of outstanding debts owed to the Federal Government, typically, to provide an incentive for debtors to repay delinquent Federal Government debts by making these debts part of their credit records. Disclosure of records is limited to the individual's name, address, Social Security number, and other information necessary to establish the individual's identity; the amount, status, and history of the claim; and the agency or program under which the claim arose. This disclosure will be made only after the procedural requirements of 31 U.S.C. 3711(f) have been followed.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Legal size files in filing cabinets.

RETRIEVABILITY:

These records are manually retrieved by name of the non-Government party, whether claimant, plaintiff, or alleged debtor. In some instances, these records are retrievable by computer using name of the party involved.

SAFEGUARDS:

Office buildings in which files are kept are locked after the close of the business day. These files are only accessible to General Counsel staff, to designated claims program specialists in the Public Health Service, and with respect to the Early Offers Pilot records, to HHS's contractor.

RETENTION AND DISPOSAL:

The records are maintained for an indefinite duration.

SYSTEM MANAGER(S) AND ADDRESS:

The agency official responsible for the system policies and practices outlined above is: The General Counsel, Department of Health and Human Services, Office of the General Counsel, Room 713F, Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

NOTIFICATION:

Any inquiries regarding this system of records should be addressed to the System Manager.

(These notification and access procedures are in accordance with Department Regulations (45 CFR 5b.5).)

RECORD ACCESS PROCEDURES:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. (These access procedures are in accordance with Department Regulations (45 CFR 5b.5(a)(2)), **Federal Register**, October 8, 1975, page 47410.)

CONTESTING RECORD PROCEDURES:

Contact the official at the address specified under System Manager(s) Address above, and reasonably identify the record, specify the information to be contested, and specify the corrective action sought, with supporting justification (i.e., how it is inaccurate, irrelevant, not timely, or incomplete). (These procedures are in accordance with Department Regulations (45 CFR 5b.7), **Federal Register**, October 8, 1975, page 47411.)

RECORD SOURCE CATEGORIES:

The information in this system comes from a number of sources including private individuals, private and public hospitals, doctors, law enforcement agencies and officials, private attorneys, accident reports, third parties, claimants or beneficiaries and their relatives, other Federal agencies, State and local governments, agencies and instrumentalities.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

Appendix

Office of the General Counsel—Headquarters Offices, Department of Health and Human Services, Humphrey Building, Room 713F, 200 Independence Avenue, SW., Washington, DC 20201.

Office of the General Counsel, Regional Attorney—Region I, Department of Health and Human Services, John F. Kennedy Federal Building, Room 2250, Government Center, Boston, Massachusetts 02203.

Office of the General Counsel, Regional Attorney—Region II, Department of Health and Human Services, Jacob K. Javitz Federal Building, Room 3908, 26 Federal Plaza, New York, New York 10278.

Office of the General Counsel, Regional Attorney—Region III, Department of Health and Human Services, The Public Ledger Building, Suite 418, 150 S. Independence Mall West, Philadelphia, Pennsylvania 19106–3499.

Office of the General Counsel, Regional Attorney—Region IV, Department of Health and Human Services, Suite 5M60, 61 Forsyth Street, Atlanta, Georgia 30303.

Office of the General Counsel, Regional Attorney—Region V, Department of Health and Human Services, Suite 700, 233 North Michigan Avenue, Chicago, Illinois 60601–5519.

Office of the General Counsel, Regional Attorney—Region VI, Department of Health and Human Services, Room 1138, 1301 Young Street, Dallas, Texas 75202.

Office of the General Counsel, Regional Attorney—Region VII, Department of Health and Human Services, Room 1711, 601 East 12th Street, Kansas City, Missouri 64106.

Office of the General Counsel, Regional Attorney—Region VIII, Department of Health and Human Services, Room 300, 1961 Stout Street, Denver, Colorado 80294.

Office of the General Counsel, Regional Attorney—Region IX, Department of Health and Human Services, Room 420, 50 United Nations Plaza, San Francisco, California 94102–4912.

Office of the General Counsel, Regional Attorney—Region X, Department of Health and Human Services, Blanchard Plaza, Suite 702, 2201 Sixth Avenue, Seattle, Washington 98121–1833.

