

Title, which has the term "state food safety task force meetings," "conference," "council," "workshop," "alliance" or other similar description to assist in the identification of the request; (2) location of the conference; (3) expected number of registrants and type of audience expected with their credentials; (4) dates of conference(s); (5) conference format and projected agenda(s), including list of principal areas or topics to be addressed; (6) physical facilities required for the conduct of the meeting; (7) justification of the conference(s), including the problems it intends to clarify and any developments it may stimulate; (8) brief biographical sketches of individuals responsible for planning the conference(s) and details concerning adequate support staff; (9) information about all related conferences held on this subject during the last 3 years (if known); (10) details of proposed per diem/subsistence rates, transportation, printing, supplies and facility rental costs; and (11) the necessary checklist and assurances pages provided in each application package. A properly formatted sample application for grants can be accessed on the Internet at: [http://www.fda.gov/ora/fed\\_state/Innovative\\_Grants.html](http://www.fda.gov/ora/fed_state/Innovative_Grants.html).

Data included in the application, if restricted with the legend (see section X. of this document), may be entitled to confidential treatment as trade secret or confidential commercial information within the meaning of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61).

Information collection requirements requested on PHS Form 5161-1 were approved and issued under the Office of Management and Budget Circular A-102.

#### **IX. Dun and Bradstreet Number (DUNS) Requirement**

As of October 1, 2003, applicants are now required to have a DUNS number to apply for a grant or cooperative agreement from the Federal government. The DUNS number is a 9-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, call 1-866-705-5711. Be certain that you identify yourself as a Federal grant applicant when you contact Dun and Bradstreet.

#### **X. Legend**

Unless disclosure is required by FOIA as amended (5 U.S.C. 552), as determined by the FOI officials of HHS or by a court, data contained in the portions of an application which have been specifically identified by page number, paragraph, etc., by the applicant as containing restricted and/or proprietary information shall not be used or disclosed except for evaluation purposes.

Dated: June 18, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-S**

### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

#### **Food and Drug Administration**

[Docket Nos. 2004M-0024, 2004M-0147, 2004M-0145, 2004M-0031, 2004M-0022, 2004M-0012, 2004M-0064, 2004M-0116, 2004M-0084, 2004M-0090, 2004M-0134]

#### **Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Division of Dockets Management.

**ADDRESSES:** Submit written requests for copies of summaries of safety and effectiveness to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

**FOR FURTHER INFORMATION CONTACT:** Thinkh Nguyen, Center for Devices and Radiological Health (HFZ-402), Food and Drug Administration, 9200

Corporate Blvd., Rockville, MD 20850, 301-594-2186.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**. Instead, the agency now posts this information on the Internet on FDA's home page at <http://www.fda.gov>. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from January 1, 2004, through March 31, 2004. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAs MADE AVAILABLE FROM JANUARY 1, 2004, THROUGH MARCH 31, 2004

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P970020(S40)/2004M-0024	Guidant Corp.	ACS MULTI-LINK RX/OTW DUET CORONARY STENT SYSTEMS	August 6, 2002
P890064(S9)/2004M-0147	Digene Corp.	DIGENE HYBRID CAPTURE 2 (HC2) HIGH-RISK HPV DNA TEST	March 31, 2003
P020006/2004M-0145	Enteric Medical Technologies, Inc.	ENTERYX PROCEDURE KIT	April 22, 2003
P020031/2004M-0031	Microsulis Corp.	MICROSULIS MICROWAVE ENDOMETRIAL ABLATION	September 23, 2003
P010059/2004M-0022	Morcher GMBH	MORCHER CAPSULAR TENSION RING, TYPES 14, 14A, and 14C	October 23, 2003
P030002/2004M-0012	Eyeonics, Inc.	CRYSTALENS MODEL AT-45 ACCOMMODATING POSTERIOR CHAMBER INTRAOCULAR LENS	November 14, 2003
P030005/2004M-0064	Guidant Corp.	CONTAK RENEWAL MODELS H125 and H120 WITH MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	January 26, 2004
P030006/2004M-0116	Celsion Corp.	PROLIEVE THERMODILATION SYSTEM	February 19, 2004
H030004/2004M-0084	Menssana Research, Inc.	HEARTSBREATH	February 24, 2004
H030003/2004M-0090	MicroMed Technology, Inc.	DEBAKEY VAD CHILD LEFT VENTRICULAR ASSIST SYSTEM	February 25, 2004
P010018(S5)/2004M-0134	Refractec, Inc.	VIEWPOINT CK SYSTEM	March 16, 2004

## II. Electronic Access

Persons with access to the Internet may obtain the documents at <http://www.fda.gov/cdrh/pmapage.html>.

Dated: June 7, 2004.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

## DEPARTMENT OF TRANSPORTATION

### Maritime Administration

[USCG-2004-16860]

### Gulf Landing LLC Liquefied Natural Gas Deepwater Port License Application; Draft Environmental Impact Statement

**AGENCY:** Coast Guard, DHS; and Maritime Administration, DOT.

**ACTION:** Notice of availability; notice of public meeting; and request for public comments.

**SUMMARY:** The Coast Guard and the Maritime Administration announce the availability of the draft environmental impact statement for the Gulf Landing, LLC Deepwater Port License Application. The proposed Gulf Landing liquefied natural gas deepwater

port would be located in the Gulf of Mexico approximately 38 miles south of Cameron, Louisiana. The Coast Guard and the Maritime Administration solicit public input on this draft environmental impact statement.

**DATES:** The draft environmental impact statement (DEIS) will be available on June 25, 2004, and comments must reach the Coast Guard on or before August 9, 2004. Additionally, an informational open house will be held in Lafayette, Louisiana on July 15, 2004, from 2 p.m. until 4 p.m., and a formal public meeting from 5 p.m. until 7 p.m.

**ADDRESSES:** The informational open house/public meeting location is: Courtyard by Marriott, 214 East Kaliste Saloon Road, Lafayette, LA 70508, telephone number 337-232-5005.

You may submit comments, identified by Coast Guard docket number USCG-2004-16860, to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods: