TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1] [2]—Continued

21 CFR citation	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Part 809 (in vitro diagnostic products for human use) and part 1040 (light-emitting products)					
Format and content of labeling for IVDs; 809.10	1,700	6	10,200	80	816,000
Advertising and promotional materials for ASRs; 809.30(d).	300	25	7,500	1	7,500
Labeling of sunlamp products—1040.20(d)	30	1	30	10	300
FD&C Action Section 502(u)					
Establishments listing <10 SUDs	161	2	322	0.1 (6 minutes)	32
Establishments listing >10 SUDs	14	45	630	0.1 (6 minutes)	63
Part 660, subparts A, C, D, E, and F: Antibody to Hepatitis B Surface Antigen; Blood Grouping Reagent; Reagent Red Blood Cells; Hepatitis B Surface Antigen; Anti-Human Globulin; Part 801 subpart A: General Labeling Provisions; Part 809, subpart B: Labeling					
Symbols glossary—660.2; antibody to Hepatitis B surface antigen requirements, 660.28; blood grouping labeling, 660.35; reagent red blood cell labeling, 660.45, hepatitis B surface antigen labeling, 660.55; anti-human globulin labeling, 801.15; medical devices labeling and use of symbols; 809.10, labeling for in vitro diagnostic products.	3,000	1	3,000	4	12,000
Part 801, subpart B					
UDI	[3] 5,987	51	[4] 305,337	0.8833 (53 minutes)	269,704
Total			20,752,542		8,754,765

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded.
[3] Maximum No. of Respondents for any regulatory requirement within each category. Individual regulatory requirements within the category may involve fewer respondents.
[4] Maximum Total Annual Responses for any regulatory requirement within each category. Individual regulatory requirements within the category may involve fewer total annual responses.

Because many labeling provisions correspond to specific recordkeeping requirements, we have accounted for burden attendant to the provisions enumerated in table 3 as third-party disclosures. These figures reflect what we believe to be the average burden incurred by respondents to applicable information collection activities.

We are revising this information collection to include OMB control number 0910–0720. Our estimated burden for the information collection reflects an overall increase of 579,633 hours and a corresponding increase of 926,823 responses/records. We attribute this adjustment to the revision of this information collection to include OMB control number 0910–0720.

Dated: August 18, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–18275 Filed 8–23–22; 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; 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, Agency, or we) 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 September 23, 2022.

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.* 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, *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.

Medical Devices; Humanitarian Use Devices—21 CFR part 814

OMB Control Number 0910–0332—Revision

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.

HUDs approved under an HDE cannot be sold for an amount that exceeds the costs of research and development, fabrication, and distribution of the device (*i.e.,* for profit), except in narrow circumstances. Under section 520(m)(6)(A)(i) of the FD&C Act, an HUD approved under an HDE is eligible to be sold for profit if the device meets the following criteria: The device is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs; or the device is intended for the treatment or diagnosis of a disease or condition that does not occur in pediatric patients, or that occurs in pediatric patients in such numbers that the development of the device for such patients is impossible, highly impracticable, or unsafe.

Section 520(m)(6)(A)(ii) of the FD&C Act, provides that the Secretary of Health and Human Services will determine the annual distribution number (ADN) for devices that meet the eligibility criteria to be permitted to be sold for profit. The Cures Act amended the FD&C Act definition of the ADN as the number of devices reasonably needed to treat, diagnose, or cure a population of 8,000 individuals in the United States.

Section 520(m)(6)(A)(iii) of the FD&C Act provides that an HDE holder immediately notify the Agency if the number of such devices distributed during any calendar year exceeds the ADN. Section 520(m)(6)(C) of the FD&C Act provides that an HDE holder may petition to modify the ADN if additional information arises.

In the **Federal Register** of April 7, 2022 (87 FR 20429), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was 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 [1]

Activity/21 CFR section or FD&C Act 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
Pediatric Subpopulation and Patient Information—515A(a)(2) of the FD&C Act (21 U.S.C. 360e–1(a)(2))	1	1	1	100	100
Exemption from Profit Prohibition Information—520(m)(6)(A)(i) and (ii) of the FD&C Act	1	1	1	50	50
Request for Determination of Eligibility Criteria—section 613(b) of the Food and Drug Administration Safety and Innovation Act	1	1	1	10	10
ADN Notification—520(m)(6)(A)(iii) of the FD&C Act	1	1	1	100	100
ADN Modification—520(m)(6)(C) of the FD&C Act	1	1	1	100	100
Total					22,756

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

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

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

TABLE 3.—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

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

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

Our estimated burden for the information collection reflects an increase of 360 total burden hours and a corresponding increase of five total annual responses. For efficiency of Agency operations, we are consolidating the related information activity and account for burden associated with HDE regulations currently approved in OMB control number 0910–0661. As a result, there is an increase in the total number of burden hours for this information collection.

Dated: August 17, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–18271 Filed 8–23–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0430]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Generic Clearance for Quick Turnaround Testing of Communication Effectiveness

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 September 23, 2022.

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.* 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 0910–0876. 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, *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.

Generic Clearance for Quick Turnaround Testing of Communication Effectiveness

OMB Control Number 0910–0876—Extension

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) enables FDA to better protect public health by helping to ensure the safety and security of the food supply. It enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. FSMA recognizes the important role consumers and stakeholders play in ensuring the safety of the food supply, which helps ensure that suppliers produce food that meets U.S. safety standards.

Occasionally, FDA will need to communicate with consumers and other stakeholders about immediate health issues that could affect public health and safety. This collection of information allows the use of fast-track methods of communication such as quick turnaround surveys, focus groups, and indepth interviews collected from consumers and other stakeholders to communicate FDA issues of immediate and important public health significance. We plan on using these methods of communication to collect vital public health and safety information.

For example, these methods of communication might be used when there is a foodborne illness outbreak, food recall, or other situation requiring expedited FDA food, dietary supplement, cosmetics, or animal food or feed communications. So that FDA may better protect the public health, the Agency needs quick turnaround information provided by this collection of information to help ensure its messaging has reached the target audience, has been effective, and, if needed, to update its communications during these events.

Respondents to this collection of information include a wide range of consumers and other FDA stakeholders such as producers and manufacturers of FDA-regulated food and cosmetic products, dietary supplements, and animal food and feed. Participation will be voluntary.

In the **Federal Register** of April 18, 2022 (87 FR 22906), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although three comments were received, they were not responsive to the four collection of information topics solicited.

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