

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity; 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Request for HUD designation—814.102 .....	20	1	20	40	800
HDE Application—814.104 .....	4	1	4	328	1,312
HDE Amendments and resubmitted HDEs—814.106 ...	20	5	100	50	5,000
HDE Supplements—814.108 .....	116	1	116	80	9,280
Notification of withdrawal of an HDE—814.116(e)(3) ...	2	1	2	1	2
Notification of withdrawal of IRB approval—814.124(b)	1	1	1	2	2
Periodic reports—814.126(b)(1) .....	50	1	50	120	6,000
Total .....					22,396

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

Activity; 21 CFR section	Number of recordkeepers	Number of records per respondent	Total annual records	Average burden per recordkeeping	Total hours
HDE Records—814.126(b)(2) .....	65	1	65	2	130

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

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN <sup>1</sup>

Activity; 21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Notification of emergency use—814.124(a) .....	22	1	22	1	22

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

The number of respondents in tables 1, 2, and 3 are an average based on data for the previous 3 years, *i.e.*, fiscal years 2017 through 2019. The number of respondents has been adjusted to reflect updated respondent data. This has resulted in an overall increase of 5,809 hours to the total estimated burden. The number of annual reports submitted under § 814.126(b)(1) in table 1 reflects 50 respondents with approved HUD applications. Under § 814.126(b)(2) in table 2, the estimated number of recordkeepers is 65.

We have also updated the burden estimate consistent with new provisions in § 814.104(b)(4)(i) regarding “Human Subject Protection; Acceptance of Data from Clinical Investigations for Medical Devices” (83 FR 7366; February 21, 2018) (approved under OMB control number 0910–0741). Section 814.104 is being amended to address submission of data from clinical investigations in a Humanitarian Device Exemption (HDE). To the extent the applicant includes data from clinical investigations, the applicant will be required to include the information and statements as described in § 814.104(b)(4)(i). Consistent with our estimate in OMB control number 0910–

0741, this revision increases our burden estimate for an HDE by 8 hours per submission.

Dated: August 7, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2020–17716 Filed 8–12–20; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2011–N–0076]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Records; Electronic Signatures

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) 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 requirements governing the acceptance of electronic records and electronic signatures.

**DATES:** Submit either electronic or written comments on the collection of information by October 13, 2020.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 13, 2020. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 13, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

### 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):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, 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-2011-N-0076 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Records; Electronic Signatures." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff 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 Dockets Management Staff. 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.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

### 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](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3521), 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.

### Electronic Records; Electronic Signatures—21 CFR Part 11

OMB Control Number 0910-0303—Extension

This information collection supports FDA regulations in part 11 (21 CFR part 11), which govern 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 us electronically provided that we have stated our 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 §§ 11.10, 11.30, 11.50, and 11.300 require the following standard operating procedures to ensure 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 to us in writing 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. We anticipate that 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.

To assist respondents with the information collection we have developed the guidance document entitled “Guidance for Industry: Part 11, Electronic Records; Electronic Signatures—Scope and Application,” available on our website at <https://www.fda.gov/media/75414/download>. While we do not believe the guidance creates any attendant burden, it describes the Agency’s thinking regarding persons who, in fulfillment of a requirement in a statute or another part of FDA’s regulations to maintain records or submit information to FDA, have chosen to maintain the records or

submit designated information electronically and, as a result, have become subject to part 11. Part 11 applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted under any records requirements set forth in Agency regulations. Part 11 also applies to electronic records submitted to the Agency under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, even if such records are not specifically identified in Agency regulations (§ 11.1).

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§ 11.100 .....	4,500	1	4,500	1	4,500

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

21 CFR section	Number of recordkeepers	Number of record per recordkeepers	Total annual records	Average burden per recordkeeping	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

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: August 5, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2020–17711 Filed 8–12–20; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2020–D–1298]

#### Acute Myeloid Leukemia: Developing Drugs and Biological Products for Treatment; Draft Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft

guidance for industry entitled “Acute Myeloid Leukemia: Developing Drugs and Biological Products for Treatment.” This draft guidance is intended to assist sponsors in the clinical development of drugs and biological products for the treatment of acute myeloid leukemia (AML). This draft guidance addresses FDA’s current thinking regarding the overall development program and clinical trial designs for the development of drugs and biological products to support an indication of treatment of AML, including indications limited to an individual phase of treatment (for example, maintenance, transplantation preparative regimen, etc.). The draft guidance addresses the topics of general drug development, efficacy endpoints, and exploratory and confirmatory trial considerations for AML drug development. In addition, the draft guidance addresses investigational new drug applications, new drug applications, and biologics licensing applications for AML drugs.

**DATES:** Submit either electronic or written comments on the draft guidance

by October 13, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time 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