Belcher
Pharmaceuticals, Inc.

NOV 2 4 2004

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Largo, FL 33773
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K042400

"510(k) Summary"

Sept. 1, 2004

1. Submission applicant & correspondent:

Name:	Belcher Pharmaceuticals, Inc.
Address:	12393 Belcher Road, Suite 420
	Largo, Florida 33773. USA
Phone:	(727) 530-9751
Contact person:	Kotha Sekharam, Ph. D

2. Name of device: Mucotrol™ Concentrated Oral gel wafer

Trade/proprietary name: Mucotrol™ Concentrated Oral gel wafer

Common or usual name: Dressing, Wound & burn, Hydrogel with drug or biologic

Classification names: Dressing, Wound & burn, Hydrogel with drug or biologic

3. Devices to which new device is substantially equivalent:

Sinclair Pharmaceuticals Gelclair™ Concentrated Oral Gel (K013056) and Carrington Labs RadiaCare ™ Oral Wound Rinse (K964852) .

4. Device description:

Belcher Pharmaceutical's Mucotrol™ concentrated oral gel wafer is compressed powder, presented as 2200 mg slow dissolving wafer. This combination of

substances, when slowly dissolved in the mouth, due to saliva, forms a protective layer over the oral mucosa.

5. Intended use of the device:

Mucotrol™ concentrated oral gel wafer 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 for diffuse apthous ulcers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 4 2004

Dr. Kotha Sekharam
President
Belcher Pharmaceuticals, Incorporated
12393 Belcher Road, Suite 420
Largo, Florida 33773

Re: K042400
Trade/Device Name: Mucotrol Concentrated Oral Gel Wafer
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: FRO
Dated: September 1, 2004
Received: September 3, 2004

Dear Dr. Sekharam:

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 (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

Indications for Use

510(k) Number (if known): K042400

Device Name: MUCOTROL™ CONCENTRATED ORAL GEL WAFER

Indications for Use: : MUCOTROL™ CONCENTRATED ORAL GEL WAFER 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 DISEASES. ALSO INDICATED FOR DIFFUSE APTHOUS ULCERS.

Prescription Use YES (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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

510(k) Number: K042400