APR 23 2009 K080978

510(k) Summary of Safety and Effectiveness (21 CFR 807.92) {21 CFR 807.87 (H)}

Walgreen's Personal Lubricating Jelly

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.87 (h), this information serves as a Summary of Safety and Effectiveness for the Walgreen's Personal Lubricating Jelly.

Submitted by: Vast Resources, 9401 De Soto Ave, Chatsworth, CA 91311

Date: September 23, 2008

Contact Person: Lorelei Chavez
Regulatory Affairs
Telephone: 818.332.4600

Common Name: Personal Lubricant

Classification Name: The General Hospital and Personal Use Device section of the General Medical Devices Panel within the FDA's Center for Medical Device & Radiological Health considers patient lubricants be **Class II** devices when promoted as being compatible for use with condoms (21 CFR §884.5300).

Predicate Device: KY Jelly, Personal Lubricant

Intended Use:
Walgreen's Personal Lubricating Jelly is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. It can ease insertion of rectal thermometers, enemas and tampons. This product is compatible with latex condoms.

Device Description
Walgreen's Personal Lubricating Jelly is a non-sterile, aqueous based personal lubricant designed to supplement the body's own natural lubrication fluids. It is specifically formulated to be a clear, non-irritating, non-greasy, gel-like liquid and is compatible for use with or without a condom during intimate sexual activity as evidenced by condom compatibility test results. Walgreen's Personal Lubricating Jelly is a water-based personal lubricant containing chlorhexidine digluconate and methylparaben as preservatives in a vehicle for glucono delta lactone, glycerin, hydroxyethylcellulose, sodium hydroxide, and purified water. This product is designed in LDPE tube w/ plastic flip-top cap.

Summary of Technological Characteristics

Walgreen's Personal Lubricating Jelly contains ingredients that are substantially equivalent to those used in the manufacture of the predicate devices. The ingredients meet specifications defined in the United State Pharmacopoeia (USP) or National Formulary (NF), and are "generally recognized as safe for their intended use" (21 CFR 172.515).

Summary of Substantial Equivalence Information:

The intended use, ingredients, and application of the proposed device are substantially equivalent to those of the predicate devices. In determining substantial equivalence, the Walgreen's Personal Lubricating Jelly has been compared with the following legally marketed device to which the Sponsor claims substantial equivalence.

The table below compares the technological characteristics of Walgreen's Personal Lubricating Jelly to the predicate device, KY Jelly Personal Lubricant.

Feature	Walgreen's Personal Lubricating Jelly- K080978	KY Jelly Personal Lubricant- K810310
Manufacturer	Vast Resources	McNeil-PPC Inc
Contains Purified Water	Yes	Yes
Contains Glycerin	Yes	Yes
Contains Gluconolactone	Yes	Yes
Contains Cellulose Thickeners	Yes	Yes
Contains Chlorhexidine Gluconate	Yes	Yes
Contains Methylparaben	Yes	Yes
Contains Sodium Hydroxide	Yes	Yes
Over the Counter Use	Yes	Yes
Labeled water soluble	Yes	Yes
Labeled condom compatible	Yes	Yes
Contains alcohol and fragrance	No	No
Container Material	Plastic	Plastic
Sterile	No	No

The product was tested by independent laboratories for condom compatibility, biocompatibility and preservative effectiveness. Final results from these tests demonstrate that the device meets established acceptance criteria in accordance with the identified industry standards. In addition, this product is identical to the predicate device which has undergone all appropriate testing and has already been on the market for over 20 years.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 23 2009

Ms. Lorelei Chavez
Regulatory Affairs Manager
Topco Sales
9401 De Soto Avenue
CHATSWORTH CA 91311

Re: K080978
Trade/Device Name: Walgreen's Personal Lubricating Jelly
Regulation Number: 21 CFR §880.5300
Regulation Name: Personal lubricant
Regulatory Class: II
Product Codes: NUC and HIS
Dated: April 2, 2009
Received: April 6, 2009

Dear Ms. Chavez:

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 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.

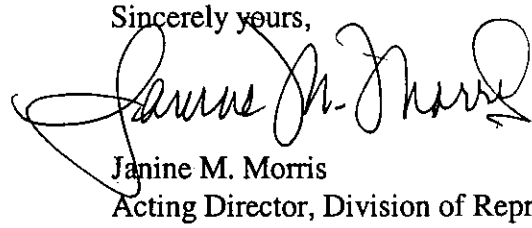
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

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

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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080978

Device Name: Walgreen's Personal Lubricating Jelly

Indications for Use: Walgreen's Personal Lubricating Jelly is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. It can ease insertion of rectal thermometers, enemas and tampons. This product is compatible with latex condoms.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K080978