Attachment 7

DEC 21 2001

K013056

510(k) Summary

September 1, 2001

1. Submission Applicant & Correspondent:
   Name: Sinclair Pharmaceuticals, Ltd.
   Address:
   Borough Road
   Godalming
   Surrey
   GU7 2AB
   United Kingdom

   Phone No.: +44 1483 428 611
   Contact Person: Denise Swift, Director of Regulatory Affairs

2. Name of Device:	Gelclair® CONCENTRATED ORAL GEL
Trade/Proprietary/Model Name:	Gelclair® CONCENTRATED ORAL GEL
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:

   Carrington Laboratories Radiacare™ Oral Wound Rinse.

4. Device Description:
Sinclair Pharmaceuticals, Ltd. Gelclair® CONCENTRATED ORAL GEL is a viscous gel formulation, which is presented in a sachet of 15ml for mixing with 40ml of water. This combination of substances, when washed around the mouth, forms a protective layer over the oral mucosa.

5. Intended Use of the Device:

Sinclair Gelclair® CONCENTRATED ORAL GEL, has a mechanical action indicated for the management of pain and relief of pain, by adhering to the mucosal surface of the mouth, soothing oral lesions of various etiologies, including: Oral Mucositis/Stomatitis (may be caused by chemotherapy or radiotherapy), irritation due to oral surgery, and traumatic ulcers caused by braces or ill fitting dentures, or disease. Also indicated also for diffuse aphthous ulcers.

6. Summary of Technological Characteristics of the Device Compared to the Predicate Devices:

The Gelclair® CONCENTRATED ORAL GEL has the same intended/indications for use as the predicate Carrington Laboratories Radiacare™ Oral Wound Rinse.

Product Name	***Sinclair Pharmaceuticals Gelclair®***	***Carrington Labs RadiaCare ™***
Ingredients	Purified Water, Propylene Glycol, Polyvinylpyrrolidone, Sodium Hyaluronate, Potassium Sorbate, Sodium Benzoate, Hydroxyethylcellulose, PEG-40 Hydrogenated Castor Oil, Disodium Edetate, Benzalkonium Chloride, Flavor, Saccharin Sodium, Glycyrrhetinic Acid	Acemannan hydrogel, Aspartame, Flavor, Fructose, Maltodextrin, Polyvinylpyrrolidone, Potassium Sorbate, Sodium Benzoate
Method of Use	Mix with water	Mix with water
Number of applications per day	Take as needed	Take as needed
Claim	Management and relief of pain, does not sting, nonirritating, safe if swallowed	Management and relief of pain, does not sting, nonirritating, safe if swallowed
Area of Use	Oral Mucosa	Oral Mucosa
Disease State	Oral Mucositis/Stomatitis/Oral Lesions	Oral Mucositis/Stomatitis/Oral Lesions
Type of Product	Concentrate for dilution	Concentrate for dilution
Presentation	Non Sterile	Non Sterile

7. Tests and Conclusions:
Extensive functional and performance testing were conducted to assess the safety and effectiveness of Gelclair® CONCENTRATED ORAL GEL. All results are satisfactory.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sinclair Pharmaceuticals, Incorporated
Ms. Priscilla Cox
Director, RA/QA
Otterbrook Engineering
1 Alder Brook
Chinley, High Peak,
UNITED KINGDOM

DEC 21 2001

Re: K013056
Trade/Device Name: Gelclair Concentrated Oral Gel
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: MGQ
Dated: December 10, 2001
Received: December 11, 2001

Dear Ms. Cox:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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). 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,

Patricia Cucente/for

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 3

Indications for Use Statement

510(k) Number (if known)

Device Name Sinclair Gelclair® CONCENTRATED ORAL GEL

Indications for Use Sinclair Gelclair® CONCENTRATED ORAL GEL, has a mechanical action indicated for the management of pain and relief of pain, by adhering to the mucosal surface of the mouth, soothing oral lesions of various etiologies, including: Oral Mucositis/Stomatitis (may be caused by chemotherapy or radiotherapy), irritation due to oral surgery and traumatic ulcers caused by braces or ill fitting dentures or disease. Also indicated also for diffuse aphthous ulcers.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K013056