

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN ¹—Continued

Activity/21 CFR section; or Form No.	Numbers of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
Total					26,632	\$11,200

¹There are no capital costs associated with this collection of information.
²Form FDA 3503 is used for both CAPs and FAPs.

Based on a review of the information collection since our last request for OMB approval, we have adjusted our burden estimate for CAPs since the average number submitted has increased over the last 10 years. Due to the increase of submissions, we estimate that 4 CAPs will be submitted annually. Thus, the estimated burden for the information collection reflects an overall increase of 2,674 hours. Our estimate of burden attributable to FAPs or CAPs is based on our experience with the information collection, which FAPs has not changed since our last review and reflects the average number of petitions we have received annually over a period of 10 years. The attendant burden we estimate also reflects an industry average, although burden associated with individual petitions may vary depending on the complexity of the petition, and the amount and type of data needed for scientific analysis.

CAPs are subject to fees. The listing fee for a CAP ranges from \$1,600 to \$3,000, depending on the intended use of the color additive and the scope of the requested amendment. A complete schedule of fees is set forth in 21 CFR 70.19. An average of two Category A and two Category B CAPs are expected per year. The maximum CAP fee for a Category A petition is \$2,600, and the maximum CAP fee for a Category B petition is \$3,000. Because an average of four CAPs are expected per calendar year, the estimated total annual operating and maintenance cost burden to petitioners for this startup cost would be less than or equal to \$11,200 ((2 × \$2,600) + (2 × \$3,000) listing fees). There are no capital costs associated with CAPs.

The labeling requirements for food and color additives were designed to specify the minimum information needed for labeling so that food and color manufacturers may comply with all applicable provisions of the FD&C Act and other specific labeling acts administered by FDA. Label information does not require any additional information gathering beyond what is already required to assure conformance with all specifications and limitations in any given food or color additive regulation. Label information does not

have any specific recordkeeping requirements unique to preparing the label. Therefore, because labeling requirements under § 70.25 for a particular color additive involve information required as part of the CAP safety review process, the estimate for number of respondents is the same for §§ 70.25 and 71.1, and the burden hours for labeling are included in the estimate for § 71.1. Also, because labeling requirements under parts 172, 173, 179, and 180 for particular food additives involve information required as part of the FAP safety review process under § 171.1, the burden hours for labeling are included in the estimate for § 171.1.

Grace R. Graham,
Deputy Commissioner for Policy, Legislation, and International Affairs.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–10132]

Agency Information Collection Activities; Proposed Collection; Comment Request; Protection of Human Subjects and Institutional Review Boards

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 information collection requirements for the tracking of medical devices.

DATES: Either electronic or written comments on the collection of information must be submitted by November 30, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 30, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2026–N–10132 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Protection of Human Subjects and Institutional Review Boards.” 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: 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, PRASStaff@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.

Protection of Human Subjects; Informed Consent; and Institutional Review Boards—21 CFR Parts 50 and 56

OMB Control Number 0910–0130—Extension

This information collection supports Agency regulations pertaining to the protection of human subjects, informed consent, and responsibilities of institutional review boards (IRBs) as set forth in parts 50 and 56 (21 CFR parts 50 and 56). Parts 50 and 56 apply to all clinical investigations regulated by FDA under sections 505(i) and 520(g) of the

Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i) and 360j(g), respectively), as well as clinical investigations that support applications for research or marketing permits for products regulated by FDA. The regulations in parts 50 and 56 are intended to protect the rights and safety of subjects involved in such investigations. The regulations also contain the standards for composition, operation, and responsibilities of IRBs that review clinical investigations regulated by FDA.

21 CFR Part 50—Protection of Human Subjects

Provisions in part 50 provide for the protection of human subjects involved in FDA-regulated clinical investigations. With few exceptions, no investigator may involve a human being as a subject in FDA-regulated research unless the investigator has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative. Basic elements of informed consent are set forth in § 50.25 (21 CFR 50.25) and include, among other things: (1) a statement of the purpose and duration of a subject’s participation in the research; (2) a description of the procedures to be followed; (3) identification of any experimental procedures; (4) a description of risks, benefits, and appropriate alternative procedures or treatments; (5) a description of extent to which confidentiality of records identifying the subject will be maintained; (6) certain contact information; and (7) a statement that participation is voluntary and may be discontinued at any time. Additional elements set forth in § 50.25 are required in the informed consent as appropriate. Exceptions to these requirements are governed by 21 CFR 50.23, which requires both investigator and physician to certify in writing that necessary elements for exception from general requirements have been satisfied; and § 50.24 (21 CFR 50.24), which covers exception from informed consent requirements for emergency research. In accordance with § 50.27 (21 CFR 50.27) informed consent must be documented, except as provided in § 56.109(c) (21 CFR 56.109(c)), which provides for an IRB to waive documentation of informed consent in certain circumstances.

Informed consent must be documented using a written consent form approved by the IRB and signed and dated by the subject or the subject’s legally authorized representative at the time of consent. For each clinical investigation reviewed by an IRB, we

believe there will typically be one associated written consent form developed by an investigator. In some cases, investigators will seek IRB approval of changes in the research and/or consent form after initial IRB approval. For some multi-institutional clinical investigations, the IRB of each institution involved may separately conduct initial and continuing review of the research, including review of the written consent form to determine whether it is in accordance with § 50.25. However, in cases where a multi-institutional clinical investigation uses a single IRB review process, there may only be one IRB conducting such reviews. Additional safeguards are required for children, as prescribed in subpart D (21 CFR 50.50 through 50.56) of the regulations.

