and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1293.

SUPPLEMENTARY INFORMATION: On November 7, 1994, Matritech, Inc., Newton, MA 02160, submitted to CDRH an application for premarket approval of the Matritech NMP22™ Test Kit. The Matritech NMP22™ Test Kit is an enzyme immunoassay for the in vitro quantitative determination of nuclear matrix protein NMP22 in stabilized voided urine. The Matritech NMP22™ Test Kit is indicated as an aid in the management of patients with transition cell carcinoma of the urinary tract (TCC/UT), after surgical treatment to identify those patients with occult or rapidly recurring TCC/UT. The Matritech NMP22™ Urine Collection Kit is intended for the collection, stabilization, and transport of human urine which will be tested using the Matritech NMP22™ Test Kit.

On November 30, 1995, the Immunology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On July 2, 1996, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before January 8, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: November 7, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 96–31246 Filed 12–6–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[HCFA–3070G–I]

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Reinstatement without change; *Title of Information Collection:* Intermediate Care Facility for the Mentally Retarded or Persons with Related Conditions Survey Report Form and Supporting Regulations 42 CFR Sections 431, 435, 440, 442 and 483, Subpart I ; *Form No.:* HCFA 3070G–I; *Use:* The survey form and supporting regulations are needed to ensure provider compliance. In order to participate in the Medicaid program as an Intermediate Care Facility for the Mentally Retarded (ICF/MR), providers must meet Federal standards. The survey report form is used to record providers' compliance with the individual standard and report it to the Federal Government. *Frequency:* annually; *Affected Public:* Business or other for-profit, Not for-profit institutions, State, Local or Tribal Govt.; *Number of Respondents:* 7200; *Total Annual Responses:* ,7200; *Total Annual Hours:* 6,074,370.

2. *Type of Information Collection Request:* Extension of currently approved collection; *Title of Information Collection:* Medicare Current Beneficiary Survey Supplement-Round 18; *Form No.:* HCFA–P–15A; *Use:* The Office of the Actuary, HCFA, conducts the Medicare Current Beneficiary Survey (MCBS) through personal interviews of a random sample of Medicare beneficiaries. When sampled persons are found to reside in a long-term care facility, interviewers use a version of the questionnaire which is specially designed to obtain data about the beneficiary's health care from knowledgeable staff members. We are preparing to convert the facility interview from a hardcopy questionnaire to a Computer Assisted Personal Interviewing (CAPI) format beginning in May, 1997. CAPI, which we are currently using in the community interviews, increases the accuracy of the interview process by automating skip patterns, customizing questions, creating computed variables such as a time line of residence history, and automatically checking completeness and consistency of responses. Concurrently, we are modifying some of the questions we currently use in the facility interview to make them more comparable to those in other surveys, particularly the Medical Expenditure Panel Survey (MEPS). These modifications are responsive to the President's initiative toward consistency and integration among surveys; *Frequency:* Annually; *Affected Public:; Number of Respondents:* 1,900; *Total Annual Responses:* 1,900; *Total Annual Hours:* 1,900.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at http://www.hcfa.gov/regs/prdact95.htm, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Analysis and Planning Staff, Attention: John Rudolph, Room C2–25–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: December 2, 1996.

Edwin J. Glatzel,

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources.

[FR Doc. 96–31145 Filed 12–6–96; 8:45 am]

BILLING CODE 4120–03–P

[ORD–094–N]

New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: October 1996

AGENCY: Health Care Financing Administration (HCFA).

ACTION: Notice.

SUMMARY: This notice identifies proposals submitted during the month of October 1996 under the authority of section 1115 of the Social Security Act and those that were approved, disapproved, pending, or withdrawn during this time period. (This notice can be accessed on the Internet at HTTP://WWW.HCFA.GOV/ORD/ORDHP1.HTML.)

DATES: We will accept written comments on these proposals. We will, if feasible, acknowledge receipt of all comments, but we will not provide written responses to comments. We will, however, neither approve nor disapprove any new proposal for at least 30 days after the date of this notice to allow time to receive and consider comments. Direct comments as indicated below.

