

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 (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: October 17, 1995.
David A. Kessler,
Commissioner of Food and Drugs.
[FR Doc. 95-26151 Filed 10-19-95; 8:45 am]
BILLING CODE 4160-01-F

Health Resources and Services Administration

Notice of filing of Annual Report of Federal Advisory Committee

Notice is hereby given that pursuant to section 13 of Public Law 92-463, the Annual Report for the following Health Resources and Service Administration's Federal Advisory Committee has been filed with the Library of Congress:

Advisory Committee on Infant Mortality

Copies are available to the public for inspection at the Library of Congress Newspaper and Current Periodical Reading Room, Room 1026, Thomas Jefferson Building, Second Street and Independence Avenue SE., Washington, DC. Copies may be obtained from: Ms. Kerry P. Nessler, Maternal & Child Health Bureau, Health Resources and Services Administration, Room 18-20, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443-2204.

Date: October 17, 1995.
Jackie E. Baum,
Advisory Committee Management Officer, HRSA.
[FR Doc. 95-26052 Filed 10-19-95; 8:45 am]
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Proposed Data Collections Available for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects. To request more information on the proposed project or to obtain a copy of the data collection plans and 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 Projects:

1. Organ Procurement and Transplantation Network Regulations—42 CFR Part 121 (Final Rule)

(OMB No. 0915-0184)—Extension and Revision—This final rule establishes the policies governing the Organ Procurement and Transplantation Network (OPTN). These rules will regulate the operation of the OPTN in four major areas: membership requirements, patient listing, organ allocation, and record maintenance and recording. The final rule contains three requirements not currently approved under the Paperwork Reduction Act, as indicated in the table below (footnote 2). The burden estimates are as follows:

Title	Number of respondents	Frequency of response	Hours per response	Total burden hours
121.3(a)(6)(ii) (Reporting) Submission of Policies & Procedures	1	4	0.5	2
121.3(a)(6)(ii) ² (Disclosure) Sending policies & procedures to OPOs	1	16	75	1,200
121.3(d)(1) (Reporting) Application requirements for OPOs, hospitals, & others	2,774	³ 1	0.5	1,387
121.5(c) ² (Reporting) Submitting criteria for organ accept.	115	1	0.1	12
121.5(c) ² (Disclosure) Sending criteria to OPOs	115	1	0.1	12
121.6(b)(4) (Reporting) Reasons for refusal	828	14	0.1	1,200
121.7(e) (Reporting) Transplant to prevent organ wastage	278	4	0.1	111
121.8(b) (Reporting) Application requirements for transplant centers:				
A. Medicare/Medicaid Approved programs & VA Hospitals	308	³ 1	0.5	154
B. Other programs	350	³ 1	2.0	700