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: February 15, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–4067 Filed 2–22–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95N–0357]

Medical Devices; Investigational Devices; Interagency Agreement Between the Food and Drug Administration and the Health Care Financing Administration; Categorization of Investigational Devices for Coverage under Medicare; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of an interagency agreement between FDA and the Health Care Financing Administration (HCFA) and a list of all FDA-approved investigational device exemptions (IDE's) and their corresponding categorization determinations for possible Medicare reimbursement. This list was compiled in accordance with the categorization criteria set forth in the interagency agreement. The HCFA/FDA interagency agreement regarding investigational devices describes procedures by which FDA will assist HCFA in identifying nonexperimental/investigational devices that are potentially covered by Medicare under a final rule recently issued by HCFA extending coverage to certain devices and related services. FDA is making the interagency agreement and the list of FDA-approved IDE's and their categorization determinations available to IDE sponsors and the public.

DATES: The HCFA final rule ''Medicare Program; Criteria and Procedures for Extending Coverage to Certain Devices and Related Services'' became effective on November 1, 1995. The HCFA/FDA interagency agreement became effective on September 8, 1995.

ADDRESSES: Submit written requests for a copy of the interagency agreement and the categorization list to the Division of Small Manufacturers Assistance (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Requests should be identified with the docket number found in brackets in the heading of this document. Send two self-addressed adhesive labels to assist that office in processing your request. Copies of the interagency agreement and the categorization list are available for public examination in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857 between 9 a.m. and 4 p.m., Monday through Friday. Copies of a facsimile of this information are available from the Center for Devices and Radiological Health's (CDRH's) Facts on Demand (1–800–899–0381). This information may also be obtained from the electronic docket administered by the Division of Small Manufacturers Assistance and is available to anyone with a video terminal or personal computer (1–800–252–1366, 1–800–222–0185, or 1–301–594–2741). Requests for reconsideration of the categorization of an IDE should be submitted in the same manner as an IDE supplement and should reference the IDE number, and be submitted in triplicate to: IDE Document Mail Center (HFZ–401), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850.

FOR FURTHER INFORMATION CONTACT: John Ensign, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION: In the Federal Register of September 19, 1995 (60 FR 48417), HCFA published a final rule in which it announced that it would consider for Medicare coverage certain devices with an FDA-approved IDE that have been categorized as nonexperimental/investigational. An FDA-approved IDE application permits a device which otherwise could not be lawfully shipped without marketing clearance, to be shipped lawfully for the purpose of conducting a clinical trial in accordance with section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) and 21 CFR parts 812 and 813.

Under section 513 of the act (21 U.S.C. 360c), all devices must be classified into one of three regulatory classes: Class I (general controls), Class II (special controls), or Class III (premarket approval). For the purposes of consideration for reimbursement under the Medicare program and in accordance with the procedures set forth in the HCFA final rule published on September 19, 1995, FDA has categorized all FDA-approved IDE's into either Category A (experimental/investigational) or Category B (nonexperimental/investigational). An experimental/investigational (Category A) device refers to an innovative device believed to be in Class III for which ''absolute risk'' of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved, and the FDA is unsure whether the device type can be safe and effective). A nonexperimental/investigational (Category B) device refers to a device believed to be in Class I or Class II, or a device believed to be

in Class III for which the incremental risk is the primary risk in question (that is, underlying questions of safety and effectiveness of the device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type. The specific criteria used to categorize the IDE's are set forth in Attachment A of the HCFA/FDA interagency agreement. In order to facilitate the processing of Medicare claims, FDA and HCFA encourage IDE sponsors to provide the IDE application numbers to the hospitals and clinical investigators participating in the sponsors' clinical investigations.

According to the September 19, 1995, HCFA final rule, IDE's which have been placed in Category B by FDA would be eligible for Medicare coverage consideration. The final coverage decision, however, will encompass other factors and thus will be made by HCFA.

By this notice, FDA is making available a list of all FDA-approved IDE's, the corresponding categorization determination (Category A or Category B), and the rationale for the determination. FDA will update this list as circumstances require and will make the revised list available through the electronic docket and Facts on Demand (details above), and in the Dockets Management Branch (address above). As set forth in the September 19, 1995, final rule, an IDE sponsor may seek reconsideration of a categorization determination by submitting a request for re-evaluation to FDA. Requests for re-evaluation should be submitted in the same manner as an IDE supplement to the IDE Document Mail Center (address above). IDE sponsors may submit this request for re-evaluation at any time, i.e., there is no time limit for submitting a reconsideration request to FDA. Further information about categorization, its effect on Medicare reimbursement, and appeal of a categorization determination, is contained in the September 19, 1995, final rule cited above.

Dated: February 12. 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health

[FR Doc. 96–4066 Filed 2–22–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

Submitted for Collection of Public Comment: Submission for OMB Review

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposals for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Granting and Withdrawal of Deeming Authority to Private Nonprofit Accreditation Organizations and the Clinical Laboratory Improvement Act (CLIA) Exemption Under State Laboratory Programs; *Form No.:* HCFA R–185; *Use:* The information required is necessary to determine whether a private accreditation organization/State licensure program standards and accreditation/licensure process is equal to or more stringent than those of CLIA; *Frequency:* Other (initial application/as needed); *Affected Public:* Not-for-profit institutions, State, local, or tribal government.

To request copies of the proposed paperwork collections referenced above, E-mail your request, including your address, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: January 24, 1996.

Kathleen B. Larson,

Director, Management Planning and Analysis Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 96–4105 Filed 2–22–96; 8:45 am]

BILLING CODE 4120–03–P

Submitted for Collection of Public Comment: Submission for OMB Review

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension; *Title of Information Collection:* Sole Community Home Health Agencies (HHA) at 42 CFR424.22(b)(2), (f) and (g); *Form No.:* HCFA R–85; *Use:* These regulations implement the rules for participation of HHAs in Medicare and the establishment and review of plans of care for home health services. These regulations make it easier for certain HHAs to meet certification and plan of care requirements. *Frequency:* Annually; *Affected Public:* Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 20; *Total Annual Hours:* 40.

To request copies of the proposed paperwork collections referenced above, E-mail your request, including your address, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch,