

NOV 25 2003

K030802

Summary of Safety and Effectiveness

Inpharma, AS
Caphosol Artificial Saliva

1. Sponsor's Name

Inpharma AS
Konnerudgt 27
4035 Drammen
Norway

2. US Agent

Bruce R. Manning
New England Biomedical Research, Inc.
96 West Main Street
Northboro, MA 01532

3. Date Prepared

November 19, 2003

4. Device Name

Caphosol Artificial Saliva
(Additional Indication)

5. Identification of Legally Marketed Device

Caphosol Artificial Saliva
K991938

6. Device Description

Caphosol is an electrolyte solution resembling human saliva, designed in part to replace the normal ionic and pH balance in the oral cavity. It is intended as a mouth rinse to moisten, lubricate, and clean the oral cavity including the mucosa of the mouth, tongue and throat. Caphosol maintains moistness in the oral cavity. It relieves diffuse dryness and fissuring of the oral mucosa, as well as painful tongue conditions due to hyposalivation. Patients having this condition are also prone to dental caries and candidal infections.

Caphosol is a partial substitute for natural saliva. Caphosol facilitates chewing and speaking; loosens tough mucus; prevent mucous membranes from sticking together; helps remove nasal crust and relieve nasal soreness; improves adherence

of dentures, and also relieves bad taste. The purpose of this premarket notification is to expand the claims for Caphosol to allow Caphosol to be marketed as an adjunct to standard oral care for treating the mucositis that may be caused by radiation or high dose chemotherapy. Relief of dryness of the oral mucosa in these conditions is associated with an amelioration of pain.

Caphosol is a preparation comprising two separately packaged aqueous solutions, a phosphate solution (Caphosol A) and a calcium solution (Caphosol B) which when both ampoule solutions are combined in equal volumes form a solution supersaturated with respect to both calcium and phosphate ions. The solution after mixing the contents of solutions A and B contains:

Ingredient:	% w/w
Dibasic Sodium Phosphate	0.032
Monobasic Sodium Phosphate	0.009
Calcium Chloride	0.052
Sodium Chloride	0.569
Purified Water	qs ad

7. Intended Use

Caphosol is indicated for dryness of the mouth or throat (hyposalivation, xerostomia), regardless of the cause and regardless of whether the conditions is temporary or permanent. Caphosol is also indicated as an adjunct to standard oral care in treating the mucositis that may be caused by radiation or high dose chemotherapy. Relief of dryness of the oral mucosa in these conditions is associated with an amelioration of pain.

Caphosol may be used 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.

8. Comparison of Technological Characteristics

The current device is identical to the predicate device.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Inpharma A.S.
C/O Mr. Bruce Manning
President
New England Biomedical Research, Incorporated
96 West Main Street
P.O. Box 809
Northborough, Massachusetts 01532

Re: K030802
Trade/Device Name: Caphosol
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LFD
Dated: August 26, 2003
Received: August 27, 2003

Dear Mr. Manning:

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,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K030802
Device Name: Caphosol

Indications For Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Robert S. Betz for Mr. Susan Penner
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K030802