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AUG 28 2013

510(k) Summary

Submitter	IGI Laboratories, Inc. 105 Lincoln Ave P.O. Box 687 Buena, NJ 08310
Contact Person	Frederick Weiss Director, QA/QC/Analytical/RA Tel: (856) 697-1441, ext 360 Fax: (856) 697-2259
Date Prepared	November 29, 2012
Trade Name	Dermiseb Cream
Common Name	Dressing, Wound & Burn, Hydrogel w/drug and/or biologic
Classification Name	Dressing, Wound & Burn, Hydrogel w/drug and/or biologic
Predicate Device	Promiseb® Topical Cream; marketed by Promius Pharma,LLC 510(k) K050158
Description	Non-sterile, off-white to slight pale-yellow colored, low odor, steroid-free, fragrance free, topical cream. Dermiseb Cream forms a physical barrier to relieve dry, waxy skin by maintaining a moist wound and skin environment, and will be marketed in a 30 g tube as a prescription device.
Indications for Use	Under the supervision of a healthcare professional, Dermiseb Cream is indicated to manage and relieve the signs and symptoms of seborrhea and seborrheic dermatitis such as itching, erythema, scaling and pain. Dermiseb Cream also aids to relieve dry, waxy skin by maintaining a moist wound and skin environment. A moist wound and skin environment is beneficial to the healing process.
Device Description and Comparison	Both the proposed and referenced predicate devices are oil-in-water emulsions, which add moisture to the skin, and form a physical barrier.
Substantial Equivalence	The product is similar in function and intended use to Promiseb® Topical Cream marketed by Promius Pharma LLC and includes identical ingredients, indicated uses, and operating principles.
Non-clinical Performance	Non-clinical testing was conducted to confirm the safe and effective performance of Dermiseb Cream.
Conclusion	Dermiseb Cream is substantially equivalent to the currently cleared and marketed Promiseb® Topical Cream.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Frederick Weiss
Vice President, Quality
IGI Labs Incorporated
105 Lincoln Avenue, P.O Box 687
Buena, New Jersey 08310

August 28, 2013

Re: K123724
Trade/Device Name: Dermiseb Cream
Regulatory Class: Unclassified
Product Code: FRO
Dated: July 23, 2013
Received: July 25, 2013

Dear Mr. Weiss:

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 contact 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. 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,

FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Statement of Indications for Use

510(k) Number (if known):

Device Name: Dermiseb Cream

Indications for Use:

Under the supervision of a healthcare professional, Dermiseb Cream is indicated to manage and relieve the signs and symptoms of seborrhea and seborrheic dermatitis such as itching, erythema, scaling and pain. Dermiseb Cream also aids to relieve dry, waxy skin by maintaining a moist wound and skin environment. A moist wound and skin environment is beneficial to the healing process.

Dermiseb Cream in indicated for use in:

- Seborrhea
- Seborrheic Dermatitis

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

Jiyoung Dang -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K123724