research results and, as appropriate, joint publication of conclusions;

(3) Providing NCHSTP access to necessary proprietary technology and/or data in support of the research activities; and

(4) Providing NCHSTP clinical grade (c-GMP) agent for use in preclinical and clinical studies covered in this collaboration.

Other contributions may be necessary for particular proposals.

**Selection Criteria**

In addition to evidence of the ability to fulfill the roles described above, proposals submitted for consideration should address, as best as possible and to the extent relevant to the proposal, each of the following:

(1) Data on the in-vitro anti-HIV activity of the agent;

(2) Animal and other data on the safety of the agent when applied to mucosal surfaces;

(3) Data on the effects of the agent on vaginal commensal microbial organisms; and

(4) Data on the in-vitro activity of the agent against other sexually transmitted organisms.

Dated: June 22, 2001.

**Joseph R. Carter,**

*Associate Director for Management and Operations, Centers for Disease Control and Prevention.*

[FR Doc. 01–16244 Filed 6–27–01; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Centers for Disease Control and Prevention

## Government-Owned Inventions; Availability for Licensing

**AGENCY:** Centers for Disease Control and Prevention, Technology Transfer Office, Department of Health and Human Services

**ACTION:** Notice.

The inventions named in this notice are owned by agencies of the United States Government and are available for licensing in the United States (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 U.S. 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 Thomas E. O'Toole, M.P.H., Deputy Director, Technology Transfer Office, Centers for Disease Control and Prevention (CDC), Mailstop E–67, 1600 Clifton Rd., Atlanta, GA 30333, telephone (404) 498–0170, facsimile (404) 498–0095, and e-mail tto@cdc.gov. Please note that a signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

**Apparatus for Applying Chemicals to Rodents**

This invention comprises a method of controlling Lyme disease by preventing the maturation of deer ticks on white-footed mice by exposing the mice to insecticides as they enter food-baited boxes. Other tick- and flea-borne diseases can also be controlled by this method.

Inventors: Gary O. Maupin *et al.* U.S. Patent Application SN: 09/595,034 (CDC Ref. #: I–031–00).

**Control of Arthropod Vectors of Parasitic Diseases**

This invention comprises a method of controlling Lyme disease by preventing the maturation of deer ticks on white-footed mice by exposing the mice to insecticides as they enter food-baited boxes. Other tick- and flea-borne diseases can also be controlled by this method.

Inventors: Gary O. Maupin *et al.* U.S. Patent Application SN: 09/595,035 (CDC Ref. #: I–032–00).

**Control of Arthropods in Rodents**

This invention comprises a method of controlling Lyme disease by preventing the maturation of deer ticks on white-footed mice by exposing the mice to insecticides as they enter food-baited boxes. Other tick- and flea-borne diseases can also be controlled by this method.

Inventors: Gary O. Maupin *et al.* U.S. Patent Application SN: 09/595,177 (CDC Ref. #: I–041–00).

**Method for Monitoring Local Reaction Associated With Injections**

A simple and inexpensive method to give patients a guideline for determining the severity of an adverse reaction that may occur at the site of injection. Patients can be instructed to notify health care providers if an inflammatory response spreads beyond a measured distance from the location of injection.

Inventor: Laurie Kamimoto, U.S. Patent Application SN: 60/238,691 (CDC Ref. #: I–036–00).

**Auscultory Training System**

This invention provides for the precise reproduction of recorded sounds. Under ordinary conditions, a sound signal is distorted by the amplifier, speakers, and the surroundings. This invention modifies the signal delivered to the speaker in such a way as to precisely reproduce the signal as it was originally recorded. The graphical user-interface allows for the easy selection and playback of individual components of a larger sound recording. This invention could have applications as a diagnostic screening tool, as a telemedicine tool, and as a teaching tool to instruct the user on the various body sounds, such as lung, bowel, or heart sounds.

Inventors: Walter McKinney *et al.* U.S. Patent Application SN: To be assigned, filed 4.30.2001. (CDC Ref. #: I–037–00).

**Peptide Vaccines Against Group A Streptococci**

The invention is a vaccine comprised of three synthetic peptides of 20–25 amino acids in length from different M proteins. The synthetic peptides can be recognized by M type-specific antibodies and are capable of eliciting functional opsonic antibodies in mice. The vaccine may have the potential to eliminate over 85% of Group A Streptococci infections and reduce by 85% the nasopharyngeal reservoir of Group A Streptococci in the United States.

Inventors: Bernard Beall *et al.* U.S. Patent Application SN: To be assigned, filed 5.18.2001. (CDC Ref. #: I–039–00)

**DNA Synthesis by the Cooperative Action of DNA Polymerase and Nuclease**

Confirmation of a diagnosis of an infectious agent usually depends upon the detection of the causative agent or its signature effect on the immune system. Nucleic acid detection methods offer the greatest sensitivity but depend upon specific hybridization of a primer or a probe, thus they can only be used to detect nucleic acids. This invention comprises a novel method of diagnostic detection which retains the sensitivity of nucleic acid based amplification methods while allowing detection of non-nucleic acid targets such as antibodies, surface proteins, or other antigenic components. Thus, no specific sequence information need be known about the potential target.

Inventors: Yuri Khudyakov, U.S. Patent Application SN: (CDC Ref. #: I–043–00)

**BACTID—Microcomputer Programs and Databases for the Identification of Enterobacteriaceae, Vibrionaceae, and Other Microorganisms**

BACTID consists of a software program coupled with a database whereby the user enters a description of an unknown microorganism which the software compares to the database for the purpose of identification of the unknown. This program allows regional diagnostic labs to access national databases which provide for greater sensitivity and specificity in identification of unknowns without the need to transfer samples to larger labs.

Inventor: John J. Farmer, U.S. Patent Application SN: Application yet to be filed. (CDC Ref. #: I–045–00)

Dated: June 22, 2001.

**Joseph R. Carter,**

*Associate Director for Management and Operation, Centers for Disease Control and Prevention.*

[FR Doc. 01–16245 Filed 6–27–01; 8:45 am]

BILLING CODE 4163–18–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 01N–0208]**

### Agency Information Collection Activities; Submission for OMB Review; Comment Request; Voluntary National Retail Food Regulatory Program Standards

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments on the collection of information by July 30, 2001.

**ADDRESSES:** Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Voluntary National Retail Food Regulatory Program Standards**

FDA has developed the Voluntary National Retail Food Regulatory Program Standards (the National Standards) to assist and promote the uniform application of provisions of the model FDA Food Code by several thousand local, State, and tribal jurisdictions that have primary responsibility for the regulation or oversight of retail level food operations. The National Standards are intended to serve as a guide to regulatory retail food program managers in the design and management of a retail food program that is focused on the reduction of risk factors know to cause foodborne illness. The National Standards also promote active management control by industry of all risk factors that may cause foodborne illness. Authority for providing such assistance is derived from section 311 of the Public Health Service Act (42 U.S.C. 243), and delegation of authority from the Public Health Service to the Commissioner of Food and Drugs related to food protection is contained in 21 CFR 5.10(a)(2) and (a)(4). Under 31 U.S.C. 1535, FDA provides financial assistance to other Federal agencies such as the Indian Health Service. FDA has established a section on the Internet at http://vm.cfsan.fda.gov/~dms/ret-toc.html under ''Federal/State Food Programs—Retail Food Safety References'' to list jurisