer Comment/Evaluation: **Acceptable.**
The DMEPA reviewer has found the proposed change to the labeling on the sachet to be acceptable. This supplement, therefore, is recommended for approval.

Jean Salemme

Digitally signed by Jean Salemme
Date: 11/29/2017 03:55:40PM
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David Lewis

Digitally signed by David Lewis
Date: 11/29/2017 04:01:16PM
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Comments: concur; recommend approval from the standpoint of CMC.

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

021187Orig1s034

OTHER REVIEW(S)

REGULATORY BUSINESS PROCESS MANAGER LABELING REVIEW

Office of Program and Regulatory Operations

Application: NDA 021187/S-037

Name of Drug: Nuvaring® (etonogestrel and ethinyl estradiol) Insert

Applicant: Organon USA Inc., a subsidiary of Merck & Co., Inc.

Material Reviewed:

Material	Submit Date	Receipt Date	Compared to
Carton and Container (Sachet)	June 9, 2017	June 9, 2017	March 2, 2004

Background and Summary Description:

The NuvaRing is provided in a foil sachet. The current sachet has labeled information printed directly on the foil sachet. This supplement proposes to move the labeled information to the front of the sachet and to add the labeling information via (b) (4). The adhesive used to affix the label will not introduce any leachables to the ring as the sachet is constructed from a foil matrix.

No change is being made in any of the approved text.

Both CMC and DMEPA reviewers have evaluated this change and recommends approval.

Review

The following are the assessments for each change identified:

Carton and Container Label:

No changes noted, as printed material from previously approved sachet is no printed via (b) (4)

Recommendations

The changes to the container label are acceptable if the noted changes are made prior to the next label printing.

{See appended electronic signature page}

Rey Cantave Date
Regulatory Business Process Manager
Office of Programs and Regulatory Operations
Office of Pharmaceutical Quality

{See appended electronic signature page}

Laya Keyvan Date
Quality Assessment Lead (Acting)
Office of Programs and Regulatory Operations
Office of Pharmaceutical Quality

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Rey Cantave

Digitally signed by Rey Cantave
Date: 12/04/2017 11:49:27AM
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Laya Keyvan

Digitally signed by Laya Keyvan
Date: 12/05/2017 02:48:34PM
GUID: 530f6b9a0000831d04a85a3c1d7c9538

LABEL, LABELING AND PACKAGING REVIEW

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)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	November 6, 2017
Requesting Office or Division:	Office of Pharmaceutical Quality (OPQ)
Application Type and Number:	NDA 021187/S-034
Product Name and Strength:	NuvaRing (etonogestrel and ethinyl estradiol)
Product Type:	Combination Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Merck
Submission Date:	June 9, 2017
OSE RCM #:	2017-2188
DMEPA Safety Evaluator:	Walter Fava RPh., MSEd.
DMEPA Team Leader:	Lolita White, PharmD.

1 REASON FOR REVIEW

The Office of Pharmaceutical Quality (OPQ), requested that we review the revised sachet label for NuvaRing to determine if it is acceptable from a medication error perspective. Merck submitted a CBE-30 Labeling supplement to provide for revisions to the sachet label to include relocating information from the back side of the sachet, and presenting the information on the front of the sachet using a 'peel-back' label.

2 MATERIALS REVIEWED

We considered the materials listed in Table 1 for this review. The Appendices provide the methods and results for each material reviewed.

Table 1. Materials Considered for this Label and Labeling Review

Material Reviewed	Appendix Section (for Methods and Results)
Product Information/Prescribing Information	A
Previous DMEPA Reviews	B
Human Factors Study	C (N/A)
ISMP Newsletters	D
FDA Adverse Event Reporting System (FAERS)*	E (N/A)
Other	F (N/A)
Labels and Labeling	G

N/A=not applicable for this review
*We do not typically search FAERS for our label and labeling reviews unless we are aware of medication errors through our routine postmarket safety surveillance

3 OVERALL ASSESSMENT OF THE MATERIALS REVIEWED

Our review of the revised sachet label notes the proposed revised sachet label relocates information from the back of the sachet, to the front of the sachet in a 'peel back' format using (b) (4) labeling.

Our review of the proposed changes to the sachet label finds the expiration dating information, 'For the Dispenser' has not been included with the (b) (4) labeling, but does appear on the outer carton where the dispenser is instructed to apply an adhesive expiration sticker provided in the carton on each sachet, since the expiration date should not exceed either 4 months from the date of removing from the refrigerator for dispensing or the pre-printed expiration date, whichever comes first. We find this acceptable.

