other countries. The most common concern is how an adequate level of safety can be verified.

Under current Federal law and regulation, FDA can only take action on imported food products based on a violation of the Federal Food, Drug, and Cosmetic Act (FFDCA). Importation of milk products without adhering to any of the three options described above, is NOT, in and of itself, a violation of the FFDCA.[1]

Based on the 1977 MOU, milk protection measures in the United States have been set by the combined efforts of FDA and the States under the NCIMS milk safety program.

Under this program the States must adopt as law and enforce the provisions of the PMO as specified in the ''Procedures''. Their collective actions are intended to insure that milk marketed in the United States meets the U.S. appropriate level of protection.

FDA works with the States to verify that the U.S. level of protection is met under authority of the Public Health Service Act (42 U.S.C.). Under this act FDA has a broad mandate to assist States technically and to evaluate their performance under the ''Procedures''. However, current regulations promulgated under this act do not provide an adequate base for direct FDA enforcement of the PMO.

If the U.S. level of protection, as currently met by consistent State enforcement of the PMO, is to continue to be met, it must be accomplished by States continuing to collectively require this level of protection.

Under U.S. trade agreements products imported from another country must be treated by States and by FDA, no less favorably than those products imported from another State.

The three options in this memorandum can be used by States to assure that the same level of safety for ''Grade A'' defined products is achieved for products produced in other countries.

In order for the agency to function within the provisions of the MOU and fulfill its food safety responsibility, FDA will note, in State program evaluations, if a State is not requiring the NCIMS ''Grade A'' level of protection in interstate or international commerce.

If after a reasonable opportunity to correct this situation, a State still does not provide their citizens with this level of protection, FDA may declare that the State is not in substantial compliance under the ''Procedures * * *''

Copies of this memorandum are enclosed for your distribution to District Milk Specialists, State milk regulatory agencies, State Laboratory Evaluation Officers and State Milk Rating Officers in your region. This memorandum is also available on the FDA Prime Connection Computer bulletin board system (Internet address: http://www.cfsan.fda.gov), and should be widely distributed to representatives of the dairy industry and other interested parties. /S/''

## II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the guidance entitled ''Importation of PMO Defined Dairy Products (M–I–00–4)'' at any time. Two copies of written comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and written and electronic comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

## III. Electronic Access

Persons with access to the Internet may obtain copies of the guidance entitled ''Importation of PMO Defined Dairy Products (M–I–00–4)'' at http://www.cfsan.fda.gov.

Dated: June 19, 2000.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 00–16292 Filed 6–28–00; 8:45 am]

**BILLING CODE 4160–01–F**

[1] Milk or cream may also need a permit under the provisions of the Federal Import Milk Act.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

**Proposed Project: AIDS Drug Assistance Program (ADAP): ADAP Monthly Client Utilization and Program Expenditures Report (OMB No. 0915–0219)—Revision**

State AIDS Drug Assistance Programs (ADAPs), funded under Title II of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act Amendments of 1996 [Pub. L. 104–146], are designed to provide low income, uninsured, and underinsured individuals with access to HIV/AIDS medications that prevent serious deterioration of health arising from HIV disease, including the prevention and treatment of opportunistic infections.

During the last several years, there has been an increasing need for pharmaceuticals among uninsured and underinsured low-income individuals who are HIV positive or diagnosed with AIDS. Due to the increasing demand, the Division of Service Systems (DSS), Health Resources and Services Administration (HRSA) recognizes the importance of program planning and budget forecasting in order to maximize resources, and proposes to revise the current data collection form to better collect relevant client utilization data and program expenditure information from State ADAPs. This data collection effort is designed to allow DSS/HRSA (the funding agency) to monitor nationwide trends in program growth, client utilization, expenditures and to assess the capacity of State ADAPs to maintain services for clients throughout the fiscal year. The revised form will improve DSS/HRSA's ability to track the prices of HIV/AIDS drugs in order to ensure that State ADAPs are receiving the best price possible, to identify emerging issues and technical assistance needs, and to share information among State ADAPs. It will also assist Title II grantees, State ADAPs, DSS/HRSA staff, and policymakers at both the Federal and State level to better understand the level of client demand for medications and the resources needed to meet those needs.

