

thereby acquire shares of Merchants & Planters Bank, all in Newport, Arkansas.

Board of Governors of the Federal Reserve System, August 23, 2016.

Michele T. Fennell,

Assistant Secretary of the Board.

[FR Doc. 2016-20532 Filed 8-25-16; 8:45 am]

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DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000-0090; Docket 2016-0053; Sequence 38]

Information Collection; Rights in Data and Copyrights

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for public comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning rights in data and copyrights.

DATES: Submit comments on or before October 25, 2016.

ADDRESSES: Submit comments identified by Information Collection 9000-0090 by any of the following methods:

- *Regulations.gov:* <http://www.regulations.gov>. Submit comments via the Federal eRulemaking portal by inputting "Information Collection 9000-0090" under the heading "Enter Keyword or ID" and selecting "Search". Select the link "Submit a Comment" that corresponds with "Information Collection 9000-0090". Follow the instructions provided at the "Submit a Comment" screen. Please include your name, company name (if any), and "Information Collection 9000-0090" on your attached document.

- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: Ms. Flowers/IC 9000-0090.

Instructions: Please submit comments only and cite Information Collection 9000-0090, in all correspondence

related to this collection. Comments received generally will be posted without change to <http://www.regulations.gov>, including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check www.regulations.gov, approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Mr. Charles Gray, Procurement Analyst, at 703-795-6328 or email charles.gray@gsa.gov.

SUPPLEMENTARY INFORMATION:

A. Purpose

Subpart 27.4, Rights in Data and Copyrights is a regulation which concerns the rights of the Government and contractors with whom the Government contracts, regarding the use, reproduction, and disclosure of information developed under such contracts. The delineation of such rights is necessary in order to protect the contractor's rights to not disclose proprietary data, and to insure that data developed with public funds is available to the public.

The information collection burdens and recordkeeping requirements included in this regulation fall into the following four categories:

(a) A provision which is to be included in solicitations where the offeror would identify any proprietary data it would use during contract performance, in order that the contracting officer might ascertain if such proprietary data should be delivered.

(b) Contract provisions which, in unusual circumstances, would be included in a contract and require a contractor to deliver proprietary data to the Government for use in evaluating work results, or is software to be used in a Government computer. These situations would arise only when the very nature of the contractor's work is comprised of limited rights data or restricted computer software and if the Government would need to see that data in order to determine the extent of the work.

(c) A technical data certification for major systems, which requires the contractor to certify that the data delivered under the contract is complete, accurate and compliant with the requirements of the contract. As this provision is for major systems only, and few civilian agencies have such major systems, only about 30 contracts should require this certification.

(d) The Additional Data Requirements clause, which is to be included in all contracts for experimental, developmental, research, or demonstration work (other than basic or applied research to be performed solely by a university or college where the contract amount will be \$500,000 or less). The clause requires that the contractor keep all data first produced in the performance of the contract for a period of three years from the final acceptance of all items delivered under the contract. Much of this data will be in the form of deliverables provided to the Government under the contract (final report, drawings, specifications, etc.). Some data, however, will be in the form of computations, preliminary data, records of experiments, etc., and these will be the data that will be required to be kept over and above the deliverables. The purpose of such recordkeeping requirements is to insure that the Government can fully evaluate the research in order to ascertain future activities and to insure that the research was completed and fully reported, as well as to give the public an opportunity to assess the research results and secure any additional information. All data covered by this clause is unlimited rights data paid for by the Government.

Paragraph (d) of the Rights in Data—General clause (52.227.14) outlines a procedure whereby a contracting officer can challenge restrictive markings on data delivered. Under civilian agency contracts, limited rights data or restricted computer software is rarely, if ever, delivered to the Government. Therefore, there may rarely be any challenges. Thus, there is no burden on the public.

B. Annual Reporting Burden

Respondents: 944.

Responses per Respondent: 2.43.

Annual Responses: 2294.

Hours per Response: 1.0.

Total Burden Hours: 2294.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate

technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals:

Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202-501-4755. Please cite OMB Control No. 9000-0090, Rights in Data and Copyrights, in all correspondence.

Dated: August 22, 2016.

Lorin S. Curit,

*Director, Federal Acquisition Policy Division,
Office of Governmentwide Acquisition Policy,
Office of Acquisition Policy, Office of
Governmentwide Policy.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0408]

Microbiology Data for Systemic Antibacterial Drugs—Development, Analysis, and Presentation; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled “Microbiology Data for Systemic Antibacterial Drugs—Development, Analysis, and Presentation.” The purpose of this guidance is to assist sponsors in the development, analysis, and presentation of microbiology data during antibacterial drug development. This guidance finalizes the draft guidance of the same name issued on September 17, 2009.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are

solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2009-D-0408 for “Microbiology Data for Systemic Antibacterial Drugs—Development, Analysis, and Presentation; Guidance for Industry; Availability.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on [http://](http://www.regulations.gov)

www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Joseph G. Toerner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 22, Rm. 6244, Silver Spring, MD 20993-0002, 301-796-1400.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Microbiology Data for Systemic Antibacterial Drugs—Development, Analysis, and Presentation.” The purpose of this guidance is to assist sponsors in the development, analysis, and presentation of microbiology data during antibacterial drug development. Microbiology data provide important information to guide clinical development of antibacterial drugs and guide clinicians on the use of an antibacterial drug for its intended indication.

This guidance finalizes the draft guidance issued on September 17, 2009