ADDRESSES: Mail correspondence to: Susan Anderson, Office of Research and Demonstrations, Health Care Financing Administration, Mail Stop C3–11–07, 7500 Security Boulevard, Baltimore, MD 21244–1850.

FOR FURTHER INFORMATION CONTACT: Susan Anderson (410) 786–3996.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 1115 of the Social Security Act (the Act), the Department of Health and Human Services (HHS) may consider and approve research and demonstration proposals with a broad range of policy objectives. These demonstrations can lead to improvements in achieving the purposes of the Act.

In exercising her discretionary authority, the Secretary has developed a number of policies and procedures for reviewing proposals. On September 27, 1994, we published a notice in the Federal Register (59 FR 49249) that specified (1) the principles that we ordinarily will consider when approving or disapproving demonstration projects under the authority in section 1115(a) of the Act; (2) the procedures we expect States to use in involving the public in the development of proposed demonstration projects under section 1115; and (3) the procedures we ordinarily will follow in reviewing demonstration proposals. We are committed to a thorough and expeditious review of State requests to conduct such demonstrations.

As part of our procedures, we publish a notice in the Federal Register with a monthly listing of all new submissions, pending proposals, approvals, disapprovals, and withdrawn proposals. Proposals submitted in response to a grant solicitation or other competitive process are reported as received during the month that such grant or bid is awarded, so as to prevent interference with the awards process.

II. Listing of New, Pending, Approved, and Withdrawn Proposals for the Month of October 1996

A. Comprehensive Health Reform Programs

1. New Proposals

The following comprehensive health reform proposal was received during the month of October:

Demonstration Title/State: State of Washington Medicaid Section 1115(a) Waiver Request—Washington.

Description: Under ''The State of Washington Medicaid Section 1115(a) Waiver Request,'' the State is requesting waivers of the 75/25 and lock-in requirements. The State's intent is for the demonstration to subsume the current 1915(b) Healthy Options Program. The State is planning innovations with encounter data, Medicaid HEDIS, and quality measures for the disabled population.

Date Received: October 2, 1996.

State Contact: Jane Beyer, Assistant Secretary, Medical Assistance Administration, Department of Social and Health Services, P.O. Box 45500, Olympia, Washington 98504–5500, (360) 586–6513.

Federal Project Officer: Nancy Goetschius, Health Care Financing Administration, Office of Research & Demonstration, Office of State Health Reform Demonstrations, Mail Stop C3–18–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

2. Pending Proposals

Demonstration Title/State: Better Access for You (BAY) Health Plan Demonstration—Alabama.

Description: Alabama proposes to create a mandatory managed care delivery system in Mobile County for non-institutionalized Medicaid beneficiaries and an expansion population of low-income women and children. The network, called the Bay Health Network, would be administered by the PrimeHealth Organization, which is owned by the University of South Alabama Foundation. The State also proposes to expand family planning benefits for pregnant women whose income is less than 133 percent of the Federal poverty level.

Date Received: July 10, 1995.

State Contact: Vicki Huff, Director, Managed Care Division, Alabama Medicaid Agency, P.O. Box 5624, Montgomery, AL 36103–5624, (334) 242–5011.

Federal Project Officer: Maria Boulmetis, Health Care Financing Administration, Office of Research and Demonstrations, Mail Stop C3–18–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Demonstration Title/State: Arizona Health Care Cost Containment System (AHCCCS)—Arizona.

Description: Arizona proposes to expand eligibility under its current section 1115 AHCCCS program to individuals with incomes up to 100 percent of the Federal poverty level.

Date Received: March 17, 1995.

State Contact: Mabel Chen, M.D., Director, Arizona Health Care Cost Containment System, 801 East Jefferson, Phoenix, AZ 85034, (602) 271–4422.

Federal Project Officer: Joan Peterson, Health Care Financing Administration, Office of Research and Demonstrations, Mail Stop C3–18–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Demonstration Title/State: The Georgia Behavioral Health Plan—Georgia.