

at the meeting or in a submission to the docket, but we emphasize that the focus of this meeting is to seek input that prioritizes feedback specifically on characteristics of the Integrated Review document. Please see information and examples relevant to the Integrated Review at <http://wcms-internet.fda.gov/drugs/news-events-human-drugs/integrated-assessment-marketing-applications-workshop-10302020-10302020>.

Furthermore, we anticipate that the most informative suggestions would not be specific to an indication, a therapeutic area, or a disease but rather apply across multiple indications, therapeutic areas, or diseases. We are particularly interested in the topics that follow:

1. We are interested in preserving for stakeholders what they find most useful in FDA reviews.

a. Comparing the Integrated Review to previous reviews, is there any information you are having difficulty locating?

b. Are you able to use the Integrated Review for the same purpose that you used previous reviews? If not, please provide specific examples.

2. We are interested in specific recommendations about any areas of the Integrated Review documentation of the Integrated Assessment that can be improved to meet the needs of stakeholders.

3. We are interested in stakeholders' views regarding the advantages and disadvantages of an interdisciplinary assessment presentation of key review issues and resulting integration of the assessments of multiple disciplines into a single Integrated Review document.

4. We would like to know whether the new format of the Integrated Review document for the Integrated Assessment can provide clarity of benefit-risk assessments and inform your knowledge of FDA's basis for making decisions.

### III. Participating in the Public Workshop

**Registration:** Please visit the following website to register: <https://www.eventbrite.com/e/integrated-assessment-of-marketing-applications-workshop-tickets-102979608782>. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Persons interested in attending this virtual public workshop must register by September 30, 2020, by 11:59 p.m. Eastern Time.

**Requests for Oral Presentations:** During online registration you may indicate if you wish to present during a

public comment session or participate in a specific session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments and requests to participate in the focused sessions. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by October 14, 2020. All requests to make oral presentations must be received by the close of registration on September 30, 2020, by 11:59 p.m. EST. If selected for presentation, submit electronic copies of any presentation materials (Power Point or PDF) to [ONDPublicMTGSupport@fda.hhs.gov](mailto:ONDPublicMTGSupport@fda.hhs.gov) no later than October 21, 2020. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

**Streaming Webcast of the Public Workshop:** This webcast for this public workshop is available at <https://collaboration.fda.gov/newdrugs103020/>. If you have never attended a Connect Pro event before, test your connection at [https://collaboration.fda.gov/common/help/en/support/meeting\\_test.htm](https://collaboration.fda.gov/common/help/en/support/meeting_test.htm). To get a quick overview of the Connect Pro program, visit [https://www.adobe.com/go/connectpro\\_overview](https://www.adobe.com/go/connectpro_overview). FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

**Transcripts:** Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at <http://wcms-internet.fda.gov/drugs/news-events-human-drugs/integrated-assessment-marketing-applications-workshop-10302020-10302020>.

Dated: August 7, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2020-17721 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-2017-N-4951]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Humanitarian Use Devices

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) 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 information collection requirements for humanitarian use devices (HUDs).

**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-2017-N-4951 for “Agency Information Collection Activities; Proposed Collection; Comment Request: Medical Devices; Humanitarian Use Devices.” 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, 240-402-7500.

- **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, 240-402-7500.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, [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.

#### Medical Devices; Humanitarian Use Devices—21 CFR Part 814

OMB Control Number 0910-0332—Extension

This collection of information implements the humanitarian use devices (HUDs) provision of section 520(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(m)) and part 814, subpart H (21 CFR part 814, subpart H). Under section 520(m) of the FD&C Act, FDA is authorized to exempt an HUD from the effectiveness requirements of sections 514 and 515 of the FD&C Act (21 U.S.C. 360d and 360e) provided that the device: (1) Is designed to treat or diagnose a disease or condition that affects no more than 8,000 individuals in the United States; (2) would not be available to a person with a disease or condition unless an exemption is granted and there is no comparable device other than another HUD approved under this exemption that is available to treat or diagnose such disease or condition; and (3) will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from the use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

Respondents may submit a humanitarian device exemption (HDE) application seeking exemption from the effectiveness requirements of sections 514 and 515 of the FD&C Act as authorized by section 520(m)(2) of the FD&C Act. The information collected will assist FDA in making determinations on the following: (1) Whether to grant HUD designation of a medical device; (2) whether to exempt an HUD from the effectiveness requirements under sections 514 and 515 of the FD&C Act, provided that the device meets requirements set forth under section 520(m) of the FD&C Act; and (3) whether to grant marketing approval(s) for the HUD. Failure to collect this information would prevent FDA from making a determination on the factors listed previously in this document. Further, the collected information would also enable FDA to determine whether the holder of an HUD is in compliance with the HUD provisions under section 520(m) of the FD&C Act.

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
<b>Total</b> .....					<b>22,396</b>

<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]  
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**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.