Director, Division of Public Health Service Claims, Room 17A–17, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

For records related to the Early Offers Pilot, Professor David A. Hyman, University of Illinois College of Law, 504 East Pennsylvania Avenue, Champaign, Illinois 61820–6909.

Dated: December 3, 2004.

Alex M. Azar II,

General Counsel,

[FR Doc. 04–27008 Filed 12–8–04; 8:45 am]

BILLING CODE 4190–26–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Nominations of Topics for Evidence-based Practice Centers

AGENCY: Agency for Healthcare Research and Quality (AHRQ), DHHS.

ACTION: Nominations of topics for evidence reports and technology assessments.

SUMMARY: AHRQ invites nominations of topics for evidence reports and technology assessments relating to the prevention, diagnosis, treatment and management of common diseases and clinical conditions, as well as topics relating to the organization and financing of health care. Previous evidence reports can be found at *http://www.ahrq.gov/clinic.epcix.htm.*

DATES: Topic nominations should be submitted by January 31, 2005, in order to be considered for fiscal year 2005. In addition to timely responses to this request for nominations, AHRQ also accepts topic nominations on an ongoing basis for consideration for future years. AHRQ will not reply to individual responses, but will consider all nominations during the selection process. Those who submitted topics that were selected will be notified by AHRQ.

ADDRESSES: Topics nominations should be submitted to Kenneth Fink, MD, MGA, MPH, Director, Evidence-based Practice Centers (EPC) Program, Center for Outcomes and Evidence, AHRQ, 540 Gaither Road, Rockville, MD 20850.

Electronic submissions to *epc@ahrq.gov.* are preferred.

FOR FURTHER INFORMATION CONTACT: Kenneth Fink, MD, MGA, MPH, Center for Outcomes and Evidence, AHRQ, 540 Gaither Road, Rockville, MD 20850; Phone: (301) 427–1617; Fax: (301 427–1640; E-mail: *kfink@ahrq.gov.*

Arrangement for Public Inspection: All nominations will be available for public inspections at the Center for Outcomes and Evidence, telephone (301) 427–1600, weekdays between 8:30 a.m. and 5 p.m. (eastern time).

SUPPLEMENTARY INFORMATION:

Background

Under Title IX of the Public Heath Service Act (42 U.S.C. 299–299c–7) as amended by Public Law 106–129 (1999), AHRQ is charged with enhancing the quality, appropriateness, and effectiveness of health care services and access to such services. AHRQ accomplishes these goals through scientific research and through the promotion of improvements in clinical practice and health systems practices, including the prevention of diseases and other health conditions.

2. Purpose and Overview

The purpose of this notice is to solicit topic nominations for evidence reports and technology assessments. Professional societies, health systems, employers, insurers, providers, and consumer groups are encouraged to nominate topics and then collaborate with AHRQ, *e.g.*, with suggestions for, and comments, on, draft assessments, as it carries out its mission to promote the practice of evidence-based health care. In this endeavor, AHRQ serves as a science partner with private-sector and public organizations in their efforts to improve the quality, effectiveness, and appropriateness of health care delivery in the United States, and to expedite the translation of evidence-based research findings into improved health care services. To undertake scientific analyses and evidence syntheses on topics of high-priority to its public and private health care partners and the health care community generally, AHRQ awards task order contracts to its Evidence-based Practice Centers (EPCs).

The EPCs produce science syntheses—evidence reports and technology assessments—that provide to public and private organizations the foundation for developing and implementing their own practice guidelines, performance measures, educational programs, and other strategies to improve the quality of health care and decisionmaking related to the effectiveness and appropriateness of specific health care technologies and services. The evidence reports and technology assessments also may be used to inform coverage and reimbursement policies. As the body of scientific studies related to organization and financing of health care grows, systematic review and analysis of these studies, in addition to clinical and behavioral research, can provide health system organizations with a scientific foundation for developing or improving system-wide policies and practices.

Each year, the AHRQ supports approximately nine evidence reports in collaboration with non-Federal partners, including national associations, medical societies, health plans, and others. Nominations of topics from non-Federal partners are solicited annually through a notice in the **Federal Register**. However, topic nominations are accepted on an ongoing basis. All nominations received in the previous year as well as topics that were previously submitted but not selected are considered for the upcoming year.

