

Dated: October 5, 2009.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0328]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Wound Dressing With Poly (Diallyl Dimethyl Ammonium Chloride) Additive; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled “Class II Special Controls Guidance Document: Wound Dressing With Poly (Diallyl Dimethyl Ammonium Chloride) (pDADMAC) Additive.” This guidance document describes a means by which wound dressing with Poly (diallyl dimethyl ammonium chloride) (pDADMAC) additive may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify wound dressing with pDADMAC additive into class II (special controls). This guidance document is being immediately implemented as the special control for wound dressing with pDADMAC additive, but it remains subject to comment in accordance with the agency’s good guidance practices (GGPs).

DATES: Submit written or electronic comments on the guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled “Class II Special Controls Guidance Document: Wound Dressing With Poly (Diallyl Dimethyl Ammonium Chloride) (pDADMAC) Additive” to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20850. Send one self-addressed adhesive label

to assist that office in processing your request, or fax your request to 301-847-8502. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance 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.regulations.gov>. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Sam Arepalli, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3612, Silver Spring, MD 20993, 301-796-6434.

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)). This guidance document will serve as the special control for wound dressing with pDADMAC additive. Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification. Because of the timeframes established by section 513(f)(2) of the act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Thus, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

II. Significance of Guidance

This guidance is being issued consistent with FDA’s GGPs regulation (§ 10.115). The guidance represents the agency’s current thinking on wound dressings with pDADMAC additive. 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive “Class II Special Controls Guidance Document: Wound Dressing With Poly (Diallyl Dimethyl Ammonium Chloride) (pDADMAC) Additive,” you may either send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number 1684 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts. **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers’ addresses), small manufacturer’s assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available at <http://www.regulations.gov>.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073; and the collections of information in 21 CFR

part 801 have been approved under OMB control number 0910-0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit 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: October 2, 2009.

Jeffrey Shuren,

Acting Director, Center for Devices and Radiological Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2009-M-0299, FDA-2009-M-0300, FDA-2009-M-0182, FDA-2009-M-0244, FDA-2009-M-0243, FDA-2009-M-0255]

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, 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, 2009, through June 30, 2009. 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, 2009, THROUGH JUNE 30, 2009.

PMA No./Docket No.	Applicant	TRADE NAME	Approval Date
P080014 FDA-2009-M-0299	Third Wave Technologies, Inc.	CERVISTA HPV HR	March 12, 2009
P080015 FDA-2009-M-0300	Third Wave Technologies, Inc.	CERVISTA HPV 16/18	March 12, 2009
P080006 FDA-2009-M-0182	Medtronic Inc.	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	April 7, 2009
P080023 FDA-2009-M-0244	Abbott Laboratories	ARCHITECT CORE REAGENT KIT, ARCHITECT CORE CALIBRATOR AND ARCHITECT CORE CONTROLS	April 10, 2009
P060023 FDA-2009-M-0243	Medtronic Sofamor Danek	BRYAN CERVICAL DISC	May 12, 2009
P060008 (S8) FDA-2009-M-0255	Boston Scientific Co.	TAXUS LIBERTE ATOM PACLITAXEL-ELUTING CORONARY STENT SYSTEM	May 21, 2009