JUL 19 2005

Summary of the safety and efficacy

1. **Submitter of the Application:**

Stiefel Laboratories, Inc.
255 Alhambra Circle, Suite 1000
Coral Gables, FL 33134

Contact Person:

Mary Jane Carr
Route 145
Oak Hill, New York 12460

Phone: (518) 239-6901 extension 8784
Fax: (518) 239-8402

2. **Proprietary Name:** MimyX™ Cream

Common/Usual Name: Dressing, Wound & Burn, Hydrogel w/Drug or Biologic

Classification Name: Dressing, Wound & Burn, Hydrogel w/Drug or Biologic

3. **Substantially Equivalent Devices:**
Stiefel Laboratories, Inc. believes that MimyX Cream is substantially equivalent to the currently marketed devices, Biafine® Wound Dressing Emulsion (Radiodermatitis Emulsion) cleared under K964240 and Sinclair Wound and Skin Emulsion cleared under K024367.

4. **Device Description:**
MimyX™ Cream is a non-sterile, semi-viscous emulsion intended for topical application. It is presented for both Prescription (requires a physician diagnosis of disease state) and Over-the-Counter (OTC) use.

5. **Intended Use of the Device:**
The prescription product requires a physician to diagnose the disease state and is indicated for the management and relief of the burning and itching associated with various types of dermatoses, including atopic dermatitis, allergic contact dermatitis and radiation dermatitis. The OTC product is indicated for general symptoms such as burning and itching associated with many common types of skin irritation. The formulation forms a protective barrier which helps to keep the wound moist, which is beneficial to the healing process.

6. **Summary of the Technological Characteristics of the Device Compared to the Predicate Device(s):**
All products referenced are non-sterile emulsions that are applied topically to relieve the symptoms of various dermatoses.

7. **Conclusions:**
Functional and performance testing has been conducted to assess the safety and efficacy of MimyX™ Cream and results are satisfactory.

Date Prepared: June 3, 2005

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 19 2005

Ms. Mary Jane Carr
Assistant Director, Regulatory Affairs
Stiefel Laboratories, Inc.
Route 145
Oak Hill, New York 12460

Re: K041342
Trade/Device Name: MimyX™ Cream
Regulatory Class: Unclassified
Product Code: MGQ
Dated: June 3, 2005
Received: June 6, 2005

Dear Ms. Carr:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041342

Device Name: MimyX™ Cream

Indications for Use:

FOR TOPICAL DERMATOLOGICAL USE ONLY

Description Rx Product:
Under the supervision of a healthcare professional, MimyX Cream is indicated to manage and relieve the burning and itching experienced with various types of dermatoses, including radiation dermatitis, atopic dermatitis and allergic contact dermatitis. MimyX Cream helps to relieve dry waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.

Directions for Use (Rx and OTC):
Apply MimyX Cream to the affected skin areas 3 times per day (or as needed), and massage gently into the skin. If the skin is broken, cover MimyX Cream with a dressing of choice.

Description OTC Product:
MimyX Cream helps to nourish skin and relieve the burning and itching associated with many common types of skin irritation. MimyX Cream may also be used to soothe minor burns, including sunburn.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(510(k) Number) K041342