Closed presentation of data. On March 20, 1997, the sponsor may present to the committee trade secret and/or confidential commercial information regarding the premarket notification submission. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Each public advisory committee meeting listed above may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. The dates and times reserved for the separate portions of each committee meeting are listed above.

The open public hearing portion of the meeting(s) shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

The Commissioner has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2, 10(d)), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, deliberation to formulate advice and recommendations to the agency on matters that do not independently justify closing.

This notice is issued under section 10(a)(1) and (a)(2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: February 25, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–5129 Filed 2–26–97; 11:04 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Application for Certification as a Federally Qualified Health Center (FQHC) (OMB No. 0915–0142); Extension and Revision

The Federally Qualified Health Center (FQHC) Look-Alike application package (OMB No. 0915–0142) was developed to certify entities as FQHC providers under Medicaid and Medicare. FQHCs receive

reasonable cost-related reimbursement under Medicaid and Medicare for a full range of primary health care services. The application for FQHC certification is divided into four components: (1) Need and Community Impact, (2) Health Services, (3) Management and Finance, and (4) Governance. Certified FQHC Look-Alikes must submit an annual recertification document with updated exhibits to retain designation as an FQHC.

In an effort to improve the procedures for certifying FQHCs, HRSA is considering revising the FQHC Look-Alike application (with parallel changes made to the recertification requirements). The revised version would update the application guidelines and exhibits to reflect current law, regulations, and practice. A revised application may also include more specific guidance on how applicants should document existing unmet need in the community.

These revisions will be developed during the next year and submitted for OMB approval in 1998. In the interim, a request for a two-year extension of OMB approval of the current forms is being submitted. Only minor technical changes have been made to the forms. Estimates of annualized hour burden are as follows:

Form name	Number of respondents	Responses per respondent	Hours per response	Total burden hours
Application	70	1	120	8,400
Recertification	231	1	20	4,620
Total	301	1	43	13,020

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Virginia Huth, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: February 10, 1997.

J. Henry Montes,

Director, Office of Policy and Information Coordination.

[FR Doc. 97–4957 Filed 2–27–97; 8:45 am]

BILLING CODE 4160–15–P

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a list of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443–0525.

Alcohol and Drug Services Study (ADSS) Phase II/III—New—Phases II and III of the ADSS will continue the collection of linked information on substance abuse treatment begun in the Phase I facility level survey. Phase II involves on-site interviews with administrators at 270 treatment facilities and a a record abstraction of client-level data on 8,800 treatment clients. Phase III consists of client followup interviews to determine post-discharge substance abuse, criminal activity, employment, and other social functioning. ADSS will provide researchers, policy makers, and providers with detailed national data on the current substance abuse treatment delivery system and clients in the system. The annualized burden is shown below.

	No. of respondents	No. of responses/respondent	Avg. burden/response	Total study burden	Annualized burden
Treatment Facilities	270	1.33	1.755 hours	630 hours	126 hours
Clients	8,800	3.38	1.125 hours	29,700 hours	5,940 hours.

Drug Abuse Warning Network (DAWN)—Extension of a currently approved collection—The Drug Abuse Warning Network (DAWN) collects data on drug-related medical emergencies and deaths as reported from about 650 hospitals and medical examiners nationwide. Used by Federal, State and local agencies, this on-going data system supports efforts to identify drug abuse trends; assesses health hazards associated with substance abuse; and schedules substances under the Controlled Substances Act. The annual burden estimate is 15,972 hours as shown below:

	No.of respondents	No.of responses per respondent	Average burden per response	Gross burden hours	IR [1] reporting hours	Total adjusted burden hours
Hospitals	500	368	0.133 hrs.	24,480	10,282	14,198
Medical Examiners	150	123	0.160 hrs.	2,957	1,183	1,774

[1] There is no burden associated with reporting by Independent Reporters (IRs), therefore these hours are not included in the Total Adjusted Burden Hours.

Written comments and recommendations concerning the proposed information collections should be sent within 30 days of this notice to: Virginia Huth, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10236, Washington, D.C. 20503.