4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-D-3592]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Certificates of Confidentiality

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. All comments should be identified with the OMB control number 0910-0130. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Protection of Human Subjects and Institutional Review Boards; Certificates of Confidentiality

OMB Control Number 0910-0130--Revision

This information collection supports Agency guidance regarding the issuance of Certificates of Confidentiality (CoCs). The 21st Century Cures Act (Cures Act) (Pub. L. 114-255, section 2012) amended the Public Health Service Act, section 301(d) (42 U.S.C. 241(d)), to help protect the privacy of human subject research participants from whom identifiable, sensitive information is being collected or used in furtherance of the research. Historically, a CoC generally protected a researcher from being compelled in a legal proceeding (such as by subpoena or court order) to disclose identifiable and sensitive information about the research participant, created or compiled for purposes of the human subject research. The Cures Act broadened the protections of the statutory provision by affirmatively prohibiting holders of CoCs from disclosing such information unless a specific exception applies. For efficiency of Agency operations, we are revising information collection currently approved under OMB Control No. 0910-0130 pertaining to the protection of human subjects and institutional review boards to include information collection pertaining to the issuance of CoCs. As information collection activity is planned and undertaken by FDA, we find consolidating related collection elements better utilizes our resources. We have developed guidance to assist respondents to the information collection with this topic and are including it in the information collection accordingly.

The Cures Act simplified certain aspects of the issuance of CoCs by requiring that CoCs be issued for federally funded human subject research that collects or uses identifiable, sensitive

information (referred to in the draft guidance as mandatory CoCs). For non-federally funded research, issuance of CoCs is not required but may be issued at the discretion of FDA (referred to in the draft guidance as discretionary CoCs) when the study involves a product subject to FDA's jurisdiction and regulatory authority. FDA intends to continue receiving such requests and will issue discretionary CoCs as appropriate.

To assist respondents with information collection attendant to CoCs, we developed the draft guidance document entitled "Certificates of Confidentiality; Draft Guidance for Sponsors, Sponsor-Investigators, Researchers, Industry, and Food and Drug Administration Staff." The draft guidance is intended to provide information on how to request a discretionary CoC, the statutory requirements for requesting such a CoC, and the statutory responsibilities associated with possessing a CoC. Although the mandatory CoC and the discretionary CoC are issued under different processes, the protections afforded by the issuance of either CoC are identical and the statutory responsibilities are applicable to both. The draft guidance was developed and issued consistent with our Good Guidance Practice regulations at 21 CFR 10.115 which provide for comment at any time. The draft guidance is available at: https://www.fda.gov/media/132966/download. We intend to finalize the draft guidance and are revising the associated information collection accordingly.

In the *Federal Register* of November 25, 2019 (84 FR 64906), we published a notice announcing the availability of the draft guidance entitled "Certificates of Confidentiality; Draft Guidance for Sponsors, Sponsor-Investigators, Researchers, Industry, and Food and Drug Administration Staff; Availability," including an analysis of burden that may be attributable to the information collection recommendations. Although we received some comments requesting that clarifying discussion be included with regard to topics covered in the guidance, no

comments were received in response to the four information collection topics solicited under the PRA.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Draft Guidance for Sponsors, Sponsor-Investigators, Researchers, Industry, and FDA Staff on CoCs	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Submissions of CoC Requests From Sponsors, Sponsor-Investigators, or Authorized Representatives	150	1	150	2	300

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

Based on the number of CoC requests we have received prior to the Cures Act, we estimate receiving approximately 150 discretionary CoC requests annually. We estimate that approximately 150 sponsors, sponsor-investigators, or authorized representatives will submit requests. Preparing and sending each request would take approximately 2 hours

Dated: June 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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