strength and weakness in order to target training and technical assistance or further research efforts, and finally, to provide a broader context for lessons learned from the impact study.

Respondents: Early Head Start directors, Early Head Start coordinators and specialists, teachers, home visitors, and parents of Early Head Start children.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Survey of Programs (2004)	[a] 595	1	3.0	1,785.0
Site Visit Protocol (2005)				
Director Protocol	25	1	3.0	75.0
Coordinator/Specialist Protocol: [b]				
Community Partnership	25	1	1.0	25.0
Disabilities	25	1	1.0	25.0
Early Childhood	25	1	1.0	25.0
Family Partnership	25	1	1.0	25.0
Home Visiting	25	1	1.0	25.0
Teacher Protocol [c]	125	1	1.5	187.5
Home Visitor Protocol [c]	125	1	1.5	187.5
Parent Protocol [c]	125	1	1.5	187.5
Total for Site Visits	25			762.5
Estimated Total Annual Burden 2004				1785.5
Estimated Total Annual Burden 2005				762.5

[a] Assumes an 85 percent response rate for the survey.
[b] Not all programs will ahve staff in each position, therefore, burden estimates for some programs may be overstated.
[c] Assumes groups interviews with up to five individuals per site. Assumes that all sites have both home visitors and teachers, although when that is not the case, the burden estimates will be overstated.

Additional Information

Copies of the proposed collections may be obtained by writing to the Administration for Children and Families, Office of Administration, 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. E-mail address: *grjohnson@acf.hhs.gov.*

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register.** Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendation for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Attn: Desk Officer for ACF, E-mail address: *Katherine_T._Astrich@omb.eop.gov.*

Dated: September 7, 2004.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 04–20782 Filed 9–14–04; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0404]

Novel Formulations of Dialysis Solutions; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to gain input from interested persons on how solutions used in hemodialysis or peritoneal dialysis should be evaluated for safety and efficacy. More specifically, the agency is interested in collecting comments on the development of formulations containing novel concentrations of electrolytes and simple sugars, but no new molecular entities.

DATES: The public meeting will be held on September 27, 2004, from 9 a.m. to 4 p.m. Written or electronic comments on dialysis solutions are welcome at any time.

ADDRESSES: The public meeting will be held at the Doubletree Hotel, 1750 Rockville Pike, Rockville, MD. Public parking is available at the hotel. The Doubletree Hotel is also accessible by Metro at the Twinbrook Station on the Red Line.

Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Norman Stockbridge, Center for Drug Evaluation and Research (HFD–110), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5365, e-mail: *Norman.Stockbridge@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is holding a public meeting to discuss the nature of development programs for solutions used in hemodialysis or peritoneal dialysis. The discussion will be limited to solutions containing only simple sugars and the electrolytes and other small molecules normally found in plasma. Solutions containing novel oncotic or osmotic agents more clearly resemble conventional drugs and are subject to conventional drug development programs, with the usual characterization of safety and effectiveness through clinical studies. The discussion will focus on the following questions:

• For solutions with no novel constituents, what clinical studies are necessary?

• Are there acceptable ranges of individual sugars and electrolytes that can be established in clinical studies so that a novel product would not need to demonstrate its ability to act as a dialysate?

• Are there additional constraints for combinations of ingredients, for example, to constrain the overall osmolarity?

• In the absence of clinical studies to show safety and effectiveness, how would appropriate instructions for use be established?

If you need special accomodations due to a disability, please contact Norman Stockbridge at least 7 days in advance.

II. Comments and Transcripts

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on dialysates. Two paper copies of any mailed comments are to be submitted, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

There will be no transcript of this meeting.

Dated: September 9, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–20809 Filed 9–10–04; 3:49 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities Under Emergency Review for the Office of Management and Budget (OMB)

The Health Resources and Services Administration (HRSA) has submitted the following request (see below) for emergency OMB review under the Paperwork Reduction Act (44 U.S.C. Chapter 35). OMB approval has been requested within 5 days of publication of this notice. A copy of the information collection plans may be obtained by accessing *http://www.bphc.hrsa.gov/freeclinicsftca* or contacting Shannon Faltens or Felicia Collins via e-mail at *FreeClinicsFTCA@hrsa.gov* or on (301) 594–0818.

Proposed Project: Free Clinics Federal Tort Claims Act (FTCA) Deeming Application: New

Congress legislated FTCA medical malpractice protection for free clinic volunteer health professionals through section 194 of the Health Insurance Portability and Accountability Act (HIPAA). Individuals eligible to participate in this program are health care practitioners volunteering at free clinics who meet specific eligibility requirements. If an individual meets all the requirements of this program, he/she can be ''deemed'' to be a Federal employee. This deemed status specifically provides immunity from medical malpractice lawsuits as a result of the performance of medical, surgical, dental, or related activities within the scope of the volunteer's work at the free clinic.

The sponsoring free clinic must submit a FTCA deeming application to HRSA on behalf of its volunteer health care professional(s). This application will require information about the sponsoring free clinic's credentialing and privileging systems, risk management practices, and quality assurance processes in order to ensure that the Federal Government is not exposed to undue liability resulting from the medical malpractice coverage of non-qualified health care professionals. Attached to the application will be a listing of specific volunteer health care professionals for whom the sponsoring free clinic is requesting deemed status.

Emergency approval is being requested because the data collection and reporting of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320. This information is needed to ensure the timely availability of data as necessary for the Secretary to make a determination for the provision of FTCA deemed status to volunteer health care professionals working at free clinics. Upon receipt of OMB approval for this submission, HRSA will publish a **Federal Register** notice to begin the process for routine clearance under 5 CFR 1320.

The burden estimate for this project is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
FTCA Deeming Application	600	1	600	2.5	1,500

Written comments and recommendations should be sent within 5 days of publication of this notice to John Kramer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503. Due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to 202–395–6974.

Dated: September 10, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04–20767 Filed 9–14–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources And Services Administration

Agency Information Collection Activities: Proposed Project: Free Clinic FTCA Program Deeming Application; Withdrawal

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of withdrawal.

SUMMARY: The Health Resources and Services Administration (HRSA) is announcing the withdrawal of the 60 day FR notice published on August 27, 2004, FR Doc. 04–19681, for public comment on the proposed data collection project related to the Free Clinic Federal Tort Claims Act (FTCA) Program deeming application. The notice is being withdrawn because the agency is requesting an emergency review and approval from OMB for the deeming application under the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

DATES: The 60 day information collection notice is withdrawn effective September 15, 2004.

FOR FURTHER INFORMATION CONTACT: Susan G. Queen, Ph.D., HRSA Reports Clearance Office, HRSA/OPE Room 14–