# 510(k) Summary

AUG 17 2010

**Submitter:**
Lil' Drug Store Products, Inc.
1201 Continental Place NE
Cedar Rapids, IA 52402

**Contact Person:**
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Director of Regulatory
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**Date:**
August 13, 2010

**Proprietary Name:**
Replens Long-Lasting Vaginal Moisturizer (in pre-filled applicators)

**Common name:**
Personal Lubricant

**Classification name:**
21 C.F.R. 884.5300 Lubricant, Patient, Vaginal, Latex Compatible
Product Code: NUC
Class: 2
Review Panel: Obstetrics/Gynecology

**Predicate Device:**

Device Name: CVS Personal Lubricant & Moisturizer
510(k) Number: K062682
Product Code: NUC, MMS

**Intended Use:**

Replens is a personal lubricant for vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible

with natural rubber latex condoms and synthetic (polyurethane and polyisoprene) condoms.

## Description of Device

Replens Vaginal Moisturizer is a non-sterile, water-based, white to off-white, non-irritating, non-greasy, non-staining vaginal gel delivered in single-use, pre-filled applicators as a long-lasting moisturizer for vaginal dryness. The use of prefilled applicators provides less mess in application. Replens Vaginal Moisturizer is intended for ongoing use, not exclusively for use during intimate sexual activity.

Replens Vaginal Moisturizer contains ingredients commonly used in other products for vaginal use sold as medical devices and cosmetics. All ingredients are either NF, USP, or are considered "generally recognized as safe for their intended use". The quantitative formulation is proprietary and considered confidential commercial information.

## Technological Characteristics of the Device

Replens Vaginal Moisturizer is substantially equivalent to the identified previously cleared vaginal lubricant predicate with respect to its design and materials, principle of operation, function, formulation, and intended use. It is also substantially equivalent to other water-based vaginal lubricants and personal lubricants being commercially marketed in the U.S.

## Summary of Performance Data

**Biocompatibility Testing:** The following biocompatibility testing has been performed on Replens Long-Lasting Vaginal Moisturizer:

- Cytotoxicity
- Acute Vaginal Irritation
- Subacute Vaginal Irritation
- Subacute Vaginal Irritation with Histological Examination
- Acute Systemic Toxicity
- Hypersensitivity
- Acute Oral toxicity
- Acute Dermal Toxicity
- Dermal Irritation
- Eye Irritation.

| Citation | No. Patients Enrolled (Replens) | Study Design* | Dosage Regimen | Duration |
|---|---|---|---|---|
| Whitehead | 32 | D-B, X-over | 2.5 g, 3 x weekly plus option of additional application prior to intercourse. | 8 weeks |
| Nachtigall | 15 | Open, parallel | 2.5 g, 3 x weekly | 3 months |
| Gelfand and Wendman | 25 | Open | 2.5 g, 3 x weekly, plus option of additional application prior to intercourse. | 3 months |

* D-B = double-blind; X-over = cross-over design

The parameters employed in the studies included the influence of Replens on vaginal pH and the vaginal mucosa, the relief of the patient's symptoms, the vaginal dryness index, determination of vaginal pH at varying time intervals after single or multiple applications of the gel, PAP smears and the completion of diary cards by the patient. All of the studies concluded that Replens was safe and well-tolerated.

**Stability Data:** Stability data confirms a shelf life of one (1) year for Replens Long-Lasting Vaginal Moisturizer.
**Preservative Effectiveness:** Replens Long-Lasting Vaginal Moisturizer has successfully passed the requirements of the USP <51> Antimicrobial Effectiveness Test.
**Dosing Consistency Study:** Dosing consistency studies confirm the pre-filled applicator delivers the required amount of gel.
**Condom Compatibility Testing:** Condom compatibility testing confirms that Replens Long-Lasting Vaginal Moisturizer does not materially affect the strength or integrity of natural rubber latex or synthetic condoms (polyurethane and polyisoprene).

