web address www.fda.gov/cder/guidance/2762dft.htm under the heading of ''Biopharmaceutic Draft Guidances;'' and the FDA draft guidance entitled ''A Guidance for Industry, Average, Population, and Individual Approaches to Establishing Bioequivalence,'' see the FDA Internet web address www.fda.gov/cder/guidance/1716dft.htm under the heading of ''Biopharmaceutic Draft Guidances;'' (2) provide comments and advice to the Clinical Pharmacology Modeling and Simulation Working Group; (3) receive updates on both FDA intramural research and the Product Quality Research Institute; and (4) provide advice on scientific issues specific to generic drugs.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 6, 2000. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 6, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 5, 2000.

Bernard A. Schwetz,

Acting Deputy Commissioner.

[FR Doc. 00–26606 Filed 10–16–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Survey of IRB Chairs Concerning the Implementation of Pediatric Research Regulations

SUMMARY: 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 National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Survey of IRB Chairs Concerning the Implementation of Pediatric Research Regulations.

Type of Information Collection Request: New.

Need and Use of Information Collection: In order to assess the protection of children who are enrolled in clinical research, it is important to determine how Institutional Review Boards (IRBs) reviewing such research interpret and implement the Federal Regulations for research with children set forth in 45 CFR 46 Subpart D. This study aims to gather this information through telephone interviews with chairpersons of IRBs that review clinical research with children. In addition, we will solicit background information on each IRB from the IRB coordinator. In particular, the survey aims to assess how IRBs assess risk/benefit levels of research with children, when IRBs permit children's assent to be waived, what information IRBs require children to be presented during the asset process, and which children are excluded from participation in riskier research. In addition, the survey will attempt to determine how the recent NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects has affected IRB review. *Frequency of Response:* Once. *Affected Public:* Individuals. *Type of Respondents:* IRB chairpersons and IRB coordinators. The annual reporting burden follows in the table below. The annualized cost to respondents is estimated at: $10,000. There are no Capital Costs to report. There are no Operating or Maintenance Cost to report.

RESPONDENT AND BURDEN ESTIMATE INFORMATION

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
IRB chairs	200	1	0.5	100
IRB coordinators	200	1	0.5	100
Total	.....	.....	.....	200

Request for Comments

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dave Wendler, Ph.D., Head, Unit on Vulnerable Populations, Department of Clinical Bioethics, NIH, Building 10, Room 1C118, 9000 Rockville Pike, Bethesda, MD 20892, or call non-toll-free number (301) 435–8726 or e-mail your request, including your address, to: DWendler@cc.nih.gov.

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received on or before December 18, 2000.

Dated: October 4, 2000.

Ezekiel Emanuel,

Chief, Department of Clinical Bioethics.

[FR Doc. 00–26581 Filed 10–16–00; 8:45 am]

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