As part of our evaluation we considered whether the proposed changes to the sachet label would require updates to the Prescriber Information (PI) or carton labeling; however, our evaluation did not identify any necessary changes at this time. We find the sachet label revision does not pose increased risk of medication errors.

4 CONCLUSION & RECOMMENDATIONS

We find the proposed revised [redacted] (b) (4) (e.g. peel back) sachet label for NuvaRing acceptable from a medication error perspective, and we have no additional recommendations at this time.

4.1 RECOMMENDATIONS FOR MERCK

We find the proposed revised [redacted] (b) (4) (e.g. peel back) sachet label for NuvaRing acceptable from a medication error perspective and we have no additional recommendations at this time.

APPENDICES: METHODS & RESULTS FOR EACH MATERIALS REVIEWED

APPENDIX A. PRODUCT INFORMATION/PRESCRIBING INFORMATION

Table 2 presents relevant product information for NuvaRing that Merck submitted on June 9, 2017.

Table 2. Relevant Product Information for NuvaRing	
Initial Approval Date	October 3, 2001
Active Ingredient	Etonogestrel/ethinyl estradiol
Indication	Prevention of pregnancy
Route of Administration	Vaginal
Dosage Form	Vaginal Ring
Strength	0.120 mg/0.015 mg per day
Dose and Frequency	One ring inserted vaginally for three weeks, then remove for one week
How Supplied/Container Closure	Carton containing three individually foil recloseable sachet pouches
Storage	Prior to dispensing to the patient, store refrigerated 2°C to 8°C (36°F to 46°F). After dispensing to the patient, NuvaRing can be stored up to 4 months at 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature. Avoid storing NuvaRing in direct sunlight or at temperatures about 30°C (86°F).

APPENDIX B. PREVIOUS DMEPA REVIEWS

On November 3, 2017, we searched DMEPA's previous reviews using the terms, NuvaRing. Our search identified three previous reviews[a, b, c], and we confirmed our previous recommendation were implemented.

(b) (4)

[b] Fava, W. Label, Labeling, and Human Factors Review for NuvaRing (NDA 21187/S-027). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2016 Sept 02. RCM No.: 2016-1460.

[c] Fava, W. Review of Revised Label and Labeling for NuvaRing (NDA 21187/S-027). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2016 Sept 29 . RCM No.: 2016-1460-1.

APPENDIX C. HUMAN FACTORS STUDY

N/A

APPENDIX D. ISMP NEWSLETTERS

D.1 Methods

On November 3, 2017, we searched the Institute for Safe Medication Practices (ISMP) newsletters using the criteria below, and then individually reviewed each newsletter. We limited our analysis to newsletters that described medication errors or actions possibly associated with the label and labeling.

ISMP Newsletters Search Strategy	
ISMP Newsletter(s)	Acute Care, Community, and Nursing
Search Strategy and Terms	Match Exact Word or Phrase: NuvaRing

D.2 Results

No reports identified from the search.

APPENDIX F. N/A

APPENDIX G. LABELS AND LABELING

G.1 List of Labels and Labeling Reviewed

Using the principles of human factors and Failure Mode and Effects Analysis,[d] along with postmarket medication error data, we reviewed the following NuvaRing labels and labeling submitted by Merck on June 6, 2017 and October 27, 2017.

- Container label
- Carton labeling

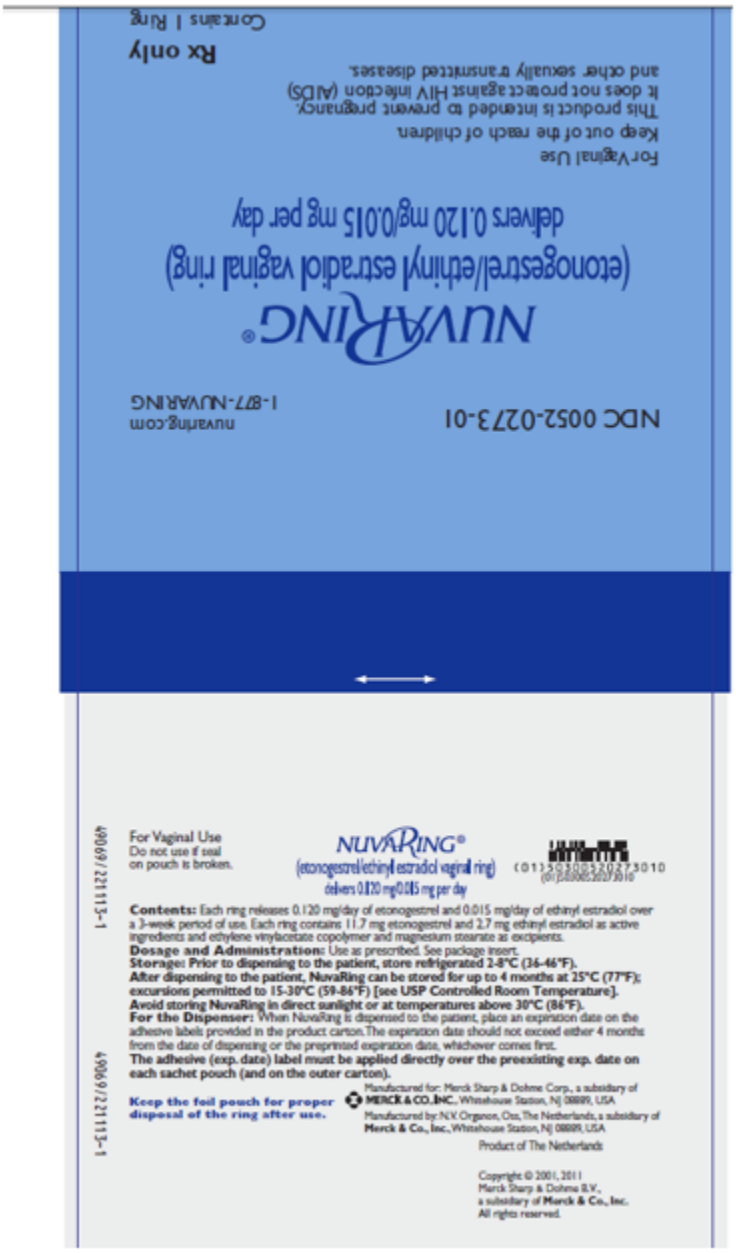
G.2 Label and Labeling Images

Proposed (b) (4) label presentation for sachet

[d] Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

2 Page(s) of Draft Labeling has been Withheld in Full as b4 (CCI/TS) immediately following this page

Currently marketed sachet label (from 2016 Annual Report)



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/s/

WALTER L FAVA
11/06/2017

LOLITA G WHITE
11/06/2017

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

021187Orig1s034

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

REQUEST FOR CONSULTATION

TO *(Division/Office)*:	FROM: REYNOLDS CANTAVE, PHARMD, OPQ/OPRO
Mail: OSE	

DATE	IND NO.	NDA NO.	TYPE OF DOCUMENT	DATE OF DOCUMENT
10.24.2017		NDA 021187/S-034	eCTD	06.09.2017

NAME OF DRUG	PRIORITY CONSIDERATION	CLASSIFICATION OF DRUG	DESIRED COMPLETION DATE
NuvaRing® (etonogestrel and ethinyl estradiol) Vaginal Ring, 0.120 mg/0.015 mg	URGENT	CONTRACEPTIVE	11.13.2017

NAME OF FIRM:

REASON FOR REQUEST

I. GENERAL

- ☐ NEW PROTOCOL
- ☐ PROGRESS REPORT
- ☐ NEW CORRESPONDENCE
- ☐ DRUG ADVERTISING
- ☐ ADVERSE REACTION REPORT
- ☐ MANUFACTURING CHANGE/ADDITION
- ☐ MEETING PLANNED BY
- ☐ PRE--NDA MEETING
- ☐ END OF PHASE II MEETING
- ☐ RESUBMISSION
- ☐ SAFETY/EFFICACY
- ☐ CONTROL SUPPLEMENT
- ☐ RESPONSE TO DEFICIENCY LETTER
- ☐ FINAL PRINTED LABELING
- ☑ LABELING REVISION
- ☐ ORIGINAL NEW CORRESPONDENCE
- ☐ FORMULATIVE REVIEW
- ☐ MEDICATION ERRORS
- ☐ OTHER *(SPECIFY BELOW)*:

II. BIOMETRICS

STATISTICAL EVALUATION BRANCH	STATISTICAL APPLICATION BRANCH
☐ TYPE A OR B NDA REVIEW ☐ END OF PHASE II MEETING ☐ CONTROLLED STUDIES ☐ PROTOCOL REVIEW ☐ OTHER (SPECIFY BELOW):	☐ CHEMISTRY REVIEW ☐ PHARMACOLOGY ☐ BIOPHARMACEUTICS ☐ OTHER (SPECIFY BELOW):

