SECTION 2

510(K) Summary

2. 510(k) Summary

MAR 2 7 2009

COLLEGIUM Pharmaceutical

2.1 510(k) Owner's Name

Collegium Pharmaceutical, Incorporated
400 Highland Corporate Drive
Cumberland, RI 02864
Device Establishment Registration Number: Collegium Pharmaceutical intends to register as a manufacturer of medical devices.

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

October 7, 2008

2.4 510(k) Device Name

Proprietary Name:	Hylatopic™ 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

- Sinclair (Atopiclair™) Wound and Skin Emulsion approved under 510(k) K024367, from Sinclair Pharmaceuticals, Ltd.
- MimyX™ Cream cleared approved 510(k) K041342, from Stiefel Laboratories, Inc.
- Locobase® Wound and Skin Emulsion approved under 510(k) K060272, from Ferndale Laboratories, Inc.

2.6 Device Description

Hylatopic™ Emollient Foam is a non-steroidal, non-sterile, off-white, low odor, fragrance free, topical aerosol foam. When Hylatopic™ 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™ 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 of the disease state and prescribes the product.

2.7 Intended Use of the Device

Under the supervision of a healthcare professional, Hylatopic™ 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™ Emollient Foam also helps to relieve dry, waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.

Hylatopic™ 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/gel/cream types that are applied topically to relieve the symptoms of various dermatoses. When Hylatopic™ 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 gel or cream.

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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™ 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
9200 Corporate Boulevard
Rockville MD 20850

MAR 27 2009

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

Re: K083024
Trade/Device Name: Hylatopic™ Emollient Foam
Regulatory Class: Unclassified
Product Code: MGQ
Dated: March 24, 2009
Received: March 25, 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 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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,

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

Enclosure

K083024 1/1

SECTION 1	SUBSECTION 1.8
GENERAL INFORMATION	Statement of Indications for Use

1.8 Statement of Indications for Use

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

Device Name: Hylatopic™ Emollient Foam

Indications For Use:

Under the supervision of a healthcare professional, Hylatopic™ 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™ Emollient Foam also helps to relieve dry, waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.

Hylatopic™ Emollient Foam is indicated for use in:

- Atopic Dermatitis
- Allergic Contact Dermatitis
- Radiation Dermatitis

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

Daniel Krone for MKM 3/27/09

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083024