guidance so that it is applicable to apnea monitors for patients of all ages. Elsewhere in this issue of the **Federal Register**, FDA is proposing to classify the apnea monitor into class II with this guidance document as the special control. FDA is issuing this draft guidance because the agency believes it is necessary to provide reasonable assurance of the safety and effectiveness of the apnea monitor.

DATES: Submit written comments on the draft guidance by December 21, 2000.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Guidance for Infant/Child Apnea Monitor 510(k) Submissions'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Joanna H. Weitershausen, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8609, ext. 164.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 21, 1995 (60 FR 9762), FDA issued a proposed rule setting forth requirements for a mandatory performance standard for the infant apnea monitor (hereinafter referred to as the 1995 proposal). Elsewhere in this issue of the **Federal Register**, FDA is withdrawing the 1995 proposal. Because of reduced mortality rates for infants at risk for death due to apparent life-threatening events, and after considering other factors, FDA no longer believes that a mandatory performance standard is needed for this class II device.

In conjunction with the withdrawal of the 1995 proposal, FDA is proposing also to create a separate classification for the apnea monitor device. This proposal, which also appears elsewhere in this issue of the **Federal Register**, will remove apnea monitors from their current classification within the generic type of device known as the breathing (ventilatory) frequency monitor (21 CFR 868.2375). The proposed rule will classify the apnea monitor as a group in class II (special controls), with an industry guidance document issued by FDA as the special control. The generic apnea monitor will include devices used to monitor apnea, i.e., the cessation of breathing, in all patient populations. The infant/child apnea monitor used on infants and children under 3 years of age will fall within the generic type of device proposed for classification as the apnea monitor.

The draft guidance describes minimum performance characteristics, testing procedures and criteria, labeling, and, as appropriate, clinical testing recommendations for infant/child apnea monitors. After considering comments on this draft guidance and further evaluating appropriate clinical study parameters, FDA intends to modify the guidance so that the final guidance document is applicable as the special control for the apnea monitor used on patients in other age groups, as well as infants and children.

II. Significance of Guidance

This guidance document represents the agency's current thinking on infant/child apnea monitor 510(k) submissions. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both. As noted above, the agency believes the performance, testing, labeling, and clinical criteria in this draft guidance are applicable as well to apnea monitors used on patients of other ages. FDA intends to modify the final guidance document accordingly. FDA invites comments on how this guidance may be adapted to apply to apnea monitors used on patients other than infants and children.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive the draft guidance entitled ''Guidance for Infant/Child Apnea Monitor 510(k) Submissions'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system and enter the document number (1178) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the Center for Devices and Radiological Health (CDRH) home page includes ''Guidance for Infant/Child Apnea Monitor 510(k) Submissions,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. ''Guidance for Infant/Child Apnea Monitor 510(k) Submissions'' is available at http://www.fda.gov/cdrh/ode.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance by December 21, 2000. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 1, 2000.

Linda S. Kahan,

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

[FR Doc. 00–24336 Filed 9–21–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–1965, HCFA–2649, HCFA–5011A & HCFA–5011B]

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

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.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Request for Hearing—Part B Medicare Claim and Supporting Regulations in 42 CFR 405.821; *Form No.:* HCFA–1965 (0938–0034); *Use:* Section 1869 of the Social Security Act authorizes a hearing for any individual who is dissatisfied with any determination and amount of benefit paid. This form is used so that a party may request a hearing by a Hearing Officer because the review determination failed to satisfy the appellant. *Frequency:* Annually, Quarterly and Monthly; *Affected Public:* Individual or Households, and Not-for-profit institutions; *Number of Respondents:* 55,000; *Total Annual Responses:* 55,000; *Total Annual Hours:* 9,167.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Request for Reconsideration of Part A Insurance Benefits and Supporting Regulations in 42 CFR 405.711; *Form No.:* HCFA–2649 (0938–0045); *Use:* Section 1869 of the Social Security Act authorizes a hearing for any individual who is dissatisfied with the intermediary's Part A determination or the benefit amount paid. This form is used by a party to request a reconsideration of the initial determination of benefits. *Frequency:* Annually, Quarterly and Monthly; *Affected Public:* Individuals or Households, and Not-for-profit institutions; *Number of Respondents:* 62,000; *Total Annual Responses:* 62,000; *Total Annual Hours:* 15,500.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Request for Part A Medicare Hearing by an Administrative Law Judge and Supporting Regulations in 42 CFR 498 Subpart D and E; *Form No.:* HCFA–5011A–U6 (0938–0486); *Use:* Section 1869 of the Social Security Act authorizes a hearing for any individual who is dissatisfied with the intermediary's Part A determination or the amount paid. This form is used by the beneficiary or other qualified appellant to request a hearing by an Administrative Law Judge if the reconsideration determination fails to satisfy the appellant. *Frequency:* Annually, Quarterly and Monthly; *Affected Public:* Individuals or Households, and Not-for-profit institutions; *Number of Respondents:* 10,000; *Total Annual Responses:* 10,000; *Total Annual Hours:* 2,500.

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Request for Part B Medicare Hearing by an Administrative Law Judge and Supporting Regulations in 42 CFR 498 Subpart D and E; *Form No.:* HCFA–5011B–U6 (0938–0567); *Use:* Section 1869 of the Social Security Act authorizes a hearing for any individual who is dissatisfied with the carrier's Part B determination or the amount paid. This form is used by the beneficiary or other qualified appellant to request a hearing by an Administrative Law Judge if the hearing officer's decision fails to satisfy the appellant. *Frequency:* Annually, Quarterly and Monthly; *Affected Public:* Individuals or Households, and Not-for-profit institutions; *Number of Respondents:* 10,000; *Total Annual Responses:* 10,000; *Total Annual Hours:* 2,500.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's Web Site Address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed 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: August 3, 2000.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 00–24344 Filed 9–21–00; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Research and Demonstration Projects for Indian Health

AGENCY: Indian Health Service, DHHS.

ACTION: Notice of Single Source Cooperative Agreement With the Center for Native American Health, College of Public Health, University of Arizona.

SUMMARY: The Indian Health Service (IHS) announces continuation of an award of a cooperative agreement to the Center for Native American Health (CNAH), College of Public Health, University of Arizona, for a demonstration project to build and expand on a unique collaborative partnership that currently exists among the CNAH, the IHS, and the Indian tribes located in the southwestern part of the country. This award is for a final 1-year continuation of a project previously funded for a 2-year period (September 1, 1998 through August 31, 2000). The continuation will be effective September 1, 2000, through August 31, 2001. Funding for the continuation period is $229,288 plus an annual in-kind contribution by the University of $94,696.

The award is issued under the authority of the Public Health Service Act, Section 301(a). A general program description is contained in the Catalog of Federal Domestic Assistance, number 93.933.

The specific objectives of the project are: to increase opportunities for sub-specialty medical care at reservation health care facilities; to increase the availability of telemedicine at reservation health care facilities; to enhance community health planning and prevention activities; to facilitate counseling of high school level Indian students for entry into health careers; and to demonstrate the possibilities of replication of this collaborative project at other sites.

Justification for Single Source: This project has been awarded for an additional 1-year continuation on a non-competitive single source basis. The CNAH is a unique organization within the University that is guided by an