

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Robert H. King, Sr., Center for Drug Evaluation and Research (HFD-003), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4150, Silver Spring, MD 20993-0002, 301-796-1242, or

Christopher Joneckis, Center for Biologics Evaluation and Research (HFM-25), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-0373.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4480.

SUPPLEMENTARY INFORMATION:**I. Background**

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH

sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In the **Federal Register** of December 17, 2009 (74 FR 66981), FDA published a notice announcing the availability of a draft tripartite guidance entitled "Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 11: Capillary Electrophoresis General Chapter." The notice gave interested persons an opportunity to submit comments by February 16, 2010.

After consideration of the comments received and revisions to the guidance, a final draft guidance entitled "Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 11: Capillary Electrophoresis General Chapter" was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies in June 2010.

The guidance provides the specific evaluation outcome from the ICH Q4B process for the Capillary Electrophoresis General Chapter harmonization proposal originating from the three-party PDG. This guidance is in the form of an annex to the core ICH Q4B guidance made available in the **Federal Register** of February 21, 2008 (73 FR 9575). When implemented, the annex will provide guidance for industry and regulators on the use of the specific pharmacopoeial texts evaluated by the ICH Q4B process. Following receipt of comments on the draft, no substantive changes were made to the annex.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.regulations.gov>, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

Dated: August 30, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket Nos. FDA-2010-M-0244, FDA-2010-M-0220, FDA-2010-M-0219, FDA-2010-M-0242, FDA-2010-M-0261, FDA-2010-M-0262, FDA-2010-M-0264, FDA-2010-M-0294, FDA-2010-M-0285]

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 data 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: Nicole Wolanski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1650, Silver Spring, MD 20993-0002, 301-796-6570.

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, 2010, through June 30, 2010. 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, 2010, THROUGH JUNE 30, 2010

PMA No. Docket No.	Applicant	TRADE NAME	Approval Date
P090018 FDA-2010-M-0244	Envoy Medical Corp.	ESTEEM TOTALLY IMPLANTABLE HEARING SYSTEM	March 17, 2010
P080029 FDA-2010-M-0220	Interventional Therapies, LLC	QUICK CLOSE VASCULAR SUTURING SYSTEM	April 8, 2010
P090022 FDA-2010-M-0219	Lenstec, Inc.	SOFTEC HD POSTERIOR CHAMBER INTRA-OCULAR LENS (PCIOL)	April 12, 2010
P080032 FDA-2010-0242	Asthmatix, Inc.	ALAIR BRONCHIAL THERMOPLASTY	April 27, 2010
P090007 FDA-2010-M-0261	Roche Diagnostics Corp.	ELECSYS ANTI-HCV IMMUNOASSAY AND ELECSYS PRECICONTROL ANTI-HCV FOR USE ON THE COBAS E411 IMMUNOASSAY ANALYZER	April 29, 2010
P090008 FDA-2010-M-0262	Roche Diagnostics Corp.	ELECSYS ANTI-HCV IMMUNOASSAY AND ELECSYS PRECICONTROL ANTI-HCV FOR USE ON THE COBAS E601 IMMUNOASSAY ANALYZER	April 29, 2010
P090009 FDA-2010-M-0264	Roche Diagnostics Corp.	ELECSYS ANTI-HCV IMMUNOASSAY AND ELECSYS PRECICONTROL ANTI-HCV FOR USE ON THE MODULAR ANALYTICS E170 ANALYZER	April 29, 2010
P050027 FDA-2010-M-0294	Karl Storz endoscopy—America, Inc.	PHOTODYNAMIC DIAGNOSTIC D-LIGHT C	May 28, 2010
P060029 FDA-2010-M-0285	Ethicon, Inc.	OMNEX SURGICAL SEALANT	June 3, 2010

II. Electronic Access

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

Dated: August 31, 2010.

Nancy K. Stade,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.