

Center, and/or Division ceilings; (8) communicates and shares knowledge with programs, OCFO Central, and CDC's OCFO budget analyst community; and (9) performs cost-benefit analysis to review financial requests and makes recommendations for future-year budget.

Budget Execution Services Branch 2 (CAJEVC). This branch supports one or more Centers and/or Offices by performing the following: (1) Provides the legal and regulatory expertise and support to execute CDC's budget within the framework of DHHS, OMB, and Congressional regulations, and policies of CDC OD; (2) manages to the expectations agreed upon in the Budget Execution Services Service Level Agreement; (3) promotes structured, ongoing partnerships with the Centers, Divisions, and Offices; (4) manages and supports programs in all aspects of funds management; (5) provides the leadership and guidance for spend plan creation and administration, in compliance with all Federal guidelines and policies, such as the Anti-Deficiency Act; (6) provides the overall analysis and reconciliation of spend plans to advise program on future spending decisions; (7) assists program officials in developing sub-allocation of Center, and/or Division ceilings; (8) communicates and shares knowledge with programs, OCFO Central, and CDC's OCFO budget analyst community; and (9) performs cost-benefit analysis to review financial requests and makes recommendations for future-year budget.

Budget Execution Services Branch 3 (CAJEVD). This branch supports one or more Centers and/or Offices by performing the following: (1) Provides the legal and regulatory expertise and support to execute CDC's budget within the framework of DHHS, OMB, and Congressional regulations, and policies of CDC OD; (2) manages to the expectations agreed upon in the Budget Execution Services Service Level Agreement; (3) promotes structured, ongoing partnerships with the Centers, Divisions, and Offices; (4) manages and supports programs in all aspects of funds management; (5) provides the leadership and guidance for spend plan creation and administration, in compliance with all Federal guidelines and policies, such as the Anti-Deficiency Act; (6) provides the overall analysis and reconciliation of spend plans to advise program on future spending decisions; (7) assists program officials in developing sub-allocation of Center, and/or Division ceilings; (8) communicates and shares knowledge with program, OCFO Central, and CDC's

OCFO Budget Analyst Community; and (9) performs cost-benefit analysis to review financial requests and makes recommendations for future-year budget.

Budget Execution Services Branch 4 (CAJEVE). This branch supports one or more Centers and/or Offices by performing the following: (1) Provides the legal and regulatory expertise and support to execute CDC's budget within the framework of DHHS, OMB, and Congressional regulations, and policies of CDC OD; (2) manages to the expectations agreed upon in the Budget Execution Services Service Level Agreement; (3) promotes structured, ongoing partnerships with the Centers, Divisions, and Offices; (4) manages and supports Program in all aspects of funds management; (5) provides the leadership and guidance for spend plan creation and administration, in compliance with all Federal guidelines and policies, such as the Anti-Deficiency Act; (6) provides the overall analysis and reconciliation of spend plans to advise program on future spending decisions; (7) assists program officials in developing sub-allocation of Center, and/or Division ceilings; (8) communicates and shares knowledge with program, OCFO Central, and CDC's OCFO Budget Analyst Community; and (9) performs cost-benefit analysis to review financial requests and makes recommendations for future-year budget.

Budget Execution Services Branch 5 (CAJEVG). This branch supports one or more Centers and/or Offices by performing the following: (1) Provides the legal and regulatory expertise and support to execute CDC's budget within the framework of DHHS, OMB, and Congressional regulations, and policies of CDC OD; (2) manages to the expectations agreed upon in the Budget Execution Services Service Level Agreement; (3) promotes structured, ongoing partnerships with the Centers, Divisions, and Offices; (4) manages and supports programs in all aspects of funds management; (5) provides the leadership and guidance for spend plan creation and administration, in compliance with all Federal guidelines and policies, such as the Anti-Deficiency Act; (6) provides the overall analysis and reconciliation of spend plans to advise Program on future spending decisions; (7) assists program officials in developing sub-allocation of Center, and/or Division ceilings; (8) communicates and shares knowledge with program, OCFO Central, and CDC's OCFO Budget Analyst Community; and (9) performs cost-benefit analysis to review financial requests and makes

recommendations for future-year budget.

Budget Execution Services Branch 6 (CAJEVH). This branch supports one or more Centers and/or Offices by performing the following: (1) Provides the legal and regulatory expertise and support to execute CDC's budget within the framework of DHHS, OMB, and Congressional regulations, and policies of CDC OD; (2) manages to the expectations agreed upon in the Budget Execution Services Service Level Agreement; (3) promotes structured, ongoing partnerships with the Centers, Divisions, and Offices; (4) manages and supports program in all aspects of funds management; (5) provides the leadership and guidance for spend plan creation and administration, in compliance with all Federal guidelines and policies, such as the Anti-Deficiency Act; (6) provides the overall analysis and reconciliation of spend plans to advise Program on future spending decisions; (7) assists program officials in developing sub-allocation of Center, and/or Division ceilings; (8) communicates and shares knowledge with programs, OCFO Central, and CDC's OCFO Budget Analyst Community; and (9) performs cost-benefit analysis to review financial requests and makes recommendations for future-year budget.

Dated: April 18, 2013.

**Sherri A. Berge,**

*Chief Operating Officer, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0380]

#### **Agency Information Collection Activities; Proposed Collection; Comment Request; Product Jurisdiction: Assignment of Agency Component for Review of Premarket Applications**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of

information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the procedure by which an applicant may obtain an assignment or designation determination for combination products.

**DATES:** Submit either electronic or written comments on the collection of information by July 1, 2013.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3794, [Jonnalynn.capezzuto@fda.hhs.gov](mailto:Jonnalynn.capezzuto@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party.

Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Product Jurisdiction: Assignment of Agency Component for Review of Premarket Applications—(OMB Control Number 0910-0523)—Extension**

This regulation relates to Agency management and organization and has two purposes. The first is to implement section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)), as added by the Safe Medical Devices Act of 1990 (Pub. L. 101-629), and amended

by the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107-250), by specifying how FDA will determine the organizational component within FDA assigned to have primary jurisdiction for the premarket review and regulation of products that are comprised of any combination of: (1) A drug and a device; (2) a device and a biological product; (3) a biological product and a drug; or (4) a drug, a device, and a biological product. The second purpose of this regulation is to enhance the efficiency of Agency management and operations by providing procedures for classifying and determining which Agency component is designated to have primary jurisdiction for any drug, device, or biological product where such jurisdiction is unclear or in dispute.

The regulation establishes a procedure by which an applicant may obtain an assignment or designation determination. The regulation requires that the request include the identity of the applicant, a comprehensive description of the product and its proposed use, and the applicant's recommendation as to which Agency component should have primary jurisdiction, with an accompanying statement of reasons. The information submitted would be used by FDA as the basis for making the assignment or designation decision. Most information required by the regulation is already required for premarket applications affecting drugs, devices, biological products and combination products. The respondents will be businesses or other for-profit organizations.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Part 3 .....	43	1	43	24	1,032

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

These burden estimates are based on the number of applications FDA received over the past two fiscal years.

Dated: April 26, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2013-N-0001]

**Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.