## Conclusion

Based on the information presented in the 510(k) notice, it is concluded that Replens Long-Lasting Vaginal Moisturizer (in pre-filled applicators) for OTC use is safe and effective for its proposed indications and is substantially equivalent in intended use, formulation, safety, and technological characteristics to the identified predicate device and other similar water-based personal lubricants.

**Clinical Studies:** The following clinical studies have been performed on Replens Long-Lasting Vaginal Moisturizer:

- Bachmann GA, Notelovitz M, Gonzalez SJ, Thompson C, Morecraft BA. (1991) Vaginal Dryness in Menopausal Women: Clinical Characteristics and Nonhormonal Treatment. Clinical Practice in Sexuality, 7(9): 1-8.
- Bachmann GA, Notelovitz M, Kelly SJ, Owens A, Thompson C. (1992) Long Term Nonhormonal Treatment of Vaginal Dryness. Clinical Practice in Sexuality, 8(8/9): 3-8.
- Zinny MA, Lee S. (1991) Double-Blind Study of the Comparative Effects of Two Gels on Vaginal pH in Postmenopausal Women. Today's Therapeutic Trends, 8(4): 65-72.
- Young R, Goldzieher J, Kaufman R. (1991) A Study of the Effects of Col-1003 In Postmenopausal Women. Unpublished.
- Nakamura R. (1991) Evaluation of Col-1003 in the treatment of vaginal dryness in postmenopausal women. Unpublished.
- Whitehead M. (1991) A Randomised Double Blind Evaluation of Col-1003, a bioadhesive polymer system vaginal moisturizing gel and, KY Brand Lubricating Jelly in the treatment of vaginal dryness in postmenopausal women receiving concomitant oral hormone replacement therapy. Unpublished
- Nachtigall LE. (1994) Comparative study: Replens versus local estrogen in menopausal women. Fertility and Sterility, 61(1): 178-180.
- Gelfand MM, Wendman E. (1994) Treating Vaginal Dryness in Breast Cancer Patients: Results of Applying a Polycarbophil Moisturizing Gel. J. Women's Health, 3(6): 427-433.

The format of the studies listed above is summarized in the table below:

| Citation | No. Patients Enrolled (Replens) | Study Design* | Dosage Regimen | Duration |
|---|---|---|---|---|
| Bachmann et al | 89 | D-B, X-over | 2.5 g per day | 5 days |
| Bachmann et al | 54 | Open | 2.5 g, 3 x weekly | 12 months |
| Zinny and Lee | 26 | D-B, parallel | 2.5 g alternate nights | 4 weeks |
| Young et al | 30 | Open | 2.5 g, 3 x weekly, plus option of additional application prior to intercourse. | 12 months |
| Nakamura | 10 | Open, X-over between treatment durations | 2.5 g daily | 1-5 days |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Lil Drug Store Products, Inc.
c/o Mr. Mark A. Job
Responsible Third Party
Regulatory Technology Services, Inc
1394 25th Street, NW
BUFFALO MN 55313

AUG 17 2010

Re: K101241
Trade/Device Name: Replens Long-Lasting Vaginal Moisturizer Gel (in pre-filled applicators)
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: July 30, 2010
Received: August 2, 2010

Dear Mr. Job:

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. 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.

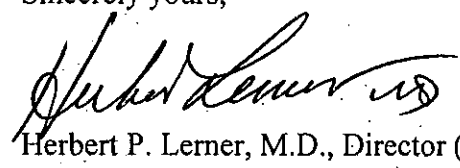
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# STATEMENT OF INDICATIONS FOR USE

**510(k) Number:** K101241

**Device Name:** Replens Long-Lasting Vaginal Moisturizer (in prefilled applicators)

**Indications for Use:** Replens is a personal lubricant for vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex condoms and synthetic (polyurethane and polyisoprene) condoms.

Prescription Use _____ OR Over-the-Counter Use __X__
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K101241