AUG 10 1999

K99 1938

510(k) SUMMARY
Inpharma Pharmaceuticals, Inc.
Caphosol™ Artificial Saliva

Submitters Information

Inpharma A.S.
Industraten 15
3400 Lier
Norway
Contact: Dr. Björn Th. Johansen
Telephone: +41 32 84 87 60

Date Prepared

June 7, 1999

Name of Device

Caphosol™ Artificial Saliva
Consisting of a mixture of two solutions Caphosol™ A – 15 mL Phosphate Solution and Caphosol™ B – 15 mL Calcium Solution

Classification Name

Artificial Saliva

Predicate Devices

GLANDOSANE (SALIVART®), Synthetic Saliva, 510(k) Notification K874106, decision date April 15, 1988, applicant was Fresenius, USA, Inc., currently distributed by Gebauer Company, Cleveland, Ohio.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 10 1999

Inpharma A.S.
c/o Mr. Bruce R. Manning
President
New England Biomedical Research, Incorporated
27 South Street
P.O. Box 809
Northborough, Massachusetts 01532

Re: K991938
Trade Name: Caphosol™ Artificial Saliva
Regulatory Class: Unclassified
Product Code: LFD
Dated: June 9, 1999
Received: June 9, 1999

Dear Mr. Manning:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

510(k) Number (if known): ____________________

Device Name: CAPHOSOL™, Artificial Saliva

Indications For Use:

Caphosol is indicated for dryness of the mouth or throat (hyposalivation, xerostomia), regardless of the cause and regardless of whether the condition is temporary or permanent.

Caphosol is indicated for relief of dryness of the oral mucosa when hyposalivation results from the following: surgery, radiotherapy near the salivary glands, chemotherapy; infection or dysfunction of the salivary glands; inflammation of the mouth or throat; fever; emotional factors such as fear or anxiety; obstruction of the salivary ducts; Sjögren's syndrome; and Bell's Palsy.

Caphosol is also indicated for dryness of the oral mucosa due to drugs such as antihistamines or atropine or other anticholinergic agents that suppress salivary secretion.

It may be used as part of an oral hygiene program for patients with dry mouth. Caphosol provides intensive hygiene of the oral cavity, and may be used to help relieve bad taste and to relieve offensive nasal discharge and crusting.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use** ______
(Per 21 CFR 801.109)

Sandra L. Shire DMD, MPH for MSR

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K991938