TRANSACTION GRANTED EARLY TERMINATION—Continued

ET date	Trans No.	ET req status	Party name
		G	Georgia Pipe Company.

FOR FURTHER INFORMATION CONTACT: Sandra M. Peay or Parcellena P. Fielding, Contact Representatives, Federal Trade Commission, Premerger Notification Office, Bureau of Competition, Room 303, Washington, DC 20580, (202) 326–3100.

By Direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 98–32658 Filed 12–8–98; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Health Care Policy and Research

Contract Review Meeting

In accordance with Section 10(a) of the Federal Advisory Committee Act (5 U.S.C. Appendix 2), announcement is made of the following technical review committee to meet during the month of December 1998:

Name: Technical Review Committee on the Agency for Health Care Policy and Research SBIR Topic 010—Tools to Assist Children/Parents Manage Their Chronic Health Needs.

Date and Time: December 14, 1998, 1:00 p.m.–5:00 p.m.

Place: Agency for Health Care Policy and Research Conference Center, 6010 Executive Boulevard, 4th Floor, Conference Room B, Rockville, Maryland, 20852.

This meeting will be closed to the public.

Purpose: The Technical Review Committee's charge is to provide, on behalf of the Agency for Health Care Policy and Research (AHCPR) Contracts Review Committee, recommendations to the Administrator, AHCPR, regarding the technical merit of contract proposals submitted in response to a specific Request for Proposals regarding the AHCPR Research SBIR Topic 010,—Tools to Assist Children/Parents Manage Their Chronic Health Needs, that was published in the Commerce Business Daily on August 27, 1998.

The purpose of these contracts is to fulfill the Agency for Health Care Policy and Research's participation in the Small Business Innovation Research program (SBIR). The Small Business Research and Development Enhancement Act of 1992 requires the agencies of the Public Health Service (PHS), Department of Health and Human Services (HHS), and other federal agencies to reserve 2.5 percent of their current fiscal year extramural budgets for research or research and development for an SBIR program. This legislation is intended to expand and improve the SBIR program; emphasize increased private sector commercialization of technology development through federal SBIR research and development; increase small business participation in federal research and development; and, foster and encourage participation of socially and economically disadvantaged small business concerns and women-owned small business concerns in the SBIR program.

In Phase I of the SBIR program the contractor will determine and report on the scientific, technical and commercial merit and feasibility of the proposed research or research and development efforts including its ability or capacity to carry out its research or R&D proposal, prior to the provision of further Federal support in Phase II.

The U.S. Department of Health and Human Services issued a Solicitation of the Public Health Service for Small Business Innovation Research Contract Proposals (PHS 99–1) for Topic No. 010 to develop ''Tools to Assist Children/Parents Manage Their Chronic Health Needs.'' An estimated 3 to 30 percent of children (between 2.5 and 25 million children ages 0–21) suffer from one or more chronic conditions. In Phase 1, the contractor will determine the factors important to families caring for chronically ill and disabled children. Offerors should propose an approach or combination of approaches to identify the factors. Some approaches to be considered are literature review, focus groups, secondary data analysis and other techniques appropriate for Phase I contracts. Then, the contractor will develop a prototype decision support tool to assist in family care of a child's chronic illness or disease. Prototype tools could include games for children with chronic illness, technologies that link families with the health care system, workbooks, interactive videos, computer-based or Internet based tools. The prototype should focus on a limited group of chronic conditions requiring families to seek care or support.

Agenda: The Committee meeting will be devoted entirely to the technical review and evaluation of contract proposals submitted in response to the above-referenced Request for Proposals.

The Administrator, AHCPR, has made a formal determination that this meeting will not be open to the public. This action is necessary to safeguard confidential proprietary information and personal information concerning individuals associated with the proposals that may be revealed during this meeting, and to protect the free exchange of views, and avoid undue interference with Committee and Department operations. This is in accordance with section 10(d) of the Federal Advisory Committee Act, 5 U.S.C., Appendix 2, implementing regulation, 41 CFR 101–6.1023 and procurement regulation, 48 CFR section 315.604(d).

