Supporting Statement
For
Administrative Detention and Banned Medical Devices
21 CFR 800.55(g)(1) & (2), 800.55(k), and 895.22
OMB Control Number 0910-0114

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) has the statutory authority under section 304(g) of the Federal Food, Drug and Cosmetic Act [21 U.S.C. 334(g)] (the Act), where officers or employees duly designated by the Secretary (FDA investigators) may detain devices during establishment inspections which are believed to be adulterated or misbranded. On March 9, 1979, FDA issued, under 21 CFR 800.55, a final regulation on Administrative Detention Procedures (44 FR 13234), under section 304(g) of the Act, which includes certain reporting requirements [800.55(g)(l) & (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.

FDA also has the statutory authority under section 516 of the Act [21 U.S.C. 360f] 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 (44 FR 29221), which issued on May 18, 1979, (21 CFR Part 895), contained certain reporting requirements, 21 CFR 895.21(d) and 895.22(a). (See Attachments 1, 2, 3, and 4 for these Regulations.)

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

21 CFR 800.55(g)(1) and (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 Act. In some cases, the appellant must include documents showing that that person has the legal right to appeal this order.

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.

21 CFR 895.21(d) – **Procedures for Banned Devices Meeting Request**

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 to 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.

2. Purpose and Use of the Information

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 if the devices which 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 which industry possesses. Thus, the collection of this information enables the Agency to perform its mission of consumer protection.

When a detention order is put into place, the Agency must know if any other devices which 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 which 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 once to require 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. FDA may use this regulation in the future in regards to

another device if the Commissioner 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.

3. Use of Information Technology and Burden Reduction

In the **Federal Register** of March 20, 1997, FDA issued a final regulation (21 CFR Part 11) that would, under certain circumstances, permit 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 Code of Federal Regulations (CFR). The use of electronic forms of record keeping 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.

There are no technical or legal obstacles to the collection of information for devices affected under these regulations. 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.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only federal agency responsible for regulating medical devices. Such regulation extends to include the administrative detention of adulterated and/or misbranded devices and the banning of any device that presents a substantial deception, unreasonable and substantial risk of illness or injury, or unreasonable, direct, and substantial danger to the health of individuals. As such, there is no duplication of effort or requirements.

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 also offers the resources of the Center for Devices and Radiological Health's (CDRH) Division of Small Manufacturers, International and Consumer Assistance (DSMICA) and the Office of Device Evaluation (ODE) staffs. DSMICA's staff provides technical and other nonfinancial assistance to small firms expressly to aid them in complying with the requirements of the Act. The activities of DSMICA 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

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.

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

The requirements of the administrative detention and banned device regulations are consistent with 5 CFR 1320.5 and applicable guidelines.

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

Notice has been published in the Federal Register on March 17, 2003 (68 FR 12706) soliciting comments on this information collection prior to its submission to the Office of Management and Budget (OMB) as required by 5 CFR 1320.8(d) (see Attachment 5). No significant 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 all forty-nine (49) administrative detentions that have been enforced in approximately twenty-two years 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.

In the past six years, in an effort to determine the burden on industry, 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. FDA has taken only one administrative detention during the past several years, and has not received any other comments from outside the Agency.

FDA has limited experience with the regulations for Banned Devices in that it was only used once to ban prosthetic hair fibers (49 FR 1177). FDA has not solicited any further comment from outside of the Agency regarding banning actions.

9. Explanation of Any Payment or Gift to Respondents

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

10. Assurance of Confidentiality Provided to Respondent

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 Hour Burden Including Annualized Hourly Costs

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

Table 1.--Estimated Annual Reporting Burden

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
800.55(g)	1	1	1	25	25
895.21(d) and 895.22(a)	26	1	26	16	416
TOTALS					441

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

Table 2.--Estimated Annual Recordkeeping Burden

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
800.55(k)	1	1	1	20	20
TOTALS					461

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

Only one administrative detention action has been taken over the past several years. 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 a firm whose devices had been detained during the past reporting period. Historically, FDA has had very few or no annual responses for this information collection.

