4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0076]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Electronic Signatures

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: Fax written comments 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 faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0303. 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, 301-796-7729, 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.

Electronic Records; Electronic Signatures

OMB Control Number 0910-0303--Extension

This information collection supports FDA regulations; specifically, in part 11 (21 CFR part 11), which sets forth criteria for acceptance of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records. Under these regulations, records and reports may be submitted to FDA electronically provided the Agency has stated its ability to accept the records electronically in an Agency-established public docket and that the other requirements of part 11 are met.

The recordkeeping provisions in part 11 (§§ 11.10, 11.30, 11.50, and 11.300) require the following standard operating procedures to assure appropriate use of, and precautions for, systems using electronic records and signatures: (1) § 11.10 specifies procedures and controls for persons who use closed systems to create, modify, maintain, or transmit electronic records; (2) § 11.30 specifies procedures and controls for persons who use open systems to create, modify, maintain, or transmit electronic records; (3) § 11.50 specifies procedures and controls for persons who use electronic signatures; and (4) § 11.300 specifies controls to ensure the security and integrity of electronic signatures based upon use of identification codes in combination with passwords. The reporting provision (§ 11.100) requires persons to certify in writing to FDA that they will regard electronic signatures used in their systems as the legally binding equivalent of traditional handwritten signatures.

The burden created by the information collection provision of this regulation is a one-time burden associated with the creation of standard operating procedures, validation, and

certification. The Agency anticipates the use of electronic media will substantially reduce the paperwork burden associated with maintaining FDA required records. The respondents are businesses and other for-profit organizations, State or local governments, Federal Agencies, and nonprofit institutions.

In the *Federal Register* of June 19, 2017 (82 FR 27838), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. No comments were received in response to the information collection topics solicited in the notice. However, one comment was received regarding a related Agency draft guidance entitled, "Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11--Questions and Answers," and the comment has been directed to the appropriate Agency components for consideration.

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

Table 1--Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	No of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
11.100	4,500	1	4,500	1	4,500

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

Table 2.--Estimated Annual Recordkeeping Burden[1]

21 CFR Section	No. of Recordkeepers	No. of Records Per Recordkeeper	Total Annual Records	Average Burden Per Recordkeeping (in hours)	Total Hours
11.10	2,500	1	2,500	20	50,000
11.30	2,500	1	2,500	20	50,000
11.50	4,500	1	4,500	20	90,000
11.300	4,500	1	4,500	20	90,000
Total					280,000

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

Dated: November 20, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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