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.

TABLE 1

Workshop Address	Date and Local Time
Long Beach Convention Center, 300 East Ocean Blvd., Long Beach, CA 90802.	Tuesday, September 26, 2000, 9 a.m. to 4:30 p.m. Pacific time.
Embassy Suites, 150 Anza Blvd., Burlingame, CA 94010, 650–340–0327.	Friday, December 8, 2000, 9 a.m. to 4:30 p.m. Pacific time.

Contact: Marcia Madrigal, Industry and Small Business Representative, Food and Drug Administration, Oakland Federal Bldg., 1301 Clay St., suite 1180N, Oakland, CA 94612, 510–637–3980; FAX 510–637–3977 or via e-mail: mmadriga@ora.fda.gov.

Registration: The registration fee is $295 for ISPE members and $450 for nonmembers (which will cover refreshments, lunch, and materials). The ISPE tax number is FEI 59–2009272. Contact ISPE for registration forms, and other registration details at ISPE 3816 W. Linebaugh Ave, suite 412, Tampa, FL 33624, 813–960–2105; FAX 813–264–2816, or visit the ISPE website at http://www.ispe.org. Registrations are due 1 week prior to the start of each course. Space is limited, therefore, interested parties are encouraged to register early. Limited onsite registration may be available. Please arrive early to ensure prompt registration. Persons needing hotel rooms for the Embassy Suites location on December 8, 2000, should mention that they are attending the FDA/SUPAC workshop. A special rate is available until November 16, 2000, or until the room block is exhausted, whichever comes first.

If you need special accommodations due to a disability, please contact ISPE at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The workshops are designed to help achieve objectives set forth in section 406 of the FDA Modernization Act of 1997 (21 U.S.C 393) and discussed in the FDA Plan for Statutory Compliance, which include working more closely with stakeholders; maximizing the availability of, and clarifying information about the process for review and submissions; and ensuring access to needed scientific and technical expertise.

The workshops also are consistent with the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121), as outreach activities by Government agencies directed to small businesses.

The topics to be discussed include the following: (1) The history of SUPAC development; (2) the impact of scale-up postapproval change guidances and of the regulation rewrite of 21 CFR 314.70 (Supplements and other changes to an approved application); (3) comparison of SUPAC immediate-release solid dosage forms, modified-release oral dosage forms, and semisolid-topical dosage forms; (4) postapproval changes sterile aqueous solutions; (5) FDA field staff's involvement in SUPAC; (6) description and use of the equipment addenda to SUPAC; and (7) facts, figures, and future directions.

Dated: June 27, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–16979 Filed 7–5–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources And Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Scholarships for Disadvantaged Students Program—New

The Scholarships for Disadvantaged Students (SDS) Program has as its purpose the provision of funds to eligible schools to provide scholarships to full-time, financially needy students from disadvantaged backgrounds enrolled in health professions and nursing programs.

To qualify for participation in the SDS program, a school must be carrying out a program for recruiting and retaining students from disadvantaged backgrounds, including students who are members of racial and ethnic minority groups (section 737(d)(1)(B) of the PHS Act). A school must meet the eligibility criteria to demonstrate that the program has achieved success based on the number and/or percentage of disadvantaged students who graduate from the school. In awarding SDS funds to eligible schools, funding priorities must be given to schools based on the proportion of graduating students going into primary care, the proportion of underrepresented minority students, and the proportion of graduates working in medically underserved communities (section 737(c) of the PHS Act).

The estimated response burden is as follows: