ADDRESSES:

DATES:

SUMMARY:

ACTION:

AGENCY:

Food and Drug Administration

[Docket No. FDA–2016–P–1026]

Medical Devices; Exemption From Premarket Notification: Method, Metallic Reduction, Glucose (Urinary, Non-Quantitative) Test System in a Reagent Tablet Format; Republication

Dated: June 14, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–14461 Filed 6–17–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FR Doc. 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.]

FOR FURTHER INFORMATION CONTACT: Ana Lolei Marsal, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4552, Silver Spring, MD 20993–0002, 301–796–8774, ana.loloeimarsal@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (1976 amendments) (Pub. L. 94–295), as amended by the Safe Medical Devices Amendments of 1990 (Pub. L. 101–629), devices are to be classified into class I (general controls) if there is information showing that the general controls of the FD&C Act are sufficient to assure safety and effectiveness; into class II (special controls) if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into
class III (premarket approval) if there is insufficient information to support classifying a device into class I or class II and the device is a life sustaining or life supporting device, or is for a use which is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the FD&C Act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendments devices), are classified through the premarket notification process under section 510(k) of the FD&C Act (21 U.S.C. 360(k)). Section 510(k) of the FD&C Act and the implementing regulations, 21 CFR part 807, require persons who intend to market a new device to submit a premarket notification (510(k)) containing information that allows FDA to determine whether the new device is “substantially equivalent” within the meaning of section 513(i) of the FD&C Act to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law FDAMA (Pub. L. 105–115). Section 206 of FDAMA, in part, added a new section, 510(m), to the FD&C Act. Section 510(m)(1) of the FD&C Act requires FDA, within 60 days after enactment of FDAMA, to publish in the Federal Register a list of each type of class II device that does not require a report under section 510(k) of the FD&C Act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the FD&C Act further provides that a 510(k) will no longer be required for these devices upon the date of publication of the list in the Federal Register. FDA published that list in the Federal Register of January 21, 1998 (63 FR 3142).

Section 510(m)(2) of the FD&C Act provides that 1 day after date of publication of the list under section 510(m)(1), FDA may exempt a device on its own initiative or upon petition of an interested person if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the Federal Register a notice of intent to exempt a device, or of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the Federal Register its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the guidance the Agency issued on February 19, 1998, entitled “Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff” (Ref. 1).

III. Proposed Class II Device Exemptions

FDA has received the following petition requesting an exemption from premarket notification for a class II device: Martin O’Connor, Germaine Laboratories, Inc., 11030 Wye Dr., San Antonio, TX 78217, for its Method, Metallic Reduction, Glucose (urinary, non-quantitative) classified under 21 CFR 862.1340. FDA previously announced that it received this petition in a notice entitled “Medical Devices: Exemption from Premarket Notification: Method, Metallic Reduction, Glucose (Urinary, Non-Quantitative) Test System in a Reagent Tablet Format” that appeared in the Federal Register of May 4, 2016 (81 FR 26802). The document was published with the incorrect docket number. This notice includes the correct docket number for the petition.

IV. Reference

The following reference is on display in the Division of Dockets Management (see ADDRESSES) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at http://www.regulations.gov. FDA has verified the Web site address, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.


Dated: June 14, 2016.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2016–14459 Filed 6–17–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Bone, Reproductive and Urologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA’s regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on October 19, 2016, from 8:15 a.m. to 5 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.

FOR FURTHER INFORMATION CONTACT: Kalyani Bhatt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: BRUDAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice.

Therefore, you should always check the Agency’s Web site at http://www.fda.gov/AdvisoryCommittees/default.htm and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION: Agenda: The committee will discuss the efficacy and safety of new drug