K050158

Attachment 6

CONFIDENTIAL

OCT 11 2006

March 5, 2004

1. **Submission Applicant & Correspondent:**

Name: Sinclair Pharmaceuticals, Ltd.

Address: Borough Road
Godalming
Surrey
GU7 2AB
United Kingdom

Phone No.: 1-972-478-4380
Contact Person: Michael Killeen

2. **Name of Device:** **SINCLAIR 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:**
   - Sinclair Wound and Skin Emulsion 510(k) K024367

4. **Device Description:**
Sinclair 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:**
Products referenced are non sterile emulsion/gel types that are applied topically to relieve the symptoms of certain dermatoses.

7. **Tests and Conclusions:**
Functional and performance testing has been conducted to assess the safety and effectiveness of **SINCLAIR 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

OCT 11 2006

Sinclair Pharmaceuticals Limited
% Mr. Michael Killeen
Executive Vice President North America
Borough Road
Godalming
Surrey
GU7 2AB
United Kingdom

Re: K050158
Trade/Device Name: **SINCLAIR SKIN EMULSION™**
Regulatory Class: Unclassified
Product Code: FRO, MGQ
Dated: July 27, 2006
Received: July 28, 2006

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.

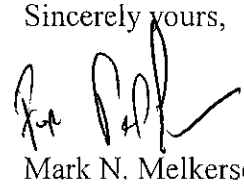
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 (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 (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

Attachment 3 - Indications for Use Statement

510(k) Number 050158	
Device Name	**SINCLAIR SKIN EMULSION ™**
Indications for Use	**FOR TOPICAL DERMATOLOGICAL USE ONLY** **Description Rx Product:** Under the supervision of a healthcare professional, Sinclair Skin Emulsion is indicated to manage and relieve the signs and symptoms of seborrhea and seborrheic dermatitis such as itching, erythema, scaling and pain. Sinclair 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 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 Skin Emulsion** with a dressing of choice. **Description OTC Product:** Sinclair Skin Emulsion helps to nourish skin and relieve the burning and itching associated with many common types of skin irritation and wounds.

Prescription Use ___√___ 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)

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

510(k) Number 1405150