U.S Food and Drug Administration
Administrative Detention and Banned Medical Devices
21 CFR 800.55(g)(1) & (g)(2), 800.55(k), 895.21(d), and 895.22
OMB Control No. 0910-0114
SUPPORTING STATEMENT

Terms of Clearance: None.

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

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)), Food and Drug Administration (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

In the Federal Register of March 9, 1979 (44 FR 13234), FDA issued under section 304(g) of the FD&C Act, a final regulation on Administrative Detention Procedures (21 CFR 800.55), which includes certain reporting requirements (§ 800.55(g)(l) 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. The final regulation for Banned Devices (21 CFR part 895), which issued on May 18, 1979 (44 FR 29214 at 29221), contained certain reporting requirements in §§ 895.21(d) and 895.22(a).

FDA is requesting approval from the Office of Management and Budget (OMB) for the following requirements:

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.

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.

FDA has only used the Banned Device regulation twice. In the first instance FDA required importers of prosthetic hair fibers to supply the Agency with data and information relating to this product. Information obtained under the reporting requirements of this regulation, which would not otherwise be available to the Agency, convinced FDA that this device should be banned from commercial distribution. In the second instance, FDA published a Federal Register Notice, collected comments from stakeholders and responded to those comments. The final rule published for powdered medical gloves contains no further requirement for collection of information from industry. FDA may use this regulation in the future in regard to another device 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. The FDA would then 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.

Responders to this information collection consist of private sector for-profit businesses.

3. Use of Improved Information Technology and Burden Reduction

The Code of Federal Regulation (CFR) (21 CFR part 11) permits, under certain circumstances, the Agency to accept electronic signatures and handwritten signatures executed to electronic records as generally equivalent to paper records and handwritten signatures executed on paper. These regulations would apply to records, submitted in electronic form, that are required in Title 21 of the CFR. The use of electronic forms for recordkeeping and reporting submissions to FDA remains voluntary. The intended effect of this regulation is to permit use of electronic technologies in a manner that is consistent with FDA's overall mission and that preserves the integrity of the Agency's enforcement activities.

Some firms use computers to store information under the recordkeeping requirements of these regulations, which has led to a decrease of industry’s time. 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 results in compliance with this regulation and eliminates the need to ban a device. It is estimated that 98% of respondents use electronic means to fulfill the Agency's requirement or request.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only Federal agency responsible for regulating medical devices. As such, there is no duplication of effort or requirements.

5. Impact on Small Businesses or Other Small Entities

It is estimated that there is only one respondent on occasion from for-profit businesses. 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 Device Evaluation (ODE) staffs. DICE's staff 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. Staff is available to respond to questions and a toll free telephone number was established to facilitate this communication link.

6. Consequences of Collecting the Information Less Frequently

It is estimated that one respondent will report on occasion. 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

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the FEDERAL REGISTER of December 21, 2018 (83 FR 65683). No comments were received.

FDA's experience with the administrative detention reporting and recordkeeping requirements has shown that most establishments maintain records required by good manufacturing practice regulations. A review of administrative detentions that have been enforced prior to this reporting period indicates that this regulation has not been an unreasonable burden on industry. In most cases, the devices were either seized or voluntarily corrected (reconditioned, relabeled, or destroyed) within the period of detention or shortly thereafter.

The last administrative detention that was conducted was in 2002 with a firm that manufactured OB/GYN devices that were labeled sterile but had never been sterilized. The firm fled the U.S. and therefore we can not ascertain any estimated reporting burden. In the previous approval for this information collection, FDA spoke with Dr. Nadeem M. Muna, President, Immuno Diagnostic Products, Inc. (North Salt Lake City, Utah, (801) 298-7535), regarding the administrative detention of immunofluorescent test kits. This is the last administrative detention that FDA has taken in which we received comments from outside the Agency.

FDA has limited experience with the regulations for Banned Devices in that it has been implemented two times, to ban prosthetic hair fibers (49 FR 1177) and to ban powdered medical gloves (81 FR 91722). FDA has not solicited any further comment from outside of the Agency regarding either of these banning actions and is primarily dependent on input received from the Federal Register Notices seeking comment.

