Medical Devices; Exception from General Requirements for Informed Consent

0910-0586
SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

   The final rule amended FDA's informed consent regulation to provide an exception to the general requirement to obtain informed consent from the subject of an investigation involving an unapproved or not cleared in vitro diagnostic device intended to identify a chemical, biological, radiological, or nuclear agent. This regulation was issued under the statutory authority provided in section 520(g)(3)(D) of the Federal Food Drug and Cosmetic Act, which outlines the criteria under which an exemption from informed consent may be permissible. It amends 21 CFR 50.23, to add paragraph (e). Section 50.23(e)(1) and (e)(2), require the investigator and an independent licensed physician to make the determination and certify in writing certain facts concerning the need for use of the investigational in vitro diagnostic device without informed consent. The investigator would submit this written certification to the institutional review board (IRB) and also, under Section 50.23(e)(3), to FDA. 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. The investigator must provide the IRB with the information required by § 50.25 and the procedures that will be used to provide this information to each subject or the subject's legally authorized representative.

   This information collection is not related to the American Recovery and Reinvestment Act of 2009 (ARRA).

2. Purpose and Use of the Information Collection

   FDA is requiring this information disclosure in order to assure that exceptions to the informed consent requirement occur only in cases in which the investigator may not obtain informed consent in sufficient time to protect the health of the subject.

   The prospective respondents are investigators who are using investigational in vitro diagnostic devices intended to identify a chemical, biological, radiological, or nuclear agent. These investigators may be private sector laboratory directors and physicians who have their own business or are affiliated with business entities such as hospitals or device manufacturers. Respondents may also include investigators affiliated with Federal or local government institutions such as public health laboratories and State health departments.

3. Use of Improved Information Technology and Burden Reduction

Respondents can use any appropriate technology to develop, maintain, and/or disseminate the required certification information. Use of computers has greatly reduced the time needed to compile, submit, and maintain the required documents. FDA estimates that 98 percent of the respondents will use electronic means to fulfill the agency's requirement.

4. Efforts to Identify Duplication and Use of Similar Information

   The Food and Drug Administration is the only agency charged with the responsibility of regulating the investigation of in vitro diagnostic medical devices that are not approved or cleared for introduction into interstate commerce. Therefore, no similar information is available that can be used or modified for the purpose described.

5. Impact on Small Businesses or Other Small Entities

   The Division of Small Manufacturers, International and Consumer Assistance (DSMICA), within FDA's Center for Devices and Radiological Health (CDRH), provides technical and nonfinancial assistance through a comprehensive program, which includes seminars and education conferences, informational materials and use of a toll-free number which may be used by firms that require information or assistance. Additional CDRH staff are available for consultation on request. We estimate that 20 percent of respondents may be considered small businesses.

6. Consequences of Collecting the Information Less Frequently

   Data will be submitted occasionally. FDA requires a certification within five days of each use of investigational in vitro diagnostic device subject to the rule without obtaining informed consent in order to assure adequate protection for subjects of such investigations.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

   There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

   In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of 04/10/2014 (79 FR 19915). We received one comment; however, it was not related to the information collection.

9. Explanation of Any Payment or Gift to Respondents

   No payment or gift will be provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

    Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information. All records and other information submitted to FDA are releasable under 21 CFR part 20. However, FOIA provides certain exemptions from mandatory public disclosures of government records (5 U.S.C. 522(b)(1)-(b)(9)). One such exemption, personnel,

medical, and similar files, disclosure of which would constitute a clearly unwarranted invasion of personal privacy, applies to patient information that may be included in these information collection provisions.

11. Justification for Sensitive Questions

    The information collection does not include questions that are of a sensitive nature, such as, sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Estimates of Annualized Burden Hours and Costs

    12 a. Annualized Hour Burden Estimate

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

Table 1.--Estimated Annual Reporting Burden					
Activity/ 21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Written certification (sent to FDA)--50.23(e)(3)	150	3	450	0.25	113
Total					113

Table 2.--Estimated Annual Third-Party Disclosure Burden					
Activity/ 21 CFR Section	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

Table 2.--Estimated Annual Third-Party Disclosure Burden					
Activity/ 21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Informed consent information--50.23(e)(4)	150	3	450	1	450
Total					1,350

From its knowledge of the in vitro diagnostic device investigations, FDA estimates that there are approximately 150 laboratory directors or physicians who could perform this type of testing and, as investigators, are required to comply with information collection and recordkeeping. FDA estimates that there are approximately 450 naturally occurring cases of this type each year. Based on its knowledge of similar types of submissions, FDA estimates that it will take about two hours to prepare each certification required by §50.23(e)(1) and (e)(2); 0.25 hours to prepare each written documentation to be submitted to FDA as required by § 50.23(e)(3); and one hour to make each of the disclosures required by § 50.23(e)(4).

12b. Annualized Cost Burden Estimate

FDA estimates the average cost to industry to be approximately $130,002. We believe the burden will be performed by Laboratory Directors and Physicians. We calculated our estimate using the May 2012 wage estimates issued by the Bureau of Labor Statistics (http://www.bls.gov/oes/current/oes_nat.htm) for "Physicians and Surgeons, All Other" (occupation code 29-1069).

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Laboratory Director	1,113	$88.86	$98,901
Physician	350	$88.86	$31,101
Total			$130,002

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

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

14. Annualized Cost to the Federal Government

FDA estimates that approximately one full time equivalent (FTE) position is required for review and processing of the information collected. An average full time equivalent (FTE) employee cost FDA/CDRH approximately $209,632,* which consists of the employee's salary and any overhead which accompanies that employee.

*Based on the FY 2012 President's Budget Request All Purpose Table – Total Program Level table.

15. Explanation for Program Changes or Adjustments

    After a review under the PRA, a portion of the burden has been changed from reporting to third-party disclosure burden. FDA feels that regarding part of the burden as third-party disclosure is more appropriate because, under 21 CFR 50(e)(1)-(e)(2) and (e)(4), respondents report information to Institutional Review Boards (IRBs).

16. Plans for Tabulation and Publication and Project Time Schedule

    FDA does not intend to publish the results of this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

    We are not requesting an exemption for display of the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

    There are no exceptions to the certification.