

Certain patients with early-stage solid tumors can be cured with local therapy alone (e.g., surgery, radiation, or chemoradiation), other patients require (neo)adjuvant systemic therapy in order to be cured, and others may progress to metastatic disease despite surgery and/or systemic therapy. ctDNA is tumor-derived fragmented DNA shed into a patient's bloodstream that is not associated with cells. ctDNA quantity can vary among individuals and depends on the type of tumor, location, stage, tumor burden, and response to therapy. ctDNA as a biomarker has a number of potential regulatory and clinical uses in the early-stage setting that may assist and expedite drug development. In the early-stage cancer setting, ctDNA may be used to detect a certain targetable alteration, to enrich a high- or low-risk population for study in a trial, to reflect a patient's response to treatment, or, potentially, as an early marker of efficacy.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Use of Circulating Tumor DNA for Early-Stage Solid Tumor Drug Development." 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. Paperwork Reduction Act of 1995

While this guidance contains no 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 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR part 800 have been approved under OMB control number 0910–0625 and the collections of information pertaining to submission of a biologics license application under section 351(k) of the Public Health

Service Act (42 U.S.C. 262(k)) have been approved under OMB control number 0910–0719.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: April 26, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4465]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Administrative Detention and Banned Medical 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: Fax written comments on the collection of information by June 2, 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. All comments should be identified with the OMB control number 0910–0114. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–45, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, 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.

Administrative Detention and Banned Medical Devices

OMB Control Number 0910–0114—Extension

FDA has the statutory authority under section 304(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 334(g)) to detain during established inspections devices that are believed to be adulterated or misbranded. Section 800.55 (21 CFR 800.55), on administrative detention, includes among other things certain reporting requirements (§ 800.55(g)(1) and (2)) and recordkeeping requirements (§ 800.55(k)). Under § 800.55(g), an appellant of a detention order must show documentation of ownership if devices are detained at a place other than that of the appellant. Under § 800.55(k), the owner or other responsible person must supply records about how the devices may have become adulterated or misbranded, in addition to records of distribution of the detained devices. These recordkeeping requirements for administrative detentions permit FDA to trace devices for which the detention period expired before a seizure is accomplished or injunctive relief is obtained.

FDA also has the statutory authority under section 516 of the FD&C Act (21 U.S.C. 360f) to ban devices that present substantial deception or an unreasonable and substantial risk of illness or injury. Section 895.21 (21 CFR 895.21), on banned devices, contains certain reporting requirements. Section 895.21(d) describes the procedures for banning a device when the Commissioner of Food and Drugs (the Commissioner) decides to initiate such a proceeding. Under 21 CFR 895.22, a manufacturer, distributor, or importer of a device may be required to submit to FDA all relevant and available data and information to enable the Commissioner to determine whether the device presents substantial deception, unreasonable and substantial risk of illness or injury, or unreasonable, direct, and substantial danger to the health of individuals.

In the **Federal Register** of November 22, 2021 (86 FR 66315), we published a 60-day notice requesting public comment on the proposed collection of

information. One comment was received communicating general support for the information collection. Although the comment suggested the Agency's

burden estimate may be too low, no figures were provided.

We estimate the burden of this collection of information 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
Administrative detention reporting requirements—800.55(g) and (h)	1	1	1	25	25
Banned devices reporting requirements—895.21(d)(8) and 895.22(a)	26	1	26	16	416
Total					441

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

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
Records regarding device adulteration or misbranding and records of distribution of detained devices—800.55(k)	1	1	1	20	20

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

During the past several years, there has been an average of less than one new administrative detention action per year. Each administrative detention will have varying amounts of data and information that must be maintained.

Administrative Detention Reporting—§ 800.55(g)(1) and (2): A person who would be entitled to claim the devices, if seized, may appeal a detention order by submitting a written request to the FDA District Director in whose district the devices are located. This written appeal could include a request for an informal hearing as defined in section 201(y) of the FD&C Act (21 U.S.C. 321(y)). In some cases, the appellant must include documents showing that that person has the legal right to appeal this order.

Movement of Detained Devices—§ 800.55(h)(2): If detained devices are not in final form for shipment, the manufacturer may move them within the establishment where they are detained to complete the work needed to put them in final form. As soon as the devices are moved for this purpose, the individual responsible for their movement shall orally notify the FDA representative who issued the detention order, or another responsible district office official, of the movement of the devices. As soon as the devices are put in final form, they shall be segregated from other devices, and the individual responsible for their movement shall orally notify the FDA representative who issued the detention order, or another responsible district office official, of their new location. The devices put in final form shall not be moved further without FDA approval.

Administrative Detention Recordkeeping—§ 800.55(k): The firm shall have, or establish, and maintain records relating to how the detained devices may have become adulterated or misbranded, records on any distribution of the devices before and after the detention period, records on the correlation of any in-process detained devices that are put in final form, records of any changes in, or process of, the devices permitted under the detention order, and records of any movement of the detained devices.

Procedures for Banned Devices Informal Hearing Request—§ 895.21(d)(8): Section 895.21(d) describes the procedures for banning a device when the Commissioner decides to initiate such a proceeding. Under § 895.21(d), the Commissioner may decide to initiate a proceeding to make a device a banned device. In that event, any interested persons may submit written comments and request an informal hearing within 30 days after the date of the publication of the proposed regulation.

Banned Devices Reporting—§ 895.22(a): A manufacturer, distributor, or importer of a device may be required to submit to FDA all relevant and available data and information to enable the Commissioner to determine whether the device presents substantial deception, unreasonable and substantial risk of illness or injury, or unreasonable, direct, and substantial danger to the health of individuals.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: April 27, 2022.

Lauren K. Roth,
Associate Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA-2011-D-0125]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007

AGENCY: Food and Drug Administration, HHS.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA 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 June 2, 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