9. Explanation of Any Payment or Gift to Respondents

FDA will not provide any payments or gifts to respondents to this information collection.

10. Assurance of Confidentiality Provided to Respondents

This ICR collects personally identifiable information (PII). In renewing this ICR, 21 CFR 800.55(g)(1) & (g)(2), 800.55(k), 895.21(d), and 895.22, staff from FDA's Center for Devices and Radiological Health, Office of the Center Director consulted the Center for Devices and Radiological Health, Office of Communications and Education, Division of Information Disclosure and the FDA Privacy Officer to identify potential risks to the privacy of individuals whose information will be handled by or on behalf of FDA in association with the Administrative Detention and Banned Medical Devices Data Collection, if finalized as proposed. In this case, the Administrative Detention and Banned Medical Devices Data Collection does solicit PII that will be collected and maintained by FDA. 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 PII submitted is the name of the responsible individual, work email address, and documents relevant to an evaluation of compliance.

FDA further 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 routinely retrieve records from the information collected. FDA also minimized the PII to be collected to protect the privacy of the individuals.

Information provided to, or obtained by, FDA is subject to release under the Freedom of Information Act (5 U.S.C. 552) and the implementing regulations contained in 21 CFR parts 20 and 21.

11. Justification for Sensitive Questions

The information required in this information collection does not include questions about sexual behavior, attitude, religious beliefs, or any other matters which are commonly considered private or sensitive in nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Documentation of ownership--800.55(g)	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[1]

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.

This regulation also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of

Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 10.30 have been approved under OMB control number 0910-0183 and the collections of information in 21 CFR part 801 have been approved under 0910-0485.

12b. Annualized Cost Burden Estimate

The annualized cost burden estimate is based on the estimated hourly wage rate for a Regulatory Affairs Professional, $72.* Based on FDA's history with administrative detentions, FDA believes that the total estimated reporting and recordkeeping burden cost to industry for this information collection will be $33,192, which is the total number of estimated annual burden hours (461) multiplied by the wage rate of $72 per hour.

**The estimated hourly wage rate for a Regulatory Affairs Professional is based on the average total compensation for a Regulatory Affairs professional, $150,422, in the Regulatory Affairs Professionals Society's "2016 Scope of Practice & Compensation Report for the Regulatory Profession" (p.11, https://www.raps.org/getattachment/Careers/Scope-of-Practice-Survey/2016-Scope-of-Practice-Compensation-Report-for-the-Regulatory-Profession.pdf.aspx?lang=en-US, viewed on 10/26/18). The hourly rate assumes a 40-hour work week and has been rounded to the nearest dollar.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Regulatory Affairs	461	$72.00	$33,192

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

There are no capital costs and/or operating and maintenance costs for this information collection.

14. Annualized Cost to the Federal Government

The annualized cost to the Federal Government, which is based upon approximately 0.1 staff years at $270,305 per position (which is the agency's projected average cost of an FTE in CDRH including their non-pay costs*), amounts to approximately $27,031. 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) and has the potential of costing the Agency thousands of dollars. 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 $10,900. This figure was derived by multiplying an average hourly attorney rate, $68.22 (May 2017 Bureau of Labor and Statistics data for occupation code 23-1011, Lawyers, https://www.bls.gov/oes/current/oes231011.htm), by 160 hours (rounded to nearest $100); plus $2,500 for transportation fees. Therefore, the estimated annual cost to the government is $40,431 ($10,900+27,0312,500).

During the approximately 30 years that the banned device regulation has been in effect, FDA has been used twice, to ban prosthetic hair fibers (21 CFR 895.101.) and powdered medical gloves (81 FR 91722).

*Based on the Food and Drug Administration fully loaded FTE cost model (domestic) for FY 2018, as provided by agency economists.

15. Explanation for Program Changes or Adjustments

There are no program changes or adjustments to the information collection burden.

16. Plans for Tabulation and Publication and Project Time Schedule

The collection of information under these regulations will not be published for statistical use.

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.