

guidance specifies the circumstances under which packages and homogenous cases of product that are not labeled with a product identifier and that are in the pharmaceutical distribution supply chain at the time of the effective date of the requirements of section 582 of the FD&C Act shall be exempted from certain requirements of section 582, it will have binding effect upon finalization.

II. Electronic Access

Persons with access to the internet may obtain the guidance document at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <https://www.regulations.gov>.

Dated: November 20, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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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 December 27, 2017.

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, PRASStaff@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 | Number of respondents | Number 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 | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response (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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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–4562]

Safety Assessment for Investigational New Drug Safety Reporting; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the public workshop entitled “Safety Assessment for IND Safety Reporting.” Convened by the Duke-Robert J. Margolis, MD, Center for Health Policy at Duke University and supported by a cooperative agreement with FDA, the purpose of the public workshop is to bring the stakeholder community together to discuss a variety of topics related to “Safety Assessment for Investigational New Drug (IND) Safety Reporting.” This public workshop is organized in response to public comments received to Docket No. FDA–2015–D–4562 for the draft guidance “Safety Assessment for IND Safety Reporting” issued in December 2015 requesting a public meeting to discuss the draft guidance and its implications. The public workshop is intended to engage external stakeholders in discussions related to finalizing the draft guidance entitled “Safety Assessment for IND Safety Reporting.”

DATES: The public workshop will be held on January 11, 2018, from 9 a.m. to 4 p.m., Eastern Time. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the Conference Center at 1777 F Street NW., Washington, DC 20006. For additional travel and hotel information, please refer to the following Web site: <https://healthpolicy.duke.edu/events/fda-ind-safety-reporting-meeting>. There will also be a live webcast for those unable to attend the meeting in person (see *Streaming Webcast of Public Workshop*).

FOR FURTHER INFORMATION CONTACT:

Lauren Wedlake, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6362, Silver Spring, MD 20993, 301–796–2728, Lauren.Wedlake@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The IND safety reporting requirements for human drugs and biological products being studied under an IND are stated in § 312.32 (21 CFR 312.32). In 2012, FDA published final guidance for industry and investigators regarding implementation of these requirements entitled “Safety Reporting Requirements for INDs and BA/BE Studies.”¹ During the evaluation of comments to the draft guidance for industry and investigators entitled “Safety Reporting Requirements for INDs and BA/BE Studies” (Docket No. FDA–2010–D–0482) and at meetings with stakeholders, FDA identified the need for additional guidance on IND safety reporting. The draft guidance for industry entitled “Safety Assessment for IND Safety Reporting” was issued in December 2015² as a follow-on to the guidance for industry and investigators entitled “Safety Reporting Requirements for INDs and BA/BE Studies” and provides recommendations for how sponsors of INDs can identify and evaluate important safety information

that must be submitted to FDA and all participating investigators under the IND safety reporting regulations at § 312.32. The focus of this draft guidance is on safety information that is only interpretable in the aggregate and therefore, this guidance is most applicable to late-stage studies and drug development programs that have multiple studies. This guidance contains recommendations on the following matters that are most relevant to sponsors’ review of aggregate data for IND safety reporting: (1) The entity that reviews aggregate data, (2) methods for aggregate analyses of safety data, (3) maintaining trial integrity while reviewing unblinded data, and (4) reporting criteria. This guidance also contains recommendations regarding the development of a plan for safety surveillance, and includes considerations and recommendations.

Timely reporting of meaningful safety information allows FDA to consider whether any changes in study conduct should be made beyond those initiated by the sponsor and allows investigators to make any needed changes to protect subjects. Simply reporting all serious adverse events, however, including those where there is little reason to consider them suspected adverse reactions (suspected adverse reactions being those with a reasonable possibility of having been caused by the drug), does not serve this purpose because it may obscure safety information that is relevant to the investigational drug. Sponsors’ effective processes for a systematic approach to safety surveillance, coupled with IND safety reporting of suspected adverse reactions to FDA and all participating investigators (and subsequent reporting to involved institutional review boards), allows all parties to focus on important safety issues and to take actions to minimize the risks of participation in a clinical trial. Sponsors are encouraged to have internal processes for governing the safety surveillance and safety reporting for their development programs. Such process may include

¹ Available at: <https://www.fda.gov/downloads/Drugs/Guidances/UCM227351.pdf>.

² <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM477584.pdf>.