Attachment 6

K024367

510(k) Summary

JUL 28 2003

December 30, 2002

1. **Submission Applicant & Correspondent:**

Name: Sinclair Pharmaceuticals, Ltd.
Address: Borough Road
Godalming
Surrey
GU7 2AB
United Kingdom

Phone No.: 1-972-939-2442
Contact Person: Michael Killeen

2. **Name of Device:** **SINCLAIR WOUND AND SKIN EMULSION ™**
Trade/Proprietary/Model Name: **SINCLAIR WOUND AND SKIN EMULSION ™**
Common or Usual Name: Dressing, Wound & Burn, Hydrogel w/Drug or Biologic
Classification Names: Dressing, Wound & Burn, Hydrogel w/Drug or Biologic

3. **Devices to Which New Device is Substantially Equivalent:**
   - Biafene Wound Dressing Emulsion (Radiodermatitis Emulsion) in 510(k) K964240, from Medix Pharmaceuticals Americas Inc. and
   - Carrasyn® Hydrogel Wound Dressing 510(k) K961758, which is also marketed under the name RadiaCare Gel Hydrogel Wound Dressing.

4. **Device Description:**
Sinclair Wound and Skin Emulsion is a non sterile viscous emulsion / gel formulation, which is presented for both Prescription (requires 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, while the OTC product is indicated for general symptoms such as burning and itching in minor skin irritations and minor burns. This formulation, when applied to the burn, injured tissue or skin, forms a protective barrier that helps to keep the wound moist.

6. **Summary of Technological Characteristics of the Device Compared to the Predicate Devices:**
All products referenced are non sterile emulsion/gel types that are applied topically to relieve the symptoms of various dermatoses.

7. **Tests and Conclusions:**
Functional and performance testing has been conducted to assess the safety and effectiveness of **SINCLAIR WOUND AND SKIN EMULSION ™** and all results are satisfactory.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 28 2003

Mr. Michael Killeen
Executive Director
Sinclair Pharmaceuticals, Ltd.
Borough Road
Godalming, Surrey
United Kingdom GU7 2AB

Re: K024367
Trade/Device Name: Sinclair Wound and Skin Emulsion™
Regulation Name: Hydrogel wound dressing and burn dressing
Regulatory Class: Unclassified
Product Code: MGQ
Dated: April 25, 2003
Received: May 6, 2003

Dear Mr. Killeen:

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 (301) 594-4659. 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K024367

Attachment 3 - Indications for Use Statement	
510(k) Number NA	
Device Name	**SINCLAIR WOUND AND SKIN EMULSION** ™
Indications for Use	FOR TOPICAL DERMATOLOGICAL USE ONLY **Description Rx Product:** Under the supervision of a healthcare professional, Sinclair Wound and Skin Emulsion is indicated to manage and relieve the burning, itching and pain experienced with various types of dermatoses, including radiation dermatitis, atopic dermatitis and allergic contact dermatitis. Sinclair Wound and Skin Emulsion may be used to relieve the pain of first and second degree burns. Sinclair Wound and Skin Emulsion 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 **Sinclair Wound and Skin Emulsion** to the affected skin areas 3 times per day (or as needed), and massage gently into the skin. If the skin is broken, cover **Sinclair Wound and Skin Emulsion** with a dressing of choice. **Description OTC Product:** Sinclair Wound and Skin Emulsion helps to nourish skin and relieve the burning and itching associated with many common types of skin irritation. Sinclair Wound and Skin Emulsion may also be used to soothe minor burns, including sunburn.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K024367

Prescription Use ____ OR Over-The Counter Use ____
(per 21 CFR 801.109)