

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR section	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
600.14; Reporting of product deviations by licensed manufacturers	3486	93	6.14	571	2.0	1,142
606.171; Reporting of product deviations by licensed manufacturers, unlicensed registered blood establishments, and transfusion services	3486	1,937	23.847	46,192	2.0	92,384
1271.350(b); Reporting requirements (human cells, tissues, and cellular and tissue-based products)	3486	93	2.61	243	2.0	486
1271.350(b) (CBER addendum report)	² 3486A	102	22.76	2,322	0.25	580.5
Total				49,328		94,592.5

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

² Five percent of the number of respondents $((1,937 + 93) \times 0.05 = 102)$ and total annual responses to CBER $((46,192 + 243) \times 0.05 = 2,322)$.

Our estimated burden for the information collection reflects an overall increase of 739 hours and a corresponding increase of 398 responses. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Dated: December 10, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-0323]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before January 27, 2020.

ADDRESSES: Submit your comments to OIRA_submission@omb.eop.gov or via facsimile to (202) 395-5806.

FOR FURTHER INFORMATION CONTACT:

Sherrette Funn, Sherrette.Funn@hhs.gov or (202) 795-7714. When submitting comments or requesting information, please include the document identifier 0990-New-30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Medical Countermeasures.gov.

Type of Collection: OMB No. 0990-0323—Extension—

Abstract: The Office of the Assistant Secretary for Preparedness and Response (ASPR), Office of the Biomedical Advanced Research and Development Authority (BARDA), is requesting an approval on an extension by OMB on a currently approved information collection.

The purpose of this collection is, in order to route product developers to the most appropriate personnel within the Department of Health and Human Services (HHS), HHS collects some basic information about the company's product through *Medical Countermeasures.gov*. Using this information and a routing system that has been developed with input from participating agencies within HHS, including the Office of the Assistant Secretary for Preparedness and Response (ASPR), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the National Institutes of Health (NIH), *Medical Countermeasures.gov* routes the meeting request to the appropriate person within HHS. ASPR is requesting an extension by OMB for a three-year clearance.

Type of respondent: Developers of medical countermeasures to naturally occurring and intentional public health threats visit the site on a monthly basis.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Meeting Request	Developers of medical countermeasures to naturally occurring and intentional public health threats.	245	1	10/60	41
Total					41

Terry Clark,

Office of the Secretary, Asst. Paperwork Reduction Act Reports Clearance Officer.

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