SEP 1 5 2003

K024148

SINCLAIR

CONFIDENTIAL

Attachment 7
510(k) Summary

December 12, 2002

1. Submission Applicant & Correspondent:

Name: Sinclair Pharmaceuticals Limited
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: **SALINUM® OR ORACLAIR**

Trade/Proprietary/Model Name: **SALINUM® OR ORACLAIR**
Common or Usual Name: Dental: Saliva, artificial
Classification Names: Dental: Saliva, artificial

3. Devices to Which New Device is Substantially Equivalent:

Gebauer Company: Salivart cleared in 510(k) K981693 and
Inpharma AB: Caphosol cleared in 510(k) K991938

4. Device Description:

SALINUM® / ORACLAIR is an oral saliva substitute which contains gel-forming substances (polysaccharides) from linseed that have lubricating and moistening properties. The product is preserved, buffered and packed in white PET (polyethylene terephthalate) bottles of various sizes with polypropylene disc top caps or single dose (2ml) polythene pipettes in strips of 10 packed in a cardboard carton.

5. Intended Use of the Device:

Under the supervision of a healthcare professional, **SALINUM®** has been formulated for the relief of chronic and temporary xerostomia (dry mouth), which may be a result of disease, medication, oncology therapy, stress or aging.

Over the counter Labeling stipulates that **ORACLAIR** has been formulated for the relief of dry

mouth symptoms such as difficulties in swallowing, speech and changes in taste. These symptoms may be brought on by disease, stress, aging or medication.

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

SALINUM® / ORACLAIR has the same intended/indications for use as the predicate devices Gebauer Company Salivart and Inpharma AB Caphosol.

Product Name	***Salinum® / Oraclair***	***Salivart***	***Caphosol***
Method of Use	Ready to use	Ready to use	Mix solutions A & B
# of applications per day	Take as needed	Take as needed	Take as needed
Claim	Symptomatic treatment of xerostomia.	Symptomatic treatment of xerostomia.	Symptomatic treatment of xerostomia.
Area of Use	Oral cavity	Oral cavity	Oral cavity
Disease State	Xerostomia	Xerostomia	Xerostomia
Type of Product	Solution	Solution	Solution
Presentation	Non Sterile	Non Sterile	Non Sterile

7. Tests and Conclusions:

Functional and performance testing has been conducted to assess the safety and effectiveness of **SALINUM®** and all results are satisfactory.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 5 2003

Ms. Denise Swift
Director of Regulatory Affairs
Sinclair Pharmaceuticals Limited
Borough Road
Godalming
Surrey
GU7 2AB
UNITED KINGDOM

Re: K024148
Trade/Device Name: Salinum® or Oraclair
Regulation Number: None
Regulation Name:
Regulatory Class: Unclassified
Product Code: LFD
Dated: March 4, 2003
Received: March 6, 2003

Dear Ms. Swift:

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) 594-4613. 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/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Attachment 3

Indications for Use Statement

510(k) Number (if known) K024148

Device Name **SALINUM® / ORACLAIR**

Indications for Use

Rx labeling:
Under the supervision of a healthcare professional, **SALINUM®** has been formulated for the relief of chronic and temporary xerostomia (dry mouth), which may be a result of disease, medication, oncology therapy, stress or aging.

Over the counter labelling
ORACLAIR has been formulated for the relief of dry mouth symptoms such as difficulties in swallowing, speech and changes in taste. These symptoms may be brought on by disease, stress, aging or medication.

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K024148

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 ✓