TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Information collection activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
Total						352,000

[1] There are no capital costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Information collection activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
CLIA Waiver Recordkeeping as discussed in FDA Guidance	13	1	13	2,800	36,400

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

We have revised the information collection to include coverage previously accounted for under OMB control number 0910–0598 and discussed in revised Agency guidance. We otherwise retain our estimates of the burden we attribute to the individual elements included in the information collection.

Dated: June 9, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–12929 Filed 6–15–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0571]

Ortho-phthalates for Food Contact Use; Request for Information

Correction

In notice document 2022–10532, appearing on pages 31090–31091, in the issue of Friday, May 20, 2022, make the following correction:

On page 31090, in the first column, in the standard document heading, the Subject line that reads ''Ortho-phthlates for Food Contact Use; Request for Information'' is corrected to read ''Ortho-phthalates for Food Contact Use; Request for Information''.

[FR Doc. C1–2022–10532 Filed 6–15–22; 8:45 am]

BILLING CODE 0099–10–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–1470]

Technical Performance Assessment of Quantitative Imaging in Radiological Device Premarket Submissions; Guidance for Industry and Food and Drug Administration Staff; 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 final guidance entitled ''Technical Performance Assessment of Quantitative Imaging in Radiological Device Premarket Submissions.'' FDA is issuing this guidance to provide recommendations for manufacturers about the information that should be included in premarket submissions for radiological devices that include quantitative imaging functions. This guidance document is broadly applicable to a variety of premarket submission types (*i.e.,* premarket approval applications (PMAs), humanitarian device exemption (HDE) applications, premarket notification (510(k)) submissions, investigational device exemption (IDE) applications, and De Novo requests) for these devices and should be used in conjunction with existing device- and submission-specific guidance documents.

DATES: The announcement of the guidance is published in the **Federal Register** on June 16, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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 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–2019–D–1470 for ''Technical Performance Assessment of Quantitative Imaging in Radiological Device Premarket Submissions.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Technical Performance Assessment of Quantitative Imaging in Radiological Device Premarket Submissions'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Jana Delfino, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, Rm. 3116, Silver Spring, MD 20993–0002, 301–796–6503.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing this guidance to provide recommendations for manufacturers about the information that should be included in premarket submissions for radiological devices that include quantitative imaging functions. This guidance document is broadly applicable to a variety of premarket submission types (*i.e.,* PMAs, HDE applications, 510(k) submissions, IDE applications, and De Novo requests) for these devices and should be used in conjunction with existing device- and submission-specific guidance documents.

This guidance document clarifies that, in general, manufacturers preparing premarket submissions for radiological devices that include quantitative imaging functions should provide performance specifications for the quantitative imaging functions, supporting performance data to demonstrate that the quantitative imaging functions meet those performance specifications, and sufficient information for the end user to obtain, understand, and interpret the values provided by the quantitative imaging functions.

A notice of availability of the draft guidance appeared in the **Federal Register** of April 19, 2019 (84 FR 16517). FDA considered comments received and revised the guidance as appropriate in response to the comments, including clarification in scope that the guidance is intended to provide recommendations for radiological devices with quantitative imaging functions, and other technical clarifications.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on technical performance assessment of quantitative imaging in radiological device premarket submissions. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov* or *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Technical Performance Assessment of Quantitative Imaging in Radiological Device Premarket Submissions'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 18017 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part or guidance	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120

21 CFR part or guidance	Topic	OMB control No.
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
"De Novo Classification Process (Evaluation of Automatic Class III Designation)"	De Novo classification process	0910–0844
"Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program and Meetings with Food and Drug Administration Staff".	Q-submissions; pre-submissions	0910–0756
800, 801, and 809	Medical Device Labeling Regulations	0910–0485

Dated: June 9, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–12930 Filed 6–15–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0955–0020]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before August 15, 2022.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 795–7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0955–0020–60D and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@hhs.gov,* or call (202) 795–7714 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: United States Core Data for Interoperability New Data Element.

Type of Collection: Revision.

OMB No.: 0955–0020—Office of the National Coordinator for Health Information Technology—Specific program collecting the data (is applicable).

Abstract: The Office of the National Coordinator for Health Information Technology is seeking the revision on a previously approved by OMB #0955–0020 information collection request item ''United States Core Data for Interoperability (USCDI) New Data Element Submission Form.'' The USCDI is a standardized set of health data classes and constituent data elements used to support nationwide, interoperable health information exchange. The USCDI Version 1 is the required standard data elements set to which all health IT developers must conform to obtain ONC certification. This certification is required for participation in some federal healthcare payment plans. In order to ensure the USCDI remains current and reflects the needs of the health IT community, ONC has established a predictable, transparent, and collaborative process to solicit broad stakeholder input to expand the USCDI. Anyone, including ONC staff, staff from other federal agencies, and other stakeholders may submit proposals for new data elements and classes. ONC will evaluate each submission and provide feedback to the submitter. ONC will draft a new version of the USCDI based on these submissions and this draft will undergo review by ONC's federal advisory committee, the Health Information Technology Advisory Committee (HITAC), as well as by the general public. Upon approval by the National Coordinator for Health Information Technology, new data classes and data elements from these submissions will be added to the newest version of the USCDI standard for integration into health information technology products such as electronic health records. ONC is seeking approval to continue to collect this information from health IT stakeholders.

Need and Proposed Use of the Information: The information collected from this submission system is needed as it will comprise the sum total of the items ONC will evaluate for addition to the next version of the USCDI. The requested data will provide supporting documentation to justify addition of the data elements to the USCDI, and, if the documentation does justify addition to the USCDI, to one of several levels of candidate data elements for future development and consideration. The requested data and ONC's evaluation of the data will be publicly available for review at any time to provide transparency and predictability in the USCDI expansion process. It will contain information about the submitter to allow ONC to provide direct feedback to submitters on ONC's evaluation of such submission.

Likely Respondents: Likely respondents to this new submission system will be various health IT stakeholders including health care providers, standards development organizations, health IT developers and vendors as well as members of the HITAC.

The total annual burden hours estimated for this ICR are summarized in the table below.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
USCDI Submission		200	1	20/60	67