The revised report will collect time-specific data for the number of enrolled clients, the number of new clients, the number of utilizing clients, the level of funds expended, and the price of HIV/AIDS drugs. A text box is provided to allow State ADAPs to report significant changes to their program, such as a projected budget shortfall, program restrictions, client waiting lists, a change in eligibility criteria, or formulary changes. On a quarterly basis, State ADAPs will report the purchase price paid on a select number of HIV

pharmaceuticals dispensed by each program. DSS/HRSA will continue to compile summary reports that are distributed back to grantees and State ADAPs on a quarterly basis. HRSA, the Department of Health and Human Services and the Office of Management and Budget also utilize these summary reports. The data collected are used to guide program planning, formulate budget recommendations, and monitor State ADAPs, especially monitoring the balance between an individual State ADAP's available resources against the client demand for medications. The burden estimates are as follows:

| HRSA form | Number of respondents | Reponses per respondent | Total responses | Hours per responses | Total burden hours |
|---|---|---|---|---|---|
| Title II ADAP Grantees (Clients and Expenditures) | 54 | 12 | 648 | 0.75 | 486 |
| Title II ADAP Grantees (Pricing) | 54 | 4 | 216 | 0.75 | 162 |
| Total | 54 | 16 | 864 | 0.75 | 648 |

Send comments to Susan G. Queen, HRSA Reports Clearance Officer, Room 14–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received on or before August 28, 2000.

Dated: June 21, 2000.

**Jane Harrison,**

*Director, Division of Policy Review and Coordination.*

[FR Doc. 00–16257 Filed 6–27–00; 8:45 am]

**BILLING CODE 4160–15–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, Public Health Service, DHHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**ADDRESSES:** Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

**High-Speed Interlaced Spin Echo Magnetic Resonance Imaging**

Jeff Duyn (CC)

DHHS Reference No. E–171–99/0 filed 30 Dec 1999

Licensing Contact: Carol Salata; 301/496–7735 ext. 232; e-mail: cs253n@nih.gov

Spin-echo acquisition in magnetic resonance imaging (MRI) facilitates the observation of anatomical abnormalities in pathologies such as brain tumors, stroke and multiple sclerosis. It can also be applied in conjunction with perfusion techniques for the investigation of function, based on susceptibility contrast agents as well as blood oxygen level dependent (BOLD) contrast. Improving the efficiency of spin echo MRI is the subject of the current invention. It provides a method of reducing scan time in multi-slice spin-echo MRI through effective use of the echo delay time between radio frequency (RF) excitation and reception. This technique has been evaluated in examples of brain scans and has indications that a substantial increase in scan speed can be achieved without loss in image signal-to-noise ratio or contrast.

**Laparoscopic Sac Holder Assembly**

McClellan M. Walther, Frank Harrington (NCI)

Serial No. 09/368,824 filed 05 Aug 1999

Licensing Contact: John Peter Kim; 301/496–7056 ext. 264; e-mail: jk141n@nih.gov

The present application describes a device and method for accessing and retrieving tissue from a body cavity through minimally invasive endoscopic procedures. Specifically, the present invention consists of a sac holding device, having a rotatable hinge joining bowed leaf elements. The bowed leaf elements form a loop which is adapted to open and close the sac by rotation of the bowed leaf elements. With this laparoscopic device, one can easily contain materials that have been targeted for removal from body cavities. Pieces of infected or cancerous tissue and body fluids are easily contained and can be removed without the danger of collateral contamination.

**Novel Diagnostic Standards for Virus Detection and Quantification**

Richard Y. Wang and James W. Shih (CC)

DHHS Reference Nos. E–228–98/0 filed 20 Apr 1999 and E–228–98/1 filed 20 Apr 2000

Licensing Contact: John Peter Kim; 301/496–7056 ext. 264; e-mail: jk141n@nih.gov

The gene amplification is a tool for the detection of trace amounts of nucleic acids and the clinical applications of this technique in diagnosis of human diseases have been widely demonstrated. There are numerous steps from sample preparation to final product analysis for gene amplification-based molecular diagnosis of clinical specimens. Small variations in each step among different samples can have profound impacts on the final results.

There is a need for stable and well-calibrated internal standards to enable to monitor every step of the amplification process, *e.g.*, sample preparation, gene amplification, and amplicon detection. The subject invention is directed to internal standards as recombinant viral particles. The particles contain modified target sequence and multiple targets can also be packaged. Particles containing RNA target sequence of human hepatitis C virus (HCV) were constructed as example. Thus, this approach in making internal standards has commercial potential in molecular testing for clinical diagnosis, blood screening, and process validation.