Because the amount of recordkeeping required for each administrative detention action will vary according to the nature of the device, the quantity detained, and its disposition, it is impossible to give an estimated annualized cost that would be accurate for each respondent. For example, the cost of maintaining this information for a warehouse, where the device was detained and voluntarily destroyed, would be much less than for a manufacturer who slowly reconditions and releases the device over a period of time. The warehouse could fulfill the recordkeeping requirements of this regulation by maintaining a copy of the shipping record showing how many units were received, while the manufacturer may have to maintain records re: components, manufacture, quality control, shipping, complaint or failure investigation, recall, reconditioning, new quality control, and new shipping. Thus, the estimated annualized cost for each respondent could range from

several dollars to several hundreds (perhaps thousands) in a small number of cases. In the past, FDA had estimated that approximately 80 hours of work worth approximately $2,000 per year was necessary for respondents to fulfill the needs of this information collection. Since this collection was last approved by OMB, the average cost per hour to conduct skills necessary to complete this information collection has risen slightly. FDA estimated the total cost for this program by checking industry wage rates reported on the Regulatory Affairs Professional Society (RAPS) March 2003 webpage. RAPS estimated that the range of average salary for regulatory affairs professionals was $60,000 to $75,000 per year, or $28 to $36 per hour. Based on FDA's history with administrative detentions over the past three years, FDA believes that the total estimated reporting and recordkeeping burden cost to industry for this information collection will be $2,240, which is the total number of hours expended (80) multiplied by the RAPS low-end average wage rate of $28 per hour.

In a previous reporting period, a large firm (Life Design Systems) reported that they spent approximately $4,000.00 in recordkeeping re: reconditioning/testing or destruction of product. However, it should be noted that this product was seized and that reconditioning and destruction did not start until after a Consent Decree was entered into. Thus, the firm would have spent $4,000.00 on recordkeeping even if the product was not administratively detained. The estimated cost for a respondent to have a hearing to appeal an administrative detention could be several thousand dollars or more, depending upon whether an attorney is involved and the documented evidence. Life Design Systems decided to appeal the administrative detention, hired a well-known law firm, hired a research firm to find case law, paid the court reporter for the transcripts, had several of their people on hand during a rather lengthy hearing, and reported that they spent over $80,000.00 on the appeal. FDA believes this to be an atypical amount and that no other appeal has cost nearly as much.

13. Estimate of Other Total Annual Cost Burden to Respondents or Recordkeepers

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 $103,000 per year, amounts to approximately $10,000. 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 $10,000. This figure was derived by multiplying an average hourly attorney rate ($50) by 160 hours, plus $2,000 for transportation fees.

During the approximately 22 years that the banned device regulation has been in effect, FDA has only used it once to ban prosthetic hair fibers (21 CFR 895.101.) For this reason, and because situations resulting in banning a device are so reactive and therefore difficult to predict, it is difficult to estimate the cost to the Federal Government imposed by this regulation

15. Explanation for Program Changes or Adjustments

There have been no changes or adjustments in burden hours or costs since this collection's last approval.

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 is not seeking an exemption from the requirement to display the effective date.

18. Exception to Certification for Paperwork Reduction Act Submissions

The requirements of the administrative detention and banned device regulations are consistent with 5 CFR 1320.9. There are no exceptions to the certification statement in item 19 of OMB Form 83-I.

19. Certification for Paperwork Reduction Act Submissions

B. Collection of Information Employing Statistical Methods

There are no statistical methods being employed in this collection of information.

List of Attachments to Supporting Statement:

Attachment 1 -	Federal Food, Drug, and Cosmetic Act, Section 304 [21 U.S.C. 334(g)]
Attachment 2 -	21 CFR Part 800.55
Attachment 3 -	Federal Food, Drug, and Cosmetic Act, Section 516 [21 U.S.C. 360(f)]
Attachment 4 -	21 CFR Part 895
Attachment 5 -	Federal Register 60 day Notice Soliciting Comments on Administrative Detention and Banned Medical Devices.