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,

1995, and plans to conduct further quality assurance oversight of the IND process. The review procedure of the committee is designed to afford an opportunity for a sponsor who does not wish to seek formal reconsideration of a pending clinical hold to have that clinical hold considered ''anonymously.'' The committee consists of senior managers of CBER, a senior official from the Center for Drug Evaluation and Research, and the FDA Chief Mediator and Ombudsman.

Clinical holds to be reviewed will be chosen randomly. In addition, the committee will review some of the clinical holds proposed for review by biological product sponsors. In general, a biological product sponsor should consider requesting review when it disagrees with FDA's scientific or procedural basis for the decision.

Requests for committee review of a clinical hold should be submitted to the FDA Chief Mediator and Ombudsman, who is responsible for selecting clinical holds for review. The committee and CBER staff, with the exception of the FDA Chief Mediator and Ombudsman, are never advised, either in the review process or thereafter, which of the clinical holds were randomly chosen and which were submitted by sponsors. The committee will evaluate the selected clinical holds for scientific content and consistency with FDA regulations and CBER policy.

The meetings of the oversight committee are closed to the public because committee discussions deal with confidential commercial information. Summaries of the committee deliberations, excluding confidential commercial information, may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. If the status of a clinical hold changes following the committee's review, the appropriate division will notify the sponsor.

For each meeting, FDA invites biological product companies to submit to the FDA Chief Mediator and Ombudsman the name and IND number of any investigational biological product trial that was placed on clinical hold during the past 12 months that they want the committee to review. Submissions should be made by January 5, 1999, for the February meeting; by March 30, 1999, for the May meeting; by June 29, 1999, for the August meeting; and by September 28, 1999, for the November meeting to Amanda Bryce Norton, FDA Chief Mediator and Ombudsman (address above).

Dated: December 1, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–32643 Filed 12–8–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–9002–N]

RIN 0938–AI13

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—Second Quarter, 1998

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice lists HCFA manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published during April, May, and June of 1998 that relate to the Medicare and Medicaid programs. It also identifies certain devices with investigational device exemption numbers approved by the Food and Drug Administration that may be potentially covered under Medicare.

Section 1871(c) of the Social Security Act requires that we publish a list of Medicare issuances in the **Federal Register** at least every 3 months. Although we are not mandated to do so by statute, for the sake of completeness of the listing, we are including all Medicaid issuances and Medicare and Medicaid substantive and interpretive regulations (proposed and final) published during this timeframe.

FOR FURTHER INFORMATION CONTACT:

Bridgett Wilhite, (410) 786–5248 (For Medicare instruction information).

Betty Stanton, (410) 786–3247 (For Medicaid instruction information).

Sharon Hippler, (410) 786–4633 (For Food and Drug Administration-approved investigational device exemption information).

Kristy Nishimoto, (410) 786–8517 (For all other information).

SUPPLEMENTARY INFORMATION:

I. Program Issuances

The Health Care Financing Administration (HCFA) is responsible for administering the Medicare and Medicaid programs, which pay for health care and related services for 38 million Medicare beneficiaries and 36 million Medicaid recipients. Administration of these programs involves (1) providing information to Medicare beneficiaries and Medicaid recipients, health care providers, and the public, and (2) effective communications with regional offices, State governments, State Medicaid Agencies, State Survey Agencies, various providers of health care, fiscal intermediaries and carriers that process claims and pay bills, and others. To implement the various statutes on which the programs are based, we issue regulations under the authority granted the Secretary under sections 1102, 1871, and 1902 and related provisions of the Social Security Act (the Act) and also issue various manuals, memoranda, and statements necessary to administer the programs efficiently.

Section 1871(c)(1) of the Act requires that we publish in the **Federal Register** at least every 3 months a list of all Medicare manual instructions, interpretive rules, and guidelines of general applicability not issued as regulations. We published our first notice June 9, 1988 (53 FR 21730). Although we are not mandated to do so by statute, for the sake of completeness of the listing of operational and policy statements, we are continuing our practice of including Medicare substantive and interpretive regulations (proposed and final) published during the 3-month time frame.

II. How to Use the Addenda

This notice is organized so that a reader may review the subjects of all manual issuances, memoranda, substantive and interpretive regulations, or Food and Drug Administration-approved investigational device exemptions published during the timeframe to determine whether any are of particular interest. We expect it to be used in concert with previously published notices. Those unfamiliar with a description of our Medicare manuals may wish to review Table I of our first three notices (53 FR 21730, 53 FR 36891, and 53 FR 50577) and the notice published March 31, 1993 (58 FR 16837). Those desiring information on the Medicare Coverage Issues Manual may wish to review the August 21, 1989 publication (54 FR 34555).

To aid the reader, we have organized and divided this current listing into five addenda. Addendum I lists the publication dates of the most recent quarterly listings of program issuances.

Addendum II identifies previous **Federal Register** documents that contain a description of all previously