collection of information under §§ 640.101(f)(2), 660.6(b), 660.36(a)(2) and (b), and 660.46(b) are manufacturers of the specific products referenced previously. The estimated number of respondents for each regulation is based on the annual number of manufacturers that submitted samples and protocols for biological products, including submissions for lot release, surveillance, licensing, or export. There are an estimated 350 manufacturers of licensed biological products, however, based on information obtained from FDA's data base system, approximately 100 manufacturers submitted samples and protocols in 1998, under the regulations cited previously. FDA estimates that approximately 86 manufacturers submitted protocols under § 610.2, and 14 manufacturers submitted protocols under the regulations for the specific products. FDA had previously estimated 80, instead of 90, manufacturers would submit samples and protocols annually under all the regulations cited previously to account for biotechnology firms that are exempt from lot release requirements. Because biotechnology firms may still be required to submit samples and protocols for purposes other than lot release, as explained previously, the number of respondents for § 610.2 in this estimate includes them. The slight increase in the total estimated number of respondents (100) is due to a normal variation in annual submissions.

The total annual responses are based on FDA's final actions completed in fiscal year 1998, which totaled 7,221, for the various submission requirements of samples and protocols for biological products. The rate of final actions is not expected to change significantly in the next few years. The hours per response are based on information provided by industry. The burden estimates provided by industry ranged from 1 to 5.5 hours. Under § 610.2, the hours per response are based on the average of these estimates and rounded to 3 hours. Under the remaining regulations, the hours per response are based on the higher end of the estimate (rounded to 5 or 6 hours) since more information is generally required to be submitted in the protocol than under § 610.2.

In the **Federal Register** of March 22, 2000 (65 FR 15341), the agency requested comments on the proposed collection of information. No significant comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
610.2	86	82.72	7,114	3	21,342
640.101(f)(2)	5	4.40	22	5	110
660.6(b)	6	11.33	68	5	340
660.36(a)(2) and (b)	1	1	1	6	6
660.46(b)	2	8	16	5	80
Total	100		7,221		21,878

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

Dated: June 27, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–16975 Filed 7–5–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1072]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Administrative Detention and Banned Medical Devices; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. This document also corrects several errors that appeared in Table 1 of a notice published in the **Federal Register** of March 31, 2000 (65 FR 17282).

DATES: Submit written comments on the collection of information by August 7, 2000.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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—21 CFR 800.55(g), 800.55(k), 895.21, and 895.22 (OMB No. 0910–0114)—Extension

FDA has the statutory authority under section 304(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 334(g)), to detain during establishment inspections devices that are believed to be adulterated or misbranded. On March 9, 1979, FDA issued a final regulation on administrative detention procedures, which includes, among other things, certain reporting requirements (§ 800.55(g) (21 CFR 800.55(g))) and recordkeeping requirements (§ 800.55(k)). Under § 800.55(g), an applicant 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 an unreasonable and substantial risk of illness or injury. The final regulation for banned devices contains certain reporting requirements (§§ 895.21(d) and 895.22(a) (21 CFR 895.21(d) and 895.22(a))). Section 895.21(d) states that if the Commissioner of Food and Drugs (the Commissioner) decides to initiate a proceeding to make a device a banned device, a notice of proposed rulemaking will be published in the **Federal Register**, and this notice will contain the finding that the device presents a substantial deception or an unreasonable and substantial risk of illness or injury. The notice will also contain the reasons why the proceeding was initiated, an evaluation of data and information obtained under other provisions of the act, any consultations with the panel, and a determination as to whether the device could be corrected by labeling or change of labeling, or change of advertising, and if that labeling or change of advertising has been made. Under § 895.21(d), any interested person may request an informal hearing and submit written comments. Under § 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.

Respondents to this collection of information are those manufacturers, distributors, or importers whose products FDA seeks to detain or ban.

In the **Federal Register** of March 31, 2000 (65 FR 17282), the agency requested comments on the proposed collection of information. No significant comments were received. Also, in the notice published in the **Federal Register** of March 31, 2000 (65 FR 17282 at 17283), Table 1 contained several errors. Table 1 of this document corrects those errors.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
800.55(g)(1) and (g)(2)	1	1	1	1	1
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	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
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.

Over the past 3 years, there has been an average of one new administrative detention action per year. Each administrative detention will have varying amounts of data and information that must be maintained. Historically, FDA's Center for Devices and Radiological Health (CDRH) has had very few or no annual responses for this information collection and normally reports one response per year. CDRH is anticipating a banning action in fiscal year 2000 that will involve 26 firms.

Dated: June 28, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–17021 Filed 7–5–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food and Drug Administration/Industry Exchange Workshop on Scale-Up and Postapproval Changes (SUPAC), Supplements, and Other Postapproval Changes; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of workshop.

SUMMARY: The Food and Drug Administration (FDA), Office of the Commissioner, Office of Regulatory Affairs, Center for Drug Evaluation and Research, and the Central Region Small Business Assistance Office, and the Pacific Region Small Business Office, in cooperation with the International Society for Pharmaceutical Engineering (ISPE) is announcing two workshops entitled FDA/Industry Exchange Workshops on Scale-Up and Postapproval Changes (SUPAC), Supplements, and Other Postapproval Changes. The workshops are intended to review the scientific, regulatory, and quality basis of SUPAC; discuss current issues; and provide attendees with information on the impact of the SUPAC guidances that have been finalized, as well as future agency efforts in this area.

Date and Time: See Table 1 following the *Location* section of this document.

Location: See Table 1 below.