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]

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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.''