August 2, 2021

Church & Dwight Co., Inc.
Supreet Sahota-Bhatti
Sr. Manager, Regulatory Affairs
500 Charles Ewing Boulevard
Ewing, NJ 08628

Re: K203818
Trade/Device Name: Replens Long-Lasting Vaginal Moisturizer
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: June 11, 2021

Dear Supreet Sahota-Bhatti:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated June 11, 2021. Specifically, FDA is updating this SE Letter (typo in the device specifications in the 510(k) summary) as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Monica Garcia, OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices, (240) 402-2791, monica.garcia@fda.hhs.gov.

Sincerely,

Monica D. Garcia -S

Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

June 11, 2021

Church & Dwight Co., Inc.
Supreet Sahota-Bhatti
Senior Manager, Regulatory Affairs
500 Charles Ewing Boulevard
Ewing, NJ 08628

Re: K203818
Trade/Device Name: Replens Long-Lasting Vaginal Moisturizer
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: May 11, 2021
Received: May 12, 2021

Dear Supreet Sahota-Bhatti:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Monica D. Garcia -S

Monica D. Garcia, Ph.D.
Assistant Director
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203818

Device Name
Replens Long-Lasting Vaginal Moisturizer

Indications for Use *(Describe)*
Replens Long-Lasting Vaginal Moisturizer is a personal lubricant for vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and to supplement the body's natural lubrication. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary – K203818

1. Submitter Information

Applicant: Church & Dwight Co., Inc.
Address: 500 Charles Ewing Boulevard
Ewing, NJ 08628

2. Correspondent Information

Contact: Supreet Sahota-Bhatti
Sr. Manager, Regulatory Affairs
Address: 469 North Harrison Street
Princeton, NJ 08543
Phone: (609) 806-7893
Email: supreet.sahota-bhatti@churchdwight.com

3. Date prepared: June 9, 2021

4. Device Information

Device Name:	Replens Long-Lasting Vaginal Moisturizer
Common Name:	Personal Lubricant
Regulation Number:	21 CFR 884.5300
Regulation Name:	Condom
Product Code:	NUC (lubricant, personal)
Regulatory Class:	Class II

5. Predicate Device Information

Device Name:	Replens Long-Lasting Vaginal Moisturizer
510(k) Number:	K101098
Manufacturer:	Church & Dwight Co., Inc.
Product Code:	NUC (lubricant, personal)

The predicate device has not been subject to a design-related recall.

6. Device Description

Replens Long-Lasting Vaginal Moisturizer is a personal lubricant that is non-sterile, water-based, and provides lubrication during intimate sexual activity. It is a smooth, white, homogenous vaginal gel packaged with a reusable applicator. This device is compatible with natural rubber latex and polyisoprene condoms and is not compatible with polyurethane condoms. Its formulation consists of Water, Glycerin, Mineral Oil, Polycarbophil, Carbomer Homopolymer Type B, Hydrogenated Palm Oil Glyceride, Sorbic Acid, Benzyl Alcohol, Ethylhexylglycerin, tocopherol, and Sodium Hydroxide. Replens Long-Lasting Vaginal Moisturizer is packaged in a 35g aluminum tube (14 applications), with a reusable two-piece, blue translucent, polyethylene applicator designed to dispense 2.5g of lubricant.

The reusable applicator is packaged with an over-wrap in clear, biaxially oriented polypropylene film. The subject device and applicator are packaged together in a carton with a consumer leaflet.

Table 1: Device Specifications for Replens Long Lasting Vaginal Moisturizer

Property	Specification
Appearance	White to off-white smooth homogenous gel
Odor	Odorless
Viscosity	30,000 – 130,000 cPs
pH	2.5 – 3.5
Osmolality	1200 – 2000 mOsm/Kg
Total Aerobic Microbial Count (TAMC per USP <61> and <1111>)	<100 cfu/g
Total Yeast and Mold Count (TYMC per USP <61> and <1111>)	<10 cfu/g
Absence of Pathogens per USP <62>	**Specification**
Pseudomonas aeruginosa	Absent/g
Staphylococcus aureus	Absent/g
Candida albicans	Absent/g
Escherichia coli	Absent/g
Salmonella sp.	Absent/g
Antimicrobial Effectiveness Testing per USP <51>	**Specification**
Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus	Not less than 2.0 log reduction from the initial count at 14 days, and no increase from the 14 day count at 28 days.
Candida albicans, Aspergillus brasiliensis	No increase from initial calculated count at 14 and 28 days

7. Indications for Use

Replens Long-Lasting Vaginal Moisturizer is a personal lubricant for vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and to supplement the body's natural lubrication. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

8. Comparison of Intended Use and Technological Characteristics with the Predicate Device

The table below compares the intended use and technological characteristics of the subject and predicate device.

