Part III of the proposed consent order prohibits respondents from representing that the experience represented by any user testimonial or endorsement of the product represents the typical or ordinary experience of members of the public who use the product, unless the representation is true and, at the time it is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation; or respondents disclose what the generally expected results would be for users of the product, or that consumers should not expect to experience similar results.

Part IV of the proposed consent order prohibits respondents from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

The remainder of the proposed consent order also contains provisions regarding record-keeping, distribution of the order, notification of changes in corporate status, notification of changes in employment of the individual respondent, the filing of a compliance report, and termination of the order.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and the proposed order or to modify their terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 01–28582 Filed 11–14–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–02–07]

Proposed Data Collections Submitted 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 Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639–7090.

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. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project

Surveillance for Bloodstream and Vascular Access Infections in Outpatient Hemodialysis Centers (0920–0442)—Renewal—National Center for Infectious Diseases (NCID), NCID Centers for Disease Control and Prevention (CDC), is proposing to renew a study of bloodstream infections, vascular access infections, hospitalization, and antimicrobial starts at U.S. outpatient hemodialysis centers. Although bloodstream and vascular access infections are common in hemodialysis patients, there was previously no system to record and track these complications.

Participation in the proposed project is voluntary. Currently about 80–90 centers report data each month. We estimate that about 100 of the approximately 4,500 U.S. outpatient hemodialysis centers will participate in the coming years. Participating centers may collect data continuously, or may discontinue participation at any time; we estimate that the average center will participate for nine months. Each month, participating centers will record the number of hemodialysis patients they treat and maintain a log of all hospitalizations and intravenous (IV) antimicrobial starts. For each hospitalization or IV antimicrobial start, further information (*e.g.,* type of vascular access, clinical symptoms, presence of a vascular access infection, and blood culture results) will be collected. These data may be reported to CDC on paper forms or via a secure Internet site. CDC aggregates this data and generates reports which are sent to participating dialysis centers.

Centers that participate in the Internet-based reporting system may also analyze their own data and print out reports as desired. Rates of bloodstream infection, vascular access infection, and antimicrobial use per 1000 patient-days will be calculated. Also, the percentage of antimicrobial starts for which a blood culture is performed will be calculated. Through use of these data, dialysis centers will be able to track rates of key infectious complications of hemodialysis. This will facilitate quality control improvements to reduce the incidence of infections, and clinical practice guidelines to improve use of antimicrobials. The total cost to the respondents is $126,000.

Form	Number of respondents	Number of responses/respondent	Average burden/response (in hours)	Total burden (in hours)
Agreement to Participate	100	1	1	100
Census Form	100	12	1	1,200
Log	100	12	1	1,200
Incident Form	100	200	12/60	4,000
Total				6,500

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