Anyone wishing to obtain information regarding this meeting should contact Sandra Robinson, Center for Quality Measurements & Improvement, Agency for Health Care Policy and Research, 2101 East Jefferson Street, Suite 501, Rockville, Maryland, 20852, telephone (301) 594–1703.

Dated: December 2, 1998.

John M. Eisenberg,

Administrator.

[FR Doc. 98–32669 Filed 12–8–98; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Health Care Policy and Research

Contract Review Meeting

In accordance with Section 10(a) of the Federal Advisory Committee Act (5 U.S.C. Appendix 2), announcement is made of the following technical review committee to meet during the month of December 1998:

Name: Technical Review Committee on the Agency for Health Care Policy and Research SBIR Topic 011—''Internet-Based Decision Support for Health Related Quality of Life Instruments.''

Date and Time: December 14, 1998, 9:00 a.m.–12:00 p.m.

Place: Agency for Health Care Policy and Research, Conference Center, Conference Room B, 6010, Executive Boulevard, 4th Floor, Rockville, Maryland 20852.

This meeting will be closed to the public.

Purpose: The Technical Review Committee's charge is to provide, on behalf of the Agency for Health Care Policy and Research (AHCPR) Contracts Review Committee, recommendations to the Administrator, AHCPR, regarding the technical merit of contract proposals submitted in response to a specific Request for Proposals regarding the SBIR Topic 011, Internet-Based Decision Support for Health Related Quality of Life Instruments, that was published in the Commerce Business Daily on August 27, 1998.

One purpose of these contracts is to fulfill the Agency for Health Care Policy and Research's participation in the Small Business Innovation Research program (SBIR). The Small Business Research and Development Enhancement Act of 1992 requires the agencies of the Public Health Service (PHS), Department of Health and Human Services (HHS), and other federal agencies to reserve 2.5 percent of their current fiscal year extramural budgets for research or research and development for an SBIR program. The legislation is intended to

expand and improve the SBIR program; emphasize increased private sector commercialization of technology developed through federal SBIR research and development; increase small business participation in federal research and development; and, foster and encourage participation of socially and economically disadvantaged small business concerns and women-owned small business concerns in the SBIR program.

In Phase I of the SBIR program the contractor will address and report on the scientific, technical and commercial merit and feasibility of its proposed research or research and development efforts and its capacity to perform the proposed work prior to the provision of further Federal support in Phase II.

The U.S. Department of Health and Human Services issued a Solicitation of the Public Health Service for SBIR Contract Proposals (PHS 99–1) for Topic No. 011 to develop ''Internet-Based Decision Support for Health Related Quality of Life Instruments''. One of the most important achievements springing from outcomes and effectiveness research in the past two decades is the recognition by the scientific and clinical communities of the essential role of the patients' perspective in assessing their own health and functioning. This conceptual advance has stimulated a proliferation in the number and applications of patient-based ''health-related quality of life'' (HRQL) measures and assessments tools. The proposed projects are to produce a world wide web (WWW) based software program that functions as a decision support tool and provides scientific guidance to researchers and clinical decision-makers in the design, evaluation and implementation of HRQL assessments. Specifically, in the Phase I application, these projects will first design a front-end web-based query application capable of retrieving information, through a web server and a query server, from a back-end database engine. The query systems will perform interactive keyword searches against various categories of data elements with cross-linked information entries at various levels of specificity.

Further, these web client applications will be platform-independent, such as those written as Java applets, to facilitate access to the knowledge base from different computer operating systems. As a prerequisite, these projects will either have direct access to existing public or proprietary HRQL knowledge bases or will have to build new databases containing a systematic review of HRQL instruments and applications.

Agenda: The Committee meeting will be devoted entirely to the technical review and evaluation of contract proposals submitted in response to the above-described Request for Proposals.

