

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0916]

Medical Device Classification Product Codes; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Medical Device Classification Product Codes." This document describes how device product codes are used in a variety of FDA program areas to regulate and track medical devices regulated by the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER).

DATES: Submit either electronic or written comments on this 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 "Medical Device Classification Product Codes" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993-0002 or the Office of Communication, Outreach and Development (HFM-40), 1401 Rockville Pike, suite 200N, Rockville, MD 20852. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to CDRH at 301-847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Diane Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1644, Silver Spring, MD 20993-0002, 301-796-6559; or

Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

Since the May 28, 1976, Medical Device Amendments were passed, the Classification Regulation Panels (parts 862 through 892 (21 CFR parts 862 through 892)) have been the basis for CDRH's Classification Product Code structure and organization. These 16 Panels have largely been the driving force for CDRH's internal organizational structure as well. These Panels were established with the 1976 Medical Device Amendments, and rulemaking is required in order to add to or modify the Panels. However, rulemaking has resulted in very few additions or modifications to the Panels and subgroups since 1976.

In order to respond to the evolution of device technology, classification product codes were created to assist in accurate identification and tracking of current medical devices and to allow for tracking and easy reference of predicate device types. Classification product codes are a method of classifying medical devices. CDRH and a subset of CBER-regulated medical device product codes consist of a three-letter combination that associates a device's type with a product classification designated for the application. Classification product codes and information associated with these devices, such as names and attributes, are assigned by CDRH to support their regulation.

The purpose of this guidance document is to educate regulated industry and FDA Staff on how, when, and why to use classification product codes for medical devices regulated by CDRH and CBER. This document describes how classification product codes are used in a variety of FDA program areas to regulate and track medical devices. This document is limited to medical devices as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)) and does not discuss classification products codes used to regulate nonmedical electronic radiation-emitting products.

The scope of the guidance document includes devices described in the existing classification under parts 862 through 892. It also describes how classification product codes are used for CBER regulated devices, which currently do not fall within this existing classification. This guidance may be

applicable to future devices. It also covers unclassified devices and devices not yet classified.

In the **Federal Register** of January 3, 2012 (77 FR 125), FDA announced the availability of the draft guidance document. Interested persons were invited to comment by May 2, 2012. Five comments were received with multiple recommendations pertaining to the administrative processes and policies regarding medical device classification product codes. In response to these comments, FDA revised the guidance document to clarify the processes and policies as appropriate.

II. Significance of Guidance

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 medical device classification product codes. 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. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov> or from CBER at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>. To receive "Medical Device Classification Product Codes," you may either send an email request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1774 to identify the guidance you are requesting.

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 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 803, subpart A through E, have been approved under OMB control number 0910-0437; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910-0120; and the

collections of information under 21 CFR part 814 have been approved under OMB control number 0910-0231.

V. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of 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, and will be posted to the docket at <http://www.regulations.gov>.

Dated: April 5, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0967]

Prescription Drug User Fee Act Patient-Focused Drug Development; Announcement of Disease Areas for Meetings Conducted in Fiscal Years 2013-2015

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of Availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the selection of disease areas to be addressed during the first 3 years of Patient-Focused Drug Development. This 5-year initiative is being conducted to fulfill FDA's performance commitments made as part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). It provides a more systematic approach for the Agency to obtain patients' input on specific disease areas, including their perspectives on their condition, its impact on daily life, and available therapies. FDA selected these disease areas based on a set of selection criteria, the perspectives of the reviewing divisions at FDA, and the public input received on a preliminary set of disease areas published in the **Federal Register** on September 24, 2012.

ADDRESSES: The general schedule of fiscal years (FY) 2013-2015 meetings concerning Patient-Focused Drug Development, information on how

stakeholders can prepare for them, and information on how stakeholders may leverage Patient-Focused Drug Development to generate input on disease areas that are not addressed through the PDUFA V commitments can be found at the Web site for Patient-Focused Drug Development: <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm>.

FOR FURTHER INFORMATION CONTACT:

Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1199, Silver Spring, MD 20993, 301-796-5003, FAX: 301-847-8443, Email: Graham.Thompson@fda.hhs.gov; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, the President signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112-144). Title I of FDASIA reauthorizes the Prescription Drug User Fee Act (PDUFA), which provides FDA with the necessary user fee resources to maintain an efficient review process for human drug and biologic products. The reauthorization of PDUFA includes performance goals and procedures that represent FDA's commitments during FY 2013-2017. These commitments are referred to in section 101 of FDASIA and are available on the FDA Web site at <http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf>.

Section X of these commitments relates to enhancing benefit-risk assessment in regulatory decision-making. A key part of regulatory decision-making is establishing the context in which the particular decision is made. For purposes of drug marketing approval, this includes an understanding of the severity of the treated condition and the adequacy of the available therapies. Patients who live with a disease have a direct stake in the outcome of FDA's decisions and are in a unique position to contribute to the understanding of their disease.

FDA has committed to obtain the patient perspective on 20 disease areas during the course of PDUFA V. For each disease area, the Agency will conduct a public meeting to discuss the disease and its impact on patients' daily lives, the types of treatment benefit that

matter most to patients, and patients' perspectives on the adequacy of available therapies. These meetings will include participation of FDA review divisions, the relevant patient community, and other interested stakeholders.

II. Disease Area Selection

On September 24, 2012, FDA published a **Federal Register** notice (77 FR 58849) that announced an opportunity for public comment on potential disease areas to be addressed throughout PDUFA V. In that notice, based on several criteria listed therein, FDA identified 39 disease areas as potential candidates for 20 public meetings and invited public comment on the preliminary list and on disease areas that were not listed. The Agency obtained public comment through a docket and a public meeting convened on October 25, 2012.

Almost 4,500 comments addressing over 90 disease areas were submitted by patients, patient advocates and advocacy groups, caregivers, healthcare providers, professional societies, scientific and academic experts, pharmaceutical companies, and others. The majority of comments were submitted by individual patients. The comments generally focused on one or more of the following: Nominations of support for individual disease areas or groups of disease areas, general suggestions for Patient-Focused Drug Development, and topics outside the scope of the program. Many comments discussed the impact of the disease on daily life and the symptoms that were most concerning to patients. Others addressed lack of treatment options or the nature of specific treatments. Over half of the comments received concerned lung cancer, narcolepsy, and interstitial lung disease. Other disease areas also received a significant number of comments, including migraine, pulmonary fibrosis, amyloidosis, myalgic encephalomyelitis/chronic fatigue syndrome, amyotrophic lateral sclerosis, chronic obstructive pulmonary disease, lysosomal storage disorders, peripheral neuropathy, dystonia, and fibromyalgia. Comments were received for numerous other disease areas not listed in this notice. Individual comments may be viewed at <http://www.regulations.gov/#!docketDetail;D=FDA-2012-N-0967>, or by visiting FDA Dockets Management at 5630 Fishers Lane, rm. 1061, HFA-305, Rockville, MD 20852.

Input from the public was particularly helpful for FDA in better understanding the aspects of diseases that are not formally measured in clinical trials as