21 CFR Part 56—Institutional Review Boards

The general standards for the composition, operation, and responsibilities of an IRB are set forth in part 56. IRBs serve in an oversight capacity by reviewing, among other things, informed consent documents and protocols for FDA-regulated studies, to make findings required to approve research, and document IRB actions. Part 56 also regulates the administrative activities of IRBs reviewing FDA-regulated research including, among

other things, identification of types of IRB records that must be prepared and maintained. Required recordkeeping includes documentation pertaining to written procedures, proposals reviewed, committee membership, meeting minutes, actions taken by the IRB, correspondence, as well as other functional and operational aspects of the IRB. Finally, the regulations describe administrative actions for noncompliance, including both disqualification of IRBs or IRB parent institutions, as well as reinstatement and alternative and additional actions.

The information collection also includes burden that may be attributable to requesting certain *Certificates of Confidentiality* (CoC). The 21st Century Cures Act (Cures Act) (Pub. L. 114–255, section 2012) amended the Public Health Service Act, section 301(d) (42 U.S.C. 241(d)), to help protect the privacy of human subject research participants from whom identifiable, sensitive information is being collected or used in furtherance of the research. The guidance document entitled, “*Certificates of Confidentiality; Guidance for Sponsors, Sponsor-Investigators, Researchers, Industry, and Food and Drug Administration Staff*” (November 2020), identifies agency contacts and provides instruction on how to request a discretionary CoC;

explains the statutory requirements for requesting such a CoC; and communicates the statutory responsibilities associated with possessing a CoC. The Cures Act simplified certain aspects of the issuance of CoCs by requiring that CoCs be issued for federally-funded human subject research that collects or uses identifiable, sensitive information (referred to in this guidance as mandatory CoCs). For non-federally funded research, issuance of CoCs is not required but may be issued at the discretion of FDA (referred to as *discretionary* CoCs). The guidance was developed and issued consistent with our Good Guidance Practice regulations at 10.115 which provide for public comment at any time. The guidance is available for download from our website at <https://www.fda.gov/media/132966/download>.

Description of Respondents: Respondents to the information collection are IRBs that review and approve clinical investigations regulated by FDA and clinical investigators of such research who obtain informed consent of human subjects prior to research participation.

We are retaining the currently approved burden estimates for the collections of information, which are 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	Total hours
56.113; suspension or termination of research ...	2,520	1	2,520	0.5 (30 minutes)	1,260
56.120(a); IRB response to lesser administration actions for noncompliance.	7	1	7	10	70
56.123; reinstatement of an IRB or an institution	1	1	1	5	5
Requests for discretionary certificates of confidentiality.	28	1	28	1	28
Total			2,556		1,363

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

Based on available data, there are approximately 2,520 IRBs overseeing FDA-regulated clinical research. We have organized the table summarizing estimated annual reporting burden to

list only one requirement per row recognizing that some provisions may also include recordkeeping or third-party disclosure tasks. We believe we have accounted for all burden

cumulatively across the information collection activity tables and invite comments on our estimates.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
50.24; exceptions from informed consent for emergency research.	8	3	24	1	24
50.27; documentation of informed consent	2,520	40	100,800	0.5 (30 minutes)	50,400

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹—Continued

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
56.115; IRB records (documentation of IRB activities), including waiver request reviews..	2,520	14.6	36,792	40	1,471,680
Total					1,522,104

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

We characterize activities associated with §§ 50.24 and 50.27 as recordkeeping burden. We assume each of the 2,520 IRBs meets an average of

14.6 times annually and assume 40 hours of person-time per meeting are required to meet the IRB recordkeeping requirements of § 56.115. We also

assume most recordkeeping is completed electronically.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
50.25; elements of informed consent	2,520	40	100,800	0.5 (30 minutes)	50,400
56.109(d); written statement about minimal risk research when documentation of informed consent is waived.	2,520	2	5,040	0.5 (30 minutes)	2,520
56.109(e); written notification to approve or disapprove research.	2,520	40	100,800	0.5 (30 minutes)	50,400
56.109(g); IRB written statement about public disclosures to sponsor of emergency research under § 50.24.	8	2	16	1	16
Total					103,336

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

We characterize activities associated with §§ 50.25 and 56.109(d) and (e) as disclosure burden. We estimate that eight IRBs per year will receive a request to review emergency research under § 50.24, thus requiring written notification under § 56.109(g) from the IRB to the sponsor. We estimate that it will take an IRB approximately 1 hour to prepare each written statement for a total of 2 hours per study. The total annual third-party disclosure burden for IRBs to fulfill this requirement is estimated at 16 hours.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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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; National Marrow Donor Program Patient Support Center Survey

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 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 October 29, 2026.

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. 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 Samantha Miller, the HRSA Information Collection Clearance Officer, at paperwork@hrsa.gov or call (301) 443–9094.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: National Marrow Donor Program Patient Support Center Survey, OMB No. 0906–0004—Revision.

Abstract: The C.W. Bill Young Cell Transplantation Program (CWBYCTP) was established by the Stem Cell Therapeutic and Research Act of 2005 (Public Law [Pub. L.] 109–129) and was reauthorized in 2010 (Pub. L. 111–264), 2015 (Pub. L. 114–104), and again in 2021 (Pub. L. 117–15). The CWBYCTP's