



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0062]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Exception From General Requirements for Informed Consent

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (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 information collection regarding exception from the general requirements for informed consent.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including

- attachments, to <https://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 <https://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-2010-N-0062 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Exception From General Requirements for Informed Consent." Received comments

will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://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 <https://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:  
<https://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 <https://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.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794.

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.

## Medical Devices; Exception From General Requirements for Informed Consent--21 CFR 50.23

OMB Control Number 0910-0586--Extension

In the Federal Register of June 7, 2006 (71 FR 32827), FDA issued an interim final rule to amend its regulations to establish a new exception from the general requirements for informed consent, to permit the use of investigational in vitro diagnostic devices to identify chemical, biological, radiological, or nuclear agents without informed consent in certain circumstances. The Agency took this action because it was concerned that, during a potential terrorism event or other potential public health emergency, delaying the testing of specimens to obtain informed consent may threaten the life of the subject. In many instances, there may also be others who have been exposed to, or who may be at risk of exposure to, a dangerous chemical, biological, radiological, or nuclear agent, thus necessitating identification of the agent as soon as possible. FDA created this exception to help ensure that individuals who may have been exposed to a chemical, biological, radiological, or nuclear agent are able to benefit from the timely use of the most appropriate diagnostic devices, including those that are investigational.

Section 50.23(e)(1) (21 CFR 50.23(e)(1)) provides an exception to the general rule that informed consent is required for the use of an investigational in vitro diagnostic device. This exception applies to those situations in which the in vitro investigational diagnostic device is used to prepare for, and respond to, a chemical, biological, radiological, or nuclear terrorism event or other public health emergency, if the investigator and an independent licensed physician make the determination and later certify in writing that: (1) There is a life-threatening situation necessitating the use of the investigational device, (2) obtaining informed consent from the subject is not feasible because there was no way to predict the need to use the investigational device when the specimen was collected and there is not sufficient time to obtain consent from

the subject or the subject's legally authorized representative, and (3) no satisfactory alternative device is available. Under the rule, these determinations are made before the device is used, and the written certifications are made within 5 working days after the use of the device. If use of the device is necessary to preserve the life of the subject and there is not sufficient time to obtain the determination of the independent licensed physician in advance of using the investigational device, § 50.23(e)(2) provides that the certifications must be made within 5 working days of use of the device. In either case, the certifications are submitted to the Institutional Review Board (IRB) and, under § 50.23(e)(3) (76 FR 36989, June 24, 2011), to FDA within 5 working days of the use of the device.

Section 50.23(e)(4) provides that an investigator must disclose the investigational status of the device and what is known about the performance characteristics of the device at the time test results are reported to the subject's health care provider and public health authorities, as applicable. Under § 50.23(e)(4), the investigator provides the IRB with the information required by § 50.25 (21 CFR 50.25) (except for the information described in § 50.25(a)(8)) and the procedures that will be used to provide this information to each subject or the subject's legally authorized representative.

FDA estimates that there are approximately 150 laboratories that could perform testing that uses investigational in vitro diagnostic devices to identify chemical, biological, radiological, or nuclear agents. FDA estimates that in the United States each year there are approximately 450 naturally occurring cases of diseases or conditions that are identified in the Centers for Disease Control and Prevention's list of category "A" biological threat agents. The number of cases that would result from a terrorist event or other public health emergency is uncertain. Based on its knowledge of similar types of submissions, FDA estimates that it will take about 2 hours to

prepare each certification. We estimate the operating and maintenance cost of \$200 for copying and mailing the information to FDA.

Based on its knowledge of similar types of submissions, FDA estimates that it will take about 1 hour to prepare a report disclosing the investigational status of the in vitro diagnostic device and what is known about the performance characteristics of the device and submit it to the health care provider and, where appropriate, to public health authorities.

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

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours	Total Operating and Maintenance Costs
Written certification (sent to FDA)-- 50.23(e)(3)	150	3	450	0.25	113	\$200

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

Table 2.--Estimated Annual Third-Party Disclosure Burden<sup>1</sup>

21 CFR Part	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Written certification (sent to IRB)-- 50.23(e)(1) and (e)(2)	150	3	450	2	900
Informed consent information-- 50.23(e)(4)	150	3	450	1	450
Total					1,350

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

Dated: April 11, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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