Dated: November 8, 2001.

Nancy E. Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 01–28616 Filed 11–14–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Emerging Practices in Child Abuse and Neglect Prevention.

OMB No. New collection.

Description: With increasing understanding and recognition of the individual and family risk factors that increase the likelihood of child maltreatment, particularly since the 1990s, the role and importance of prevention has been vigorously promoted. As a consequence, the development, funding, and implementation of programs and initiatives with a specific focus on prevention, have proliferated around the country. However, the precise nature of these efforts—and their effectiveness—is not yet well understood, and information has not been systematically documented. By identifying and showcasing effective and emerging practices, this project will disseminate the best available information on effective and emerging child abuse and neglect prevention practices to researchers, advocates, practitioners, and policymakers in the prevention community.

Respondents: The universe of potential respondents consists of the child abuse and neglect professional community in its entirety, which includes practitioners, service providers, policy makers in state and local agencies, researchers, advocates, and other affiliated parties.

Annual Burden Estimates

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Track I: Effective practices	10—30	1	6	60—180
Track II: Promising practices	150—200	1	4	600—800
Estimated total annual burden hours				660–980

In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments 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) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: November 7, 2001.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 01–28554 Filed 11–14–01; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 00D–1557 and 00D–1558]

Medical Devices; Class II Special Controls Guidance Document: Indwelling Blood Gas Analyzers; Final Guidance for Industry and FDA; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Class II Special Controls Guidance Document: Indwelling Blood Gas Analyzers; Final Guidance for Industry and FDA.'' This guidance document describes the controls FDA believes will provide reasonable assurance of the safety and effectiveness of three anesthesiology devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule reclassifying indwelling blood gas analyzers from class III to class II (special controls).

DATES: Submit written or electronic comments on the guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Class II Special Controls Guidance Document: Indwelling Blood Gas Analyzers; Final Guidance for Industry and FDA'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), 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. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this 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. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Christy Foreman, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200

Corporate Blvd., Rockville, MD 20850, 301–443–8609.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance document was developed as a special controls guidance to support the reclassification of three anesthesiology devices from class III (premarket approval) to class II (special controls). The three devices are:

- Indwelling blood carbon dioxide partial pressure (Pco_2) analyzer (21 CFR 868.1150),
- Indwelling blood hydrogen ion concentration (pH) analyzer (21 CFR 868.1170), and
- Indwelling blood oxygen partial pressure (Po_2) analyzer (21 CFR 868.1200).

The guidance document combines and supersedes the guidances entitled ''Guidance for Electrical Safety, Electromagnetic Compatibility and Mechanical Testing for Indwelling Blood Gas Analyzer Premarket Notification Submissions'' and ''Guidance for Indwelling Blood Gas Analyzer 510(k) Submissions'' which, in turn, incorporated the special controls listed separately in the March 15, 1999 (64 FR 12774), proposal to reclassify these devices. In the **Federal Register** of November 22, 2000 (65 FR 70357), FDA announced the availability of the two guidance documents that were intended to serve as special controls and invited interested persons to comment on the guidances by February 20, 2001. In that same issue of the **Federal Register** (65 FR 70325), FDA reopened the comment period for 90 days to allow comments regarding the proposed reclassification of the three anesthesiology devices from class III into class II. FDA received no comments on the proposed reclassification of the three devices.

FDA received one comment on the document entitled ''Guidance for Indwelling Blood Gas Analyzer 510(k) Submissions'' that was proposed as a special control for the devices. The comment, submitted by Diametrics Medical Ltd., disagreed that all clinical studies should be designated ''significant risk'' and be conducted under an investigational device exemption (IDE).

FDA agrees with the comment and has modified the guidance. With the exception of devices employing new technology, studies of the device are nonsignificant risk. These nonsignificant risk studies are exempt from IDE requirements in accordance with § 812.2(c)(2) (21 CFR 812.2(c)(2)), but must be performed in accordance with parts 50 and 56 (21 CFR parts 50 and 56). However, if the device employs new technology (i.e., technology different from that used in a legally marketed indwelling blood gas analyzers), FDA has determined that studies of this device are significant risk, as defined in 21 CFR 812.3(m)(4) and, therefore, do not qualify for the abbreviated requirements of § 812.2(b). In addition to the requirement of having an FDA-approved IDE, sponsors of such trials must comply with the regulations governing institutional review boards (part 56) and informed consent (part 50).

Designation of this guidance as a special control means that manufacturers attempting to establish that their device is substantially equivalent to a predicate indwelling blood gas analyzer should demonstrate that the proposed device complies with either the specific recommendations of this guidance or some alternate control that provides equivalent assurance of safety and effectiveness.

II. Significance of Guidance

This guidance document represents the agency's current thinking concerning indwelling blood gas analyzers. 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 and regulations.

The agency has adopted good guidance practices (GGPs) and published the final rule, which set forth the agency's regulations for the development, issuance, and use of guidance documents (21 CFR 10.115). This guidance document is issued as a level 2 guidance in accordance with the GGP regulations.

III. Electronic Access

In order to receive ''Class II Special Controls Guidance Document: Indwelling Blood Gas Analyzers; Final Guidance for Industry and FDA'' 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. At the second voice prompt, press 1 to order a document. Enter the document number (1126) 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 Internet access. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, 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. A search capability for all CDRH guidance documents is available at http://www.fda.gov/cdrh/guidance.html. Guidance documents are also available on the Dockets Management Branch Internet site at http://www.fda.gov/ohrms/dockets.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this guidance at any time. Submit two copies of any comments, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 5, 2001.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 01–28562 Filed 11–14–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4650–N–82]

Notice of Submission of Proposed Information Collection to OMB; Automated Clearing House (ACH) Program Application—Title I Insurance Charge Payments System

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The propose information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* December 17, 2001.

ADDRESSES: Interested persons are invited to submit comments regarding