Reports and assessments usually require about 12 months for completion. AHRQ widely disseminates the EPC evidence reports and technology assessments, both electronically and in print. The EPC evidence reports and technology assessments do not make clinical recommendations or recommendations regarding reimbursement and coverage policies.

3. Role/Responsibilities of Partners

Nominators of topics selected for development of an EPC evidence report or technology assessment assume the role of partners of AHRQ and the EPCs. Partners have defined roles and responsibilities. AHRQ places high value on these cooperative relationships, and takes into consideration a partner organization's past performance of these responsibilities, when considering whether to accept additional topics nominated by that organization in subsequent years. Specifically, partners are expected to serve as resources to EPCs as they develop the evidence reports and technology assessments related to the nominated topic; serve as external peer reviewers of relevant draft evidence reports and assessments; and commit to timely translation of the EPC reports and assessments into their own quality improvement tools (*e.g.*, clinical practice guidelines, performance measures), educational programs, and reimbursement policies; and dissemination of these derivative products to their membership as appropriate. AHRQ also is interested in members' use of these derivative products and the products' impact on enhanced health care. AHRQ looks to its partners to provide the use and impact data on products that are based on EPC evidence reports and technology assessments.

4. Topics for Reports

The EPCs prepare evidence reports and technology assessments on topics for which there is significant demand for information by health care providers, insurers, purchasers, health-related societies, and patient advocacy organizations. Such topics may include the prevention, diagnosis and/or treatment of particular clinical and behavioral conditions, use of alternative or complementary therapies, and appropriate use of commonly provided services, procedures, or technologies. Topics also may include issues related to the organization and financing of care such as risk adjustment methodologies, market performance measures, provider payment mechanisms, and insurance purchasing tools, as well as measurement or evaluation of provider integration of new scientific findings regarding health care and delivery innovations. Previous evidence reports can be found at *http://www.ahrq.gov/clinic/epcix.htm.*

AHRQ is very interested in receiving topic nominations from professional societies and organizations comprised of members of minority populations, as well as topic nominations that have significant impact on AHRQ priority populations including low income groups, minority groups, women, children, the elderly, and individuals with special health care needs, such as those with disabilities, those who need chronic care or end-of-life health care, or those who live in inner-city and rural areas.

5. Topic Nomination

Nominations of topics for AHRQ evidence reports and technology assessments should focus on specific aspects of prevention, diagnosis, treatment and/or management of a particular condition; an individual procedure, treatment, or technology; or a specific health care organizational or financial strategy. The processes that AHRQ employs to select clinical and behavioral topics as well as organization and financing topics nominated by the EPCs is described below. For each topic, the nominating organization must provide the following information:

A. Rationale and supporting evidence on the relevance and importance of the topic;

B. Three to five focused questions on the topic to be addressed;

C. Plans for rapid translation of the evidence reports and technology assessments into clinical guidelines, performance measures, educational programs, or other strategies for strengthening the quality of health care services, or plans to inform development of reimbursement or coverage policies;

D. Plans for use and/or dissemination of these derivative products, *e.g.,* to membership if appropriate; and,

E. Process by which the nominating organization will measure the use of these products and impact of such use.

6. Topic Selection

Factors that will be considered in the selection of topics for AHRQ evidence report and technology assessment topics include:

A. Burden of disease including severity, incidence and/or prevalence or relevance of organizational/financial topic to the general population and/or AHRQ's priority populations;

B. Controvery or uncertainty about the topic and availability of scientific data to support the systematic review and analysis of the topic;

C. Total costs associated with a condition, procedure, treatment, technology, or organization/financial topic taking into account the number of people needing such care, the unit cost of care, and related or indirect costs;

D. Potential for achieving clinically significant variations in the prevention, diagnosis, treatment, or management of a disease or condition; or in changing the use of a procedure or technology; informing and improving patient and/or provider decisionmaking; improving health outcomes; and/or reducing costs;

E. Relevance to the needs of the Medicare, Medicaid and other Federal health care programs; and,

F. Nominating organization's plan to disseminate derivative products, measure use and impact of these products on outcomes, or otherwise incorporate the report into its managerial or policy decisionmaking.

