K093051

SECTION 2

510(K) Summary

2. 510(k) Summary

COLLEGIUM Pharmaceutical

2.1 510(k) Owner's Name

DEC - 7 2009

Collegium Pharmaceutical, Incorporated
400 Highland Corporate Drive
Cumberland, RI 02864
Device Establishment Registration Number: 3005150234

2.2 Contact Individual

Ronald M. Gurge, Ph.D.
Associate Director, Product Research & Development
Collegium Pharmaceutical, Incorporated
401-762-2000, Extension 41
401-762-2043 (fax)
rgurge@collegiumpharma.com

2.3 Date Summary Prepared

September 29, 2009

2.4 510(k) Device Name

Proprietary Name:	Hylatopic™ Plus Emollient Foam
Common/Usual Name:	Dressing, Wound & Burn, Hydrogel w/drug and/or biologic
Classification Name:	Dressing, Wound & Burn, Hydrogel w/drug and/or biologic
Panel:	General & Plastic Surgery
CFR Number:	Unclassified
Product code:	MGQ

SECTION 2

510(k) SUMMARY (Cont'd)

2.5 Devices to Which New Device is Substantially Equivalent

- Mimyx® Cream approved under 510(k) K041342, from Stiefel Laboratories, Inc.
- Epiceram® Skin Barrier Emulsion approved under 510(k) K052643, from Ceragenix Corporation.
- Hylatopic™ Emollient Foam approved under 510(k) K083024, from Collegium Pharmaceutical, Inc.

2.6 Device Description

Hylatopic™ Plus Emollient Foam is a non-steroidal, non-sterile, off-white, low odor, fragrance free, topical aerosol foam. When Hylatopic™ Plus Emollient Foam is dispensed, foam is formed. The propellant in the foam dissipates very quickly and the foam is then rubbed on the affected skin. The Hylatopic™ Plus Emollient Foam when applied to diseased skin forms a protective barrier that helps to maintain a moist wound and skin environment. This device is presented as a prescription product that requires the physician to diagnosis the disease state and prescribe the product.

2.7 Intended Use of the Device

Under the supervision of a healthcare professional, Hylatopic™ Plus Emollient Foam, an aerosol-based emollient foam, is indicated to manage and relieve the burning, itching and pain experienced with various types of dermatoses, including atopic dermatitis, allergic contact dermatitis and radiation dermatitis. Hylatopic™ Plus Emollient Foam also helps to relieve dry, waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.

Hylatopic™ Plus Emollient Foam provides a non-steroidal alternative for the management of symptoms associated with various types of dermatoses.

2.8 Summary of Technological Characteristics of the Device Compared to the Predicate Devices

All predicate devices referenced are non-sterile, emulsion/cream/foam types that are applied topically to relieve the symptoms of various dermatoses. When Hylatopic™ Plus Emollient Foam is dispensed, foam is formed. The propellant in the foam dissipates very quickly and the foam is then rubbed on the affected skin. The rubbed in product is equivalent to a cream.

SECTION 2

510(k) SUMMARY (Cont'd)

2.9 Tests and Conclusions

Functional and performance testing has been conducted to assess the safety and effectiveness of Hylatopic™ Plus Emollient Foam and all results are satisfactory.

2.10 Performance Standards

To the best of our knowledge there are no performance standards applicable to these devices that have been adopted under section 514 of the Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Collegium Pharmaceutical, Inc.
% Ronald M. Gurge, Ph.D.
Associate Director
Product Research & Development
400 Highland Corporate Drive
Cumberland, Rhode Island 02864

DEC - 7 2009

Re: K093051
Trade/Device Name: Hylatopic™ Plus Emollient Foam
Regulation Number: Unclassified
Regulation Name: N/A
Regulatory Class: N/A
Product Code: FRO, MGQ
Dated: September 29, 2009
Received: September 30, 2009

Dear Dr. Gurge:

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 (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/cdrh/mdr/ 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/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

K093051

1.8 Statement of Indications for Use

510(k) Number (if known): This submission

Device Name: Hylatopic™ Plus Emollient Foam

Indications For Use:

Under the supervision of a healthcare professional, Hylatopic™ Plus Emollient Foam, an aerosol-based emollient foam, is indicated to manage and relieve the burning, itching and pain experienced with various types of dermatoses, including atopic dermatitis, allergic contact dermatitis and radiation dermatitis. Hylatopic™ Plus Emollient Foam also helps to relieve dry, waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.

Hylatopic™ Plus Emollient Foam is indicated for use in:

- Atopic Dermatitis
- Allergic Contact Dermatitis
- Radiation Dermatitis

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093051