

(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: Thinh Nguyen, Center for Devices and Radiological Health (HFZ-402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2186, ext. 152.

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 April 1, 2006, through June 30, 2006. 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 APRIL 1, 2006, THROUGH JUNE 30, 2006

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P050021/2006M-0161	QLT, Inc.	CERALAS I LASER & CERALINK SLIT LAMP ADAPTER	December 20, 2005
P040052/2006M-0264	MonoGen, Inc.	MONOPREP PAP TEST (MPPT)	March 3, 2006
P040028/2006M-0148	Medispectra, Inc.	LUMA CERVICAL IMAGING SYSTEM	March 16, 2006
P050012/2006M-0200	Dexcom, Inc.	DEXCOM (STS) CONTINUOUS GLUCOSE MONITORING SYSTEM	March 24, 2006
P050026/2006M-0162	QLT, Inc.	QUALTEL ACTIVIS LASER & ZSL30 ACT, ZSL120 ACT, and HSBMBQ ACT SLIT LAMP ADAPTERS	April 4, 2006
P030008(S4)/2006M-0199	SurgiVision Refractive Consultants	WAVELIGHT ALLEGRETTO WAVE EXCIMER LASER SYSTEM	April 19, 2006
P040033/2006M-0193	Smith & Nephew Orthopaedics	BIRMINGHAM HIP RESURFACING (BHR) SYSTEM	May 9, 2006
P050047/2006M-0235	Inamed Corp.	JUVEDERM 24HV, JUVEDERM 30, and JUVEDERM 30HV GEL IMPLANTS	June 2, 2006

II. Electronic Access

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

Dated: September 15, 2006.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N-0107]

Food and Drug Administration-Regulated Products Containing Nanotechnology Materials; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: This is an update to previous notice that the Food and Drug Administration (FDA) will hold a public meeting October 10, 2006, on nanotechnology as it relates to FDA-regulated products. The primary purpose of this update is to notify the public that preregistration to attend or speak at the public meeting will close on September 29, 2006. The purpose of the meeting is to help FDA further its understanding of developments in

nanotechnology materials that pertain to FDA-regulated products. FDA is interested in learning about the kinds of new nanotechnology material products under development in the areas of foods (including dietary supplements), food and color additives, animal feeds, cosmetics, drugs and biologics, and medical devices, whether there are new or emerging scientific issues that should be brought to FDA's attention, and any other scientific issues about which the regulated industry, academia, and the interested public may wish to inform FDA concerning the use of nanotechnology materials in FDA-regulated products.

DATES AND TIMES: The public meeting will be held October 10, 2006, from 9 a.m. to 5 p.m.

REGISTRATION: You may preregister to attend or make a presentation at <http://www.fda.gov/nanotechnology/>. Preregistration to make a presentation will close on September 29, 2006; however, there will be onsite registration to attend on a first-come, first-served basis until the room capacity is reached. Onsite registration will be open at the meeting site at 8:30 a.m. on October 10. Once room capacity is reached, individuals will be offered the opportunity to observe the meeting from an overflow room located at the meeting site.

If time permits, there will be an open public session. Individuals who have not preregistered to make a presentation can register onsite if they wish to present public comments. While every effort will be made to provide an open public session after all preregistered speakers have made presentations, it is recommended that you preregister if you would like to make a presentation. Onsite registration to make a presentation will be taken on a first-come, first-served basis. Individuals who register at the meeting to speak may be allotted less time to speak than preregistered speakers, depending on the number of registrants.

We will post the agenda at <http://www.fda.gov/nanotechnology/> prior to the meeting.

ADDRESSES: The public meeting will be held at the Natcher Auditorium, National Institutes of Health Campus (NIH), 9000 Rockville Pike, bldg. 45, Bethesda, MD. We will also post the address for the meeting at <http://www.fda.gov/nanotechnology/>. Note that parking is limited on the NIH Campus and that security procedures are in effect. For further information on parking and security see <http://www.nih.gov/about/visitorsecurity.htm>.

Written or electronic comments may be submitted by November 10, 2006. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Poppy Kendall, Food and Drug Administration (HF-11), 5600 Fishers Lane, Rockville, MD 20857, 301-827-3360, FAX: 301-594-6777, e-mail: poppy.kendall@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Why Are We Holding a Public Meeting?

Previous **Federal Register** Notices (71 FR 19523, April 14, 2006; 71 FR 46232, August 11, 2006) contain detailed supplemental information regarding the rationale and background for the meeting.

For more information about FDA's role regarding nanotechnology products, see our Web page at <http://www.fda.gov/nanotechnology/>.

II. How Can You Participate?

You can participate through oral presentation at the meeting or through written or electronic material submitted to the docket. The length of the presentations will be determined by the number of speakers who preregister and the time available. Based on the requests received so far, the presentations are likely to be less than 8 minutes long. In order to maximize the number of people who have the opportunity to present their views at this public meeting, each individual or organization will be limited to one opportunity to present views at the meeting. However, written material of any length can be submitted to the docket.

Individuals and organizations with common interests are encouraged to consolidate or coordinate their presentations. FDA will give the registered speakers an estimated timeframe for their presentations by October 4 through email to the address provided during preregistration. Persons should arrive early to make sure that they are present to make their presentation in case we are ahead of schedule.

In a previous notice we indicated the possibility of holding concurrent sessions. However, based on the number of requests for presentation received so far it appears that all can be

accommodated by one general session. A final decision on whether there will be concurrent sessions will be made following the cutoff date for registration and will be communicated through the posted agenda at <http://www.fda.gov/nanotechnology/> and e-mail to registered speakers.

We ask that you preregister by September 29 (see **REGISTRATION**) if you intend to provide an oral presentation. If time permits, there will be an open public session at the meeting. However, individuals who register at the meeting to speak may be allotted less time to speak than preregistered speakers, depending on the number of registrants. The information provided during preregistration will help us determine further how to organize the day.

III. Will Meeting Transcripts Be Available?

Following the meeting, transcripts will be available for review at the Division of Dockets Management (see **ADDRESSES**).

IV. How Should You Send Comments on the Issues?

An open public docket has been established. Individuals may submit their comments either in writing or electronically to the docket. All comments should include the docket number found in brackets in the heading of this document (see **ADDRESSES**). Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals have the option of submitting one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Listing of Grants for Research Projects

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Notice.