K060145

APR 14 2006

ALBERTO CULVER

ALBERTO-CULVER COMPANY

RESEARCH AND DEVELOPMENT

SECTION V
510(k) SUMMARY

Submitter Alberto-Culver USA, Inc.
2525 Armitage Avenue
Melrose Park, IL 60106

Contact Person Richard E. Main
Senior Manager, Global Regulatory Affairs
Phone: (708) 450-3153 Fax: (708) 450-2551

Date Submitted January 20, 2006

Proprietary Name(s) FDS Intimate Lubricant,
FDS Intimate Warming Lubricant

Predicate Name(s): K-Y® Brand ULTRA*gel*™/MC Personal Lubricant manufactured by Personal Products Company Division of McNeil-PPC, Inc. (K020827)

Astroglide® Brand Personal Lubricant manufactured by Biofilm, Inc. (K935299)

K-Y® Brand Warming Liquid™ Personal Lubricant manufactured by Personal Products Company Division of McNeil-PPC, Inc. (K021492)

Astroglide® Warming Liquid manufactured by Biofilm, Inc. (K041432)

Common Name Lubricant, Patient, Vaginal, Latex Compatible

Classification Name 21 CFR 884.5300 Product Code NUC

Description of Device
The FDS Intimate Lubricant formula is non-sticky, non-staining, non-greasy and is compatible with latex condoms in laboratory testing. It is a water soluble, clear, high viscosity, gel-like liquid. Because it is water soluble, FDS Intimate Lubricant is easily rinsed off with water. The product can reduce friction during sexual intercourse thereby

enhancing sexual intimacy. It is compatible with latex condoms as demonstrated in Condom Compatibility Testing conducted according to the standards as defined by ASTM D 3492. FDS Intimate Warming Lubricant is neither a contraceptive nor a spermicide. The product is packaged in a convenient to use pump bottle.

The FDS Intimate Warming Lubricant is a non-sticky, non-staining, non-greasy gel for use as a personal lubricant. This product imparts a gentle warming sensation when applied to the skin. The product can reduce friction during sexual intercourse thereby enhancing sexual intimacy. It is compatible with latex condoms as demonstrated in Condom Compatibility Testing conducted according to the standards as defined by ASTM D 3492. FDS Intimate Warming Lubricant is neither a contraceptive nor spermicide.

It contains only United States Pharmacopeia (USP) or National Formulary (NF) ingredients, all of which are listed as "generally recognized as safe".

Intended Use

FDS Intimate Lubricant and FDS Warming Lubricant are intended as personal lubricant to be used with or without a condom.

The lubricous nature of this product helps to supplement the body's own natural lubricating fluids, thereby relieving friction to help enhance the ease and comfort of intimate sexual activity. This lubricant may be safely applied to vaginal, anal or penile tissues for purpose of lubrication, and moisturization and is compatible with latex condoms. FDS Intimate Warming Lubricant has the additional benefit of imparting a warming sensation when applied to the genital area.

Regulatory Status

Per 21 CFR, 880.6375, Patient lubricant is defined as a Class I medical device intended for medical purposes that is used to lubricate a body orifice to facilitate entry of a diagnostic or therapeutic device. Patient lubricants are not exempt from 510(k) clearance. Additionally when used as an accessory to a condom, (a Class II medical device) the lubricant is considered, by FDA, as a Class II Medical Device requiring 510(k) clearance.

Technological Characteristics

The FDS Intimate Lubricant and FDS Warming Lubricant formulas are proprietary. The products have no exceptional technological characteristics and consist mainly of safe water-soluble GRAS status ingredients similar to K-Y® Brand ULTRA*gel*™/MC Personal Lubricant manufactured by Personal Products Company, Division of McNeil-PPC, Inc., Skillman, NJ, Astroglide® Brand Personal Lubricant manufactured by Biofilm, Inc., K-Y® Brand Warming Liquid™ Personal Lubricant manufactured by Personal Products Company, Division of McNeil-PPC, Inc., Skillman, NJ, and Astroglide® Warming Liquid manufactured by Biofilm, Inc

Substantial Equivalence
FDS Intimate Lubricant and FDS Warming Lubricant have been shown, in laboratory tests, to be substantially equivalent to the currently marketed to K-Y® Brand ULTRA*gel*™/MC Personal Lubricant manufactured by Personal Products Company, Division of McNeil-PPC, Inc., Skillman, NJ, Astroglide® Brand Personal Lubricant manufactured by Biofilm, Inc., K-Y® Brand Warming Liquid™ Personal Lubricant manufactured by Personal Products Company, Division of McNeil-PPC, Inc., Skillman, NJ, and Astroglide® Warming Liquid manufactured by Biofilm, Inc.

Both devices have the same intended use with a minor variation in formula ingredients. The gentle warming technology is the special feature of the FDS Warming Lubricant product.

Summary of Performance Data:

Preclinical Testing of Formulation:
Biocompatibility safety studies according to International Standard ISO 10993 and General Program Memorandum G95-1 on FDS Intimate Lubricant and FDS Warming Lubricant were conducted by an outside laboratory, in compliance with Good Laboratory Practices (GLPs). Results from these studies demonstrated that FDS Intimate Lubricant and FDS Warming Lubricant were not considered to be contact sensitizing agents, nor were they associated with systemic toxicity.

Compatibility Testing of FDS Personal Lubricant with Latex Condoms
Using ASTM Method D3492: lubricated and Non-lubricated latex condoms are exposed to the test substance for prescribed time periods and conditions. After exposure, condoms undergo strength and leakage tests to determine the effect of exposure on the physical integrity using water treated control condoms as comparators.
A predicate substance, KY Jelly, is also tested for comparative purposes.

Acute Vaginal Mucosal Irritation Assay using the SkinEthic In-Vitro Reconstituted Human Vaginal Epithelial Tissue Model The test products were evaluated for their capacity to induce cytopathic effects on the SkinEthic *in vitro* reconstituted human vaginal epithelial tissue model .After topical application of the product onto reconstituted vaginal mucosa, cultures were incubated at 37°C, 5% CO_2 for 10 minutes, 1 hour, 3 hours and 24 hours.

Cell viability was assessed by the MTT assay for each time point, on duplicate cultures: FDS Intimate Warming Lubricant induced a decrease of cell viability after 24 hours of contact; histology analysis showed histological alterations already after 10 minutes of contact. FDS Intimate Lubricant did not have any significant effect on cell viability and on tissue morphology.

Acute Eye Irritation Assay Using Reconstituted Human Corneal Epithelial Tissue
The test products were evaluated for their capacity to induce cytopathic effects on human corneal epithelium reconstituted by in vitro cell culture. After topical application of each

product onto human corneal epithelium, cultures were incubated at 37°C, 5% CO_2 for 10 minut4es, 1 hour, 3 hours and 24 hours. Cell viability was assessed by MTT assay for each time point, on duplicate cultures, according to the viability test (qualitative results). FDS Intimate Lubricant Warming was found to be very slightly irritant, and the FDS Intimate Lubricant a non-irritant. FDS Intimate Lubricant Warming inducted histological alterations already after 10 minutes of contact. The FDS Intimate Lubricant did not have any significant effect on tissue morphology.

Human Clinical Testing

A) In a Human Repeated Insult Patch Test, this product was compared to the currently marketed K-Y® Brand Warming Liquid™ Personal Lubricant for its potential for contact sensitization. Under the conditions of this test no evidence of contact sensitization was elicited.

B) An In-Home Consumer Use Study was conducted by an independent market research firm to determine how well the FDS Lubricant delivers against expectation set by the packaging language. Statistical analysis and interpretation of the test results were made relative to the targeted performance claims:

"Non-Messy, Convenient Pump!"
"Warming Intimate Lubricant"
"Warms on Contact"
"For Enhanced Intimacy and Pleasure"
"Fragrance Free"
"Gentle, Long-Lasting Formula"

Preclinical and Clinical testing have provided scientific evidence that this device is as safe, as effective, and performs as well as or better than the predicate device.

Study Characteristics

N/A

Identifying Numbers of all applicable IDE's, NDA's, IND's, PMA's, PDP's or 510(k)'s previously submitted by the applicant for this device

None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

APR 14 2006

Mr. Rick Main
Senior Manager
Global Regulatory Affairs
Alberto Culver Company
2525 Armitage Avenue
MELROSE PARK IL 60160-1163

Re: K060145
Trade/Device Name: FDS Intimate Lubricant, FDS Intimate Warming Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: January 19, 2006
Received: January 19, 2006

Dear Mr. Main:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

CONFIDENTIAL

SECTION IV

INDICATIONS FOR USE STATEMENT

510 (K) Number (if known) K060145

Device Name: FDS Intimate Lubricant, FDS Intimate Warming Lubricant

Indications for Use:

Personal lubrication and lubrication of a body orifice to facilitate entry of a diagnostic or therapeutic device, as a moisturizer for vaginal dryness, to enhance condom use and the ease of intimate activity.

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

Conference of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over the Counter ✓

Donald St. Pierre

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060145