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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier J. COOKE

Food and Drug Administration

[Docket No. 2003N-0222]

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, 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.

DATES: Submit written or electronic comments on the collection of information by *[insert date 60 days after date of publication in the Federal Register.]*

ADDRESSES: Submit written comments 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.fda.gov/dockets/ecomments>. All comments should be identified with the docket number found in brackets in the heading of this document.

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FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

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, 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: (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

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 (Public Law 101–629), and amended by the Medical Device User Fee and Modernization Act of 2002 (Public Law 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; (3) a biological and a drug; or (4) a drug, a device, and a biological. 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.

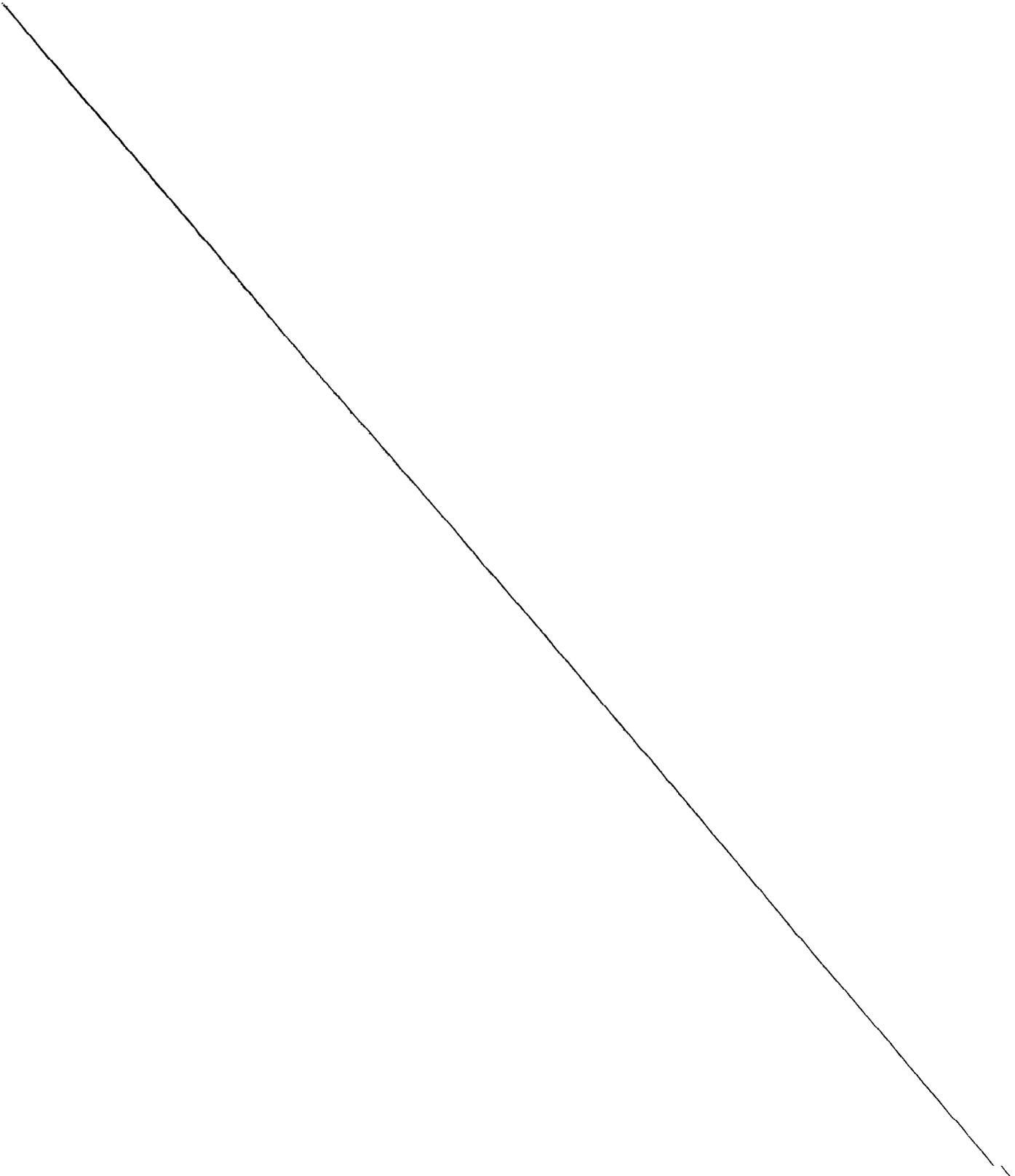
The regulation establishes a procedure by which an applicant may obtain an assignment or designation determination. The regulation requires that the request include the identity of the applicant, a comprehensive description of the product and its proposed use, and the applicant's recommendation as to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

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

ESTIMATED ANNUAL REPORTING BURDEN¹

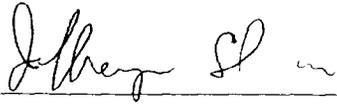
21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3	28	1	28	24	672

¹ There are no capital costs or operating and maintenance costs associated with this collection of information



Dated: 6-16-03
June 16, 2003.

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Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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