

United States Food and Drug Administration
Administrative Detention and Banned Medical Devices

OMB Control No. 0910-0114 --EXTENSION

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) regulations. Under the statutory authority of section 304(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 334(g)), FDA officers or employees duly designated by the Secretary of Health and Human Services (FDA investigators) may, during establishment inspections, detain devices that are believed to be adulterated or misbranded. <http://www.gpo.gov/fdsys/pkg/USCODE-2010-title21/pdf/USCODE-2010-title21-chap9-subchapIII-sec334.pdf>

Implementing regulations regarding administrative detention procedures are found in 21 CFR 800.55, which includes certain reporting requirements (§ 800.55(g)(1) and (g)(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, as well as records of distribution of the detained devices. These recordkeeping requirements for administrative detentions allow FDA to trace devices for which the detention period expired before a seizure is accomplished or injunctive relief is obtained.

Under section 516 of the FD&C Act (21 U.S.C. 360f), FDA also has the statutory authority to ban devices that present substantial deception, or unreasonable and substantial risk of illness or injury, or unreasonable, direct, and substantial danger to the health of individuals. Implementing regulations regarding banned devices are found in 21 CFR part 895 and include certain reporting requirements in §§ 895.21(d) and 895.22(a).

We therefore request extension of OMB approval of the information collection provisions found in 21 CFR 800.55 and Part 895, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

Data and information collected under the reporting and recordkeeping requirements of the administrative detention and banned device regulations are used by the Agency to determine whether the devices that are believed to be adulterated and/or misbranded; present substantial deception, unreasonable and substantial risk of illness or injury, or unreasonable, direct, and substantial danger to the health of individuals, are removed from the marketplace. If the FDA did not have these regulations, it would not have access to certain types of data and information that

industry possesses. Thus, the collection of this information enables the Agency to perform its mission of protecting the public health.

When a detention order is put into place, the Agency must know whether any other devices that would be subject to the order were distributed prior to that time to assure that those devices are removed from the marketplace and do not cause any adverse effects. The recordkeeping requirement of the Administrative Detention regulation gives FDA the authority to obtain distribution information that the Agency might not otherwise have. This recordkeeping requirement may also provide FDA with an answer for how the devices became adulterated and/or misbranded.

If the Commissioner of Food and Drugs believes that more information is necessary for the Agency to determine whether the device presents a substantial deception, an unreasonable and substantial risk of illness or injury, or unreasonable, direct, and substantial danger to the health of individuals, FDA would require that the manufacturer, distributor, or importer submit all relevant and available data and information. After consulting with the appropriate classification panel, FDA may initiate a proceeding to ban the device by publishing a proposed regulation in the Federal Register. After affording all interested persons an opportunity for an informal hearing on the proposal, FDA will affirm, modify, or revoke the proposed regulation. If the proposal is affirmed or modified, the Agency will publish a final regulation banning the device.

3. Use of Improved Information Technology and Burden Reduction

FDA regulations permit, under certain circumstances, the acceptance electronic signatures and handwritten signatures executed to electronic records as generally equivalent to paper records and handwritten signatures executed on paper (21 CFR part 11). These regulations apply to records, submitted in electronic form, that are required in Title 21 of the CFR. The intended effect of this regulation is to permit use of electronic technologies in a manner that is consistent with our overall mission and that preserves the integrity of FDA enforcement activities. Some firms utilize electronic means to satisfy recordkeeping requirements. CAD-CAM (Computer Assisted Drawing - Computer Assisted Manufacturing), lasers, photo-etching, etc., are also used to assist manufacturers in making changes to the devices or device labeling. This may result in compliance with this regulation and may eliminate the need to ban a device. We estimate 98% of respondents will use electronic means to complete the information collection.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

These regulations apply equally to all firms, regardless of the size of the establishment, if the product in question is believed to be adulterated or misbranded, in the case of administrative detentions, or presents an unreasonable risk or deception to the public, in the case of banning a device. FDA offers the resources of the Center for Devices and Radiological Health's (CDRH) Division of Industry and Consumer Education (DICE) and the Office of Product Evaluation and Quality (OPEQ) staffs.