III. BIOPHARMACEUTICS

- ☐ DISSOLUTION
- ☐ BIOAVAILABILTY STUDIES
- ☐ PHASE IV STUDIES
- ☐ DEFICIENCY LETTER RESPONSE
- ☐ PROTOCOL-BIOPHARMACEUTICS
- ☐ IN-VIVO WAIVER REQUEST

IV. DRUG EXPERIENCE

- ☐ PHASE IV SURVEILLANCE/EPIDEMIOLOGY PROTOCOL
- ☐ DRUG USE e.g. POPULATION EXPOSURE, ASSOCIATED DIAGNOSES
- ☐ CASE REPORTS OF SPECIFIC REACTIONS (List below)
- ☐ COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP
- ☐ REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY
- ☐ SUMMARY OF ADVERSE EXPERIENCE
- ☐ POISON RISK ANALYSIS

V. SCIENTIFIC INVESTIGATIONS

- ☐ CLINICAL
- ☐ PRECLINICAL

COMMENTS/SPECIAL INSTRUCTIONS:

Consult DMEPA for their opinion about changes to the sachet package.

SIGNATURE OF REQUESTER REYNOLDS B. CANTAVE, PHARMD	METHOD OF DELIVERY (Check all that apply) ☑ EMAIL ☑ DARRTS ☐ HAND
SIGNATURE OF RECEIVER	SIGNATURE OF DELIVERER

APPEARS THIS WAY ON ORIGINAL

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

/s/

REYNOLDS B CANTAVE
10/24/2017

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021187/S-034

CBE SUPPLEMENT – ACKNOWLEDGEMENT

Organon USA Inc., a subsidiary of Merck & Co., Inc.
Attention: Shawn Moylan
Regulatory Liaison, Global Regulatory Affairs
351 North Sumneytown Pike
P.O.Box 1000, UG2C-50
North Wales, PA 19454

Dear Mr. Moylan:

We have received your Supplemental New Drug Application (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA or the Act) for the following:

NDA NUMBER: 021187

SUPPLEMENT NUMBER: 034

PRODUCT NAME: NuvaRing® (etonogestrel and ethinyl estradiol) Vaginal Ring, 0.120 mg/0.015 mg

DATE OF SUBMISSION: June 9, 2017

DATE OF RECEIPT: June 9, 2017

This supplemental application, submitted as a "Changes Being Effected in 30 days" supplement, proposes the following changes: A change to the Nuvaring sachet package, to use a (b) (4) or stick-on label, rather than a printed-on back label, for labeling the Nuvaring sachet package.

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on August 8, 2017 in accordance with 21 CFR 314.101(a).

If the application is filed, the goal date will be December 9, 2017.

CONTENT OF LABELING

If you have not already done so, promptly submit the content of labeling [21 CFR 314.50 (l)] in structured product labeling (SPL) format to the FDA automated drug registration and listing system (eLIST) as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that includes the proposed labeling changes, with the addition of any labeling changes in pending previously submitted CBE supplements. Failure to submit the content of labeling in SPL format may result in a refusal-to-file action.

SUBMISSION REQUIREMENTS

Cite the application number listed above at the top of the first page of all submissions to this application. Send all submissions, electronic or paper, including those sent by overnight mail or courier, to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Bone, Reproductive, and Urologic Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

All regulatory documents submitted in paper should be three-hole punched on the left side of the page and bound. The left margin should be at least three-fourths of an inch to assure text is not obscured in the fastened area. Standard paper size (8-1/2 by 11 inches) should be used; however, it may occasionally be necessary to use individual pages larger than standard paper size. Non-standard, large pages should be folded and mounted to allow the page to be opened for review without disassembling the jacket and refolded without damage when the volume is shelved. Shipping unbound documents may result in the loss of portions of the submission or an unnecessary delay in processing which could have an adverse impact on the review of the submission. For additional information, see http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/ucm073080.htm.

If you have questions, contact Rey Cantave, Regulatory Business Process Manager, at (240) 402-4035.

Sincerely,

{See appended electronic signature page}

Reynolds B. Cantave, B.S., PharmD
Regulatory Business Process Manager
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Rey
Cantave

Digitally signed by Rey Cantave
Date: 7/06/2017 11:16:05AM
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