Table 2: Comparator Table for Subject and Predicate Devices

	Replens Long-Lasting Vaginal Moisturizer K203818 Subject Device	**Replens Long-Lasting Vaginal Moisturizer K101098 Predicate Device**	**Comparison**
Device Classification Name	Lubricant, Personal	Lubricant, Personal	**Same**
Product Code	NUC	NUC	**Same**
Indications for Use	Replens Long-Lasting Vaginal Moisturizer is a personal lubricant for vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and to	Replens Long-Lasting Vaginal Moisturizer is a personal lubricant for vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort	**Same:** The indications have a minor difference in wording; however, the intended uses of both devices are the same

	supplement the body's natural lubrication. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.	of intimate sexual activity and to supplement the body's natural lubrication. This product is compatible with natural rubber latex and synthetic (polyurethane and polyisoprene) condoms.	
Form	White to off-white smooth homogenous gel	White to off-white smooth homogenous gel	**Same**
Water soluble	Yes	Yes	**Same**
Water-Based	Yes	Yes	**Same**
Primary ingredients	Water, Glycerin, Mineral Oil, Polycarbophil, Carbomer Homopolymer Type B, Hydrogenated Palm Oil Glyceride, Sorbic Acid, Benzyl Alcohol, Ethylhexylglycerin, tocopherol, and Sodium Hydroxide	Water, Glycerin, Mineral Oil, Polycarbophil, Carbomer Homopolymer Type B, Hydrogenated Palm Oil Glyceride, Sorbic Acid, Methylparaben, Sodium Hydroxide	**Different:** The formulation of the subject device is slightly different than the predicate device. Differences in personal lubricant formulation do not raise different questions of safety and effectiveness (S&E).
Over the counter use	Yes	Yes	**Same**
Sterile	No	No	**Same**
pH	2.5 – 3.5	2.5 – 3.5	**Same**
Osmolality	1200 – 2000 mOsm/Kg	N/A	**Different:** The osmolality of the predicate device is not currently tested for release. Differences in personal lubricant osmolality do not raise different questions of S&E.
Condom Compatibility	Compatible with natural rubber latex and polyisoprene	Compatible with natural rubber latex, polyisoprene, and polyurethane	**Different:** The subject device is not compatible with polyurethane condoms. Differences in personal lubricant compatibility do not raise different questions of S&E.
Biocompatibility Tested	Yes	Yes	**Same**
Antimicrobial Effectiveness Tested	Yes	Yes	**Same**
Microbial Limits	Total mold/yeast count < 10 cfu/g Total aerobic microbial count < 100 cfu/g Absence of pathogenic organisms (*Candida albicans, Pseudomonas aeruginosa, Staphylococcus aureus, Escherichia coli,*	Total mold/yeast count <10 cfu/g Total aerobic microbial count <100 cfu/g Absence of pathogenic organisms (*Candida albicans, Pseudomonas aeruginosa, Staphylococcus*	**Same**

	Salmonella)	*aureus)*	
Packaging	35g Aluminum Tube (14 applications) Reusable, two-piece, blue translucent, plastic (polyethylene) applicator.	35g Aluminum Tube (14 applications) Reusable, two-piece, blue translucent, plastic (polyethylene) applicator.	**Same**
Shelf life	22 months	36 months	**Different:** The subject device has a shorter shelf-life than the predicate device. Differences in shelf-life do not raise different questions of S&E.

The subject and predicate devices have different technological characteristics including differences in formulation, shelf life, and device specifications, as shown in the table above. The differences in technological characteristics between the subject and predicate device do not raise different questions of safety and effectiveness.

9. Summary of Non-Clinical Performance Testing

Biocompatibility

Biocompatibility studies, including cytotoxicity, sensitization, vaginal irritation, and acute systemic toxicity testing were performed in accordance with the 2020 FDA guidance document *Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process"* and ISO 10993- 1:2009 as follows:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2010)
- Vaginal Irritation (ISO 10993-10:2010)
- Acute Systemic Toxicity (ISO 10993-11:2017)

The results of this testing demonstrated that Replens Long-Lasting Moisturizer is non-cytotoxic, non-irritating, non-sensitizing, and non-systemically toxic.

Shelf-Life

The subject device has a shelf-life of 22-months. Results from testing demonstrated that the device can maintain its specifications (as shown in Table 1) over the duration of its shelf-life.

Condom Compatibility

Replens Long-Lasting Vaginal Moisturizer was tested in accordance with ASTM D7661-10 "Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms" and was determined to be compatible with natural rubber latex and polyisoprene condoms. It was determined not to be compatible with polyurethane condoms.

10. Conclusion

The results of the performance testing described above demonstrate that Replens Long-Lasting Vaginal Moisturizer is as safe and effective as the predicate device and supports a determination of substantial equivalence.