The Administrator, AHCPR, has made a formal determination that this meeting will not be open to the public. This action is necessary to safeguard confidential proprietary information and personal information concerning individuals associated with the proposals that may be revealed during this meeting, and to protect the free exchange of views, and avoid undue interference with Committee and Department operations. This is in accordance with section 10(d) of the Federal Advisory Committee Act 5, U.S.C., Appendix 2, implementing regulations, 41 CFR 101–6.1023 and procurement regulations, 48 CFR section 315.604(d).

Anyone wishing to obtain information regarding this meeting should contact Yen-Pin Chiang, Center for Outcomes and Effectiveness Research, 6010 Executive Boulevard, Suite 300, Rockville, Maryland 20852, (301) 594–4035.

Dated: December 2, 1998.

John M. Eisenberg,

Administrator.

[FR Doc. 98–32670 Filed 12–8–98; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Investigational Biological Product Trials; Procedure to Monitor Clinical Hold Process; Meeting of Review Committee and Request for Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the 1999 meetings of the clinical hold review committee, which reviews the clinical holds that the Center for Biologics Evaluation and Research (CBER) has placed on certain investigational biological product trials. FDA is inviting any interested biological product company to use this confidential mechanism to submit to the committee for its review the name and number of any investigational biological product trial placed on clinical hold during the past 12 months that the company wants the committee to review.

DATES: The meetings will be held on February 9, 1999; May 11, 1999; August 10, 1999; and November 9, 1999. Biological product companies may submit review requests for the February meeting by January 5, 1999; for the May meeting by March 30, 1999; for the August meeting by June 29, 1999; and for the November meeting by September 28, 1999.

ADDRESSES: Submit clinical hold review requests to Amanda Bryce Norton, FDA Chief Mediator and Ombudsman, Office of the Commissioner (HF–7), Food and Drug Administration, 5600 Fishers Lane, rm. 14–105, Rockville, MD 20857, 301–827–3390.

FOR FURTHER INFORMATION CONTACT: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: FDA's regulations in part 312 (21 CFR part 312) provide procedures that govern the use of investigational new drugs and biologics in human subjects. If FDA determines that a proposed or ongoing study may pose significant risks for human subjects or is otherwise seriously deficient, as discussed in the investigational new drug regulations, it may order a clinical hold on the study. The clinical hold is one of FDA's primary mechanisms for protecting subjects who are involved in investigational new drug or biologic trials. Section 312.42 describes the grounds for ordering a clinical hold.

A clinical hold is an order that FDA issues to a sponsor to delay a proposed investigation or to suspend an ongoing investigation. The clinical hold may be ordered on one or more of the investigations covered by an investigational new drug application (IND). When a proposed study is placed on clinical hold, subjects may not be given the investigational drug or biologic as part of that study. When an ongoing study is placed on clinical hold, no new subjects may be recruited to the study and placed on the investigational drug or biologic, and patients already in the study should stop receiving therapy involving the investigational drug or biologic unless FDA specifically permits it.

When FDA concludes that there is a deficiency in a proposed or ongoing clinical trial that may be grounds for ordering a clinical hold, ordinarily FDA will attempt to resolve the matter through informal discussions with the sponsor. If that attempt is unsuccessful, a clinical hold may be ordered by or on behalf of the director of the division that is responsible for the review of the IND.

FDA regulations in § 312.48 provide dispute resolution mechanisms through which sponsors may request reconsideration of clinical hold orders. The regulations encourage the sponsor to attempt to resolve disputes directly with the review staff responsible for the review of the IND. If necessary, the sponsor may request a meeting with the review staff and management to discuss the clinical hold.

CBER began a process to evaluate the consistency and fairness of practices in ordering clinical holds by instituting an oversight committee to review clinical holds (see 61 FR 1033, January 11, 1996). CBER held its first clinical hold review committee meeting on May 17,