DICE provides technical and other nonfinancial assistance to small firms expressly to aid them in complying with the requirements of the FD&C Act. The activities of DICE include participating in and presenting conferences, workshops, seminars on the application and interpretation of relevant

regulations, consulting with individual firms/sponsors, and development and dissemination of educational materials.

6. Consequences of Collecting the Information Less Frequently

It is estimated that respondents will report, occasionally. The collection of data and information under these regulations is conducted on a very infrequent basis and only as necessary. Thus, FDA could not adequately protect the public health if this information were conducted less frequently. There are no legal obstacles to reducing the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

FDA published a 60-day notice for public comment in the *Federal Register* of November 29, 2024 (89 FR 94734). We received no comments.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The Administrative Detention and Banned Medical Devices Data Collection includes the name of the responsible individual, work email address, and documents relevant to an evaluation of compliance. FDA determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Administrative detention reporting requirements-- 800.55(g) & (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

Table 2.--Estimated Annual Recordkeeping Burden

21 CFR Section	No. of Recordkeepers	No. 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

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. FDA's estimate of the burden under the administrative detention provision is based on FDA's discussion with one of the firms whose devices had been detained.

Reporting

21 CFR 800.55(g)(1) and (g)(2)--Administrative Detention Reporting

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.

21 CFR 800.55(h)(2)--Movement of Detained Devices

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.

21 CFR 895.21(d)(8)--Procedures for Banned Devices Informal Hearing Request

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.

21 CFR 895.22(a)--Banned Devices Reporting

A manufacturer, distributor, or importer of a device may be required to submit to the FDA all relevant and available data and information to enable the Commissioner to determine whether the device presents substantial deception, unreasonable, direct, and substantial danger to the health of individuals.

Recordkeeping

21 CFR 800.55(k)--Administrative Detention Recordkeeping

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.

12b. Annualized Cost Burden Estimate

We expect that approximately half of the hour burden will be work performed by a Regulatory Affairs Professional. The estimated hourly wage rate for a Regulatory Affairs Professional is based on the mean hourly wage rate for a Lawyer, \$84.84 (May 2023 Bureau of Labor and Statistics data, occupation code 23-1011, https://www.bls.gov/oes/current/oes_nat.htm#23-0000), then doubled to account for benefits and overhead, and rounded to the nearest dollar (\$170 per hour). The total estimated reporting and recordkeeping burden cost to industry for this information collection is \$78,370, which is the total number of estimated annual burden hours (461) multiplied by the wage rate of \$170 per hour.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Regulatory Affairs Professional	461	\$170	\$78,370

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

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

14. Annualized Cost to the Federal Government

The estimated annual cost to the Federal Government is based upon approximately 0.1 staff years at \$348,722 per position (the fully loaded cost of an FTE, including non-pay costs, based on an internal cost model for FY 2023), and amounts to approximately \$34,872.

Additional costs will be incurred if the administrative detention is appealed and a hearing is conducted to determine if the Agency had cause to take such an action. This hearing must be conducted in accordance with 21 CFR 800.55(g)(3). The cost to the Federal Government for one appeal hearing, which is based upon the staff hours necessary to review and prepare for a hearing, plus the cost of transporting General Counsel Attorneys to the district office where the devices were detained, is approximately \$29,700. This estimate was derived by multiplying the wage rate for a Lawyer, \$170 per hour,* by 160 hours; plus \$2,500 for transportation fees. Therefore, the estimated annual cost to the government for an appeal hearing is \$29,700 (\$27,200 + \$2,500).

* The mean hourly wage rate for a Lawyer, \$84.84 (May 2023 Bureau of Labor and Statistics data, occupation code 23-1011, https://www.bls.gov/oes/current/oes_nat.htm#23-0000), then doubled to account for benefits and overhead, and rounded to the nearest dollar (\$170 per hour).

15. Explanation for Program Changes or Adjustments

Based on our evaluation of the information collection we have made no adjustment to our current estimates.

16. Plans for Tabulation and Publication and Project Time Schedule

The information collected will not be published or tabulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.