MAY 17 1999

San-Mar Laboratories Inc.

MANUFACTURING • PRODUCT DEVELOPMENT
CONTRACT FILLING • CREATIVE PACKAGING

AESTHETIC SKIN CARE
CREMES • GELS • LOTIONS
HAIR PRODUCTS • SHAMPOOS
PHARMACEUTICALS

ABBREVIATED 501(k)-SUMMARY

SUBMITTER'S NAME: San-Mar Laboratories, Inc.

ADDRESS: 4 Warehouse Lane
Elmsford, New York 10523

TELEPHONE: (914) 592-3130

FAX: (914) 592-2586

CONTACT PERSON: Irwin Silverberg
Vice President

DATE PREPARED: September 1, 1998

NAME OF DEVICE

PROPRIETARY NAME: CVS PERSONAL LUBRICANT

COMMON/USUAL NAME: Personal Lubricant

CLASSIFICATION NAME: Patient Lubricant-Class I

PREDICATE DEVICE: Astroglide Personal Lubricant, K935291

DESCRIPTION OF DEVICE: "CVS Personal Lubricant" is a clear , colorless and odorless personal lubricant, which is composed of the following ingredients; Purified Water, Glycerin, Propylene Glycol, Polyquaternium #5, Methyparaben and Propylparaben. The "CVS Personal Lubricant" bottle is composed of high density polyethylene plastic.

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

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS: Astroglide Personal Lubricant and "CVS Personal Lubricant" consist of a water and glycerin base, with the addition of thickening and preservative ingredients.

SUBSTANTIAL EQUIVALENCE: The ingredients used in the manufacture of "CVS Personal Lubricant" are substantially the same as those used to manufacture Astroglide Personal Lubricant.

While the actual percentage of each ingredient may vary slightly, it is likely, given the nature of the ingredients and the usual quantities found in such formulations, that such variation is not significant.

Therefore, "CVS Personal Lubricant" is substantially equivalent to Astroglide Personal Lubricant, manufactured by BioFilm, Inc., Vista, CA 92083.

STATEMENT: San-Mar Laboratories, Inc. believes that all information submitted herewith is truthful and accurate and that no material facts have been omitted.

DOCUMENTATION REFERENCES:

21 Code of Federal Regulations, April 1, 1997-Parts 800, 801, 803, 804, 807, 814, 820, 821, 860, 880.

21 CFR Part 820 Medical Devices; Qualiy System Regulation; Current Good Manufacturing Practice; Final Rule, October 7, 1996.

Federal Food, Drug, and Cosmetic Act, As Amended July 1993, Chapter V, Sec. 501, 502, 503, and 513.

Federal Medical Device Quality System Final Rule, October 7, 1996, 21 CFR Parts 808, 812, 820.

The New 501(k) Paradigm-Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications-Final Guidance, March 20, 1998.

FDA Modernization Act of 1997-Guidance for the Device Industry on Implementation of Highest Priority Provisions, February 6, 1998.

Guidance Addendum: How to Submit a Premarket Notification [501(k)], March, 1995.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 1999

Mr. Irwin Silverberg
Vice-President
San-Mar Laboratories, Inc.
4 Warehouse Lane
Elmsford, New York 10523

Re: K983216
CVS Personal Lubricant
Dated: March 26, 4 1999
Received: April 1, 1999
Regulatory Class: II
21 CFR 884.5300/Procode: 85 HIS

Dear Mr. Silverberg:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CONFIDENTIAL

510(k) Number (if known): K983216

Device Name: CVS PersonalLubricant Liquid

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, and to enhance condom use and the ease of intimate activity.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K983216/S002