

2. Modeling natural history of disease, specifically methodological considerations and challenges in characterizing the natural relationship between pharmacodynamic markers and clinical outcomes.

3. Clinical trial simulations based on disease progression/natural history models to support drug development and regulatory decisions.

Dated: February 16, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-N-4951]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Humanitarian Use Devices

**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 March 26, 2021.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>.

[www.reginfo.gov/public/do/PRAMain](https://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. The OMB control number for this information collection is 0910-0332. Also include the FDA docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, [PRASStaff@fda.hhs.gov](mailto: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.

#### 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.

In the **Federal Register** of August 13, 2020 (85 FR 49379), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although two comments were received, they were not responsive to the four collection of information topics solicited.

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 institutional review board 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 recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
HDE Records—814.126(b)(2) .....	62	1	62	2	124

<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 5,803 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. Based on further review, the estimated number of recordkeepers has been adjusted from 65 respondents to 62 respondents in table 2 to reflect the most current data available. Therefore, under § 814.126(b)(2) in table 2, the estimated number of recordkeepers is 62.

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 an 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: February 16, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021–03746 Filed 2–23–21; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Information Collection Request Title: Rural Health Clinic COVID–19 Testing Program Data Collection, OMB No. 0906–0056—Extension

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA’s ICR only after the 30 day comment period for this notice has closed.

**DATES:** Comments on this ICR should be received no later than March 26, 2021.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://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.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information

Collection Clearance Officer at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443–1984.

#### SUPPLEMENTARY INFORMATION:

*Information Collection Request Title:* Rural Health Clinic COVID–19 Testing Program Data Collection, OMB No. 0906–0056—Extension.

*Abstract:* This ICR is for continued approval of the Rural Health Clinic (RHC) COVID–19 Testing Program Data Collection. HRSA is proposing to continue this data collection with no changes. The current performance measures are collected electronically in the RHC COVID–19 Testing Report (CTR), which funded providers access via [rhccovidreporting.com](http://rhccovidreporting.com). RHC COVID–19 Testing Program Data Collection supports the HRSA requirement to monitor and report on funds distributed under the Paycheck Protection Program and Health Care Enhancement Act. Signed into law on April 24, 2020, the Paycheck Protection Program and Health Care Enhancement Act appropriated \$225 million to RHCs to support COVID–19 testing efforts, expand access to testing in rural communities, and other related expenses. On May 20, 2020, HRSA issued funding as one-time payments to 2,406 RHC organizations based on the number of certified clinic sites they operate, providing \$49,461.42 per clinic site (4,549 RHC clinic sites total across the country).

The RHC CTR collects monthly, aggregate data from funded organizations. Funded organizations provide basic identifying information, report on the number of and location of testing sites, indicate how they used the funds, and report the total number of patients tested and the number of tests with a positive result.

Funded organizations must report the number of patients tested and the number of positive tests on a monthly