7. Submission of Nominations

Topics nominations should be submitted to Kenneth Fink, MD, MGA, MPH, Director, Evidence-based Practice Centers (EPC) Program, Center for Outcomes and Evidence, AHRQ, 540 Gaither Road, Rockville, MD 20850. Electronic submissions to *epc@ahrq.gov* are preferred.

Dated: November 30, 2004.

Carolyn M. Clancy,

Director.

[FR Doc. 04–27058 Filed12–8–04; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004P–0519]

Cottage Cheese Deviating From Identity Standard; Temporary Permit for Market Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a temporary permit has been issued to Wells' Dairy, Inc., to market test cottage cheese that deviates from the U.S. standard of identity for cottage cheese. The purpose of the temporary permit is to allow the applicant to measure consumer acceptance of the product, identify mass production problems, and assess commercial feasibility.

DATES: This permit is effective for 15 months, beginning on the date the permit holder introduces or causes the introduction of the test product into interstate commerce, but not later than March 9, 2005.

FOR FURTHER INFORMATION CONTACT: Ritu Nalubola, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2371.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 130.17 concerning temporary permits to facilitate market testing of foods deviating from the requirements of the standards of identity issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341), FDA is giving notice that a temporary permit has been issued to Wells' Dairy, Inc., 1 Blue Bunny Dr., P.O. Box 1310, Le Mars, IA 51031.

The permit covers limited interstate marketing tests of these products:

1. Blue Bunny Brand
   - ''Cottage cheese, 4% milkfat, homestyle, large curd'' 24 ounces (oz);
   - ''Cottage cheese, 4% milkfat, original, small curd'' 32 oz;
   - ''Cottage cheese, 4% milkfat, original, small curd'' 24 oz;
   - ''Cottage cheese, 4% milkfat, original, small curd'' 12 oz;
   - ''Cottage cheese, 2% milkfat, reduced fat'' 24 oz;
   - ''Cottage cheese, 2% milkfat, reduced fat'' 12 oz;
   - ''Cottage cheese, 1% milkfat, lowfat'' 24 oz;
   - ''Cottage cheese, 1% milkfat, lowfat'' 12 oz; and
   - ''Cottage cheese, Health Smart, fat free'' 24 oz.

2. Great Value Brand
   - ''Cottage cheese, 4% milkfat, large curd'' 24 oz;
   - ''Cottage cheese, 4% milkfat, large curd'' 16 oz;
   - ''Cottage cheese, 4% milkfat, small curd'' 24 oz;
   - ''Cottage cheese, 4% milkfat, small curd'' 16 oz;
   - ''Cottage cheese, 1% milkfat, lowfat, small curd'' 24 oz;
   - ''Cottage cheese, 1% milkfat, lowfat, small curd'' 16 oz; and
   - ''Cottage cheese, fat free, small curd'' 24 oz.

3. ShurFresh Brand
   - ''Cottage cheese, 4% milkfat, small curd'' 24 oz.

These cottage cheese products may deviate from the U.S. standard of identity for cottage cheese (21 CFR 133.128) in that the products are formulated using fluid ultrafiltered (UF) skim milk. Fluid UF skim milk is obtained by subjecting skim milk to a physical separation process called ultrafiltration using a membrane with a pore size of 10,000 Daltons molecular weight cutoff, resulting in the partial loss of lactose, minerals, water-soluble vitamins, and water present in skim milk. The casein-to-whey protein ratio of skim milk is not altered during the ultrafiltration process. The moisture content of fluid UF skim milk so obtained is about 80 percent. Fluid UF skim milk is added to skim milk at a level needed to increase the total solids of the cheese milk by 5 to 25 percent. The physical, chemical, and sensory properties characteristic of cottage cheese are not altered in the test product. The fluid UF skim milk will be declared in the ingredient statement of the finished cottage cheese as ''ultrafiltered skim milk.'' The test product meets all the requirements of the standard with the exception of the use of fluid UF skim milk. The purpose of the temporary permit is to allow the applicant to measure consumer acceptance of the product, identify mass production problems, and assess commercial feasibility.

This permit provides for the temporary marketing of a total of 15 million pounds (6.8 million kilograms) of the test product. The test products will be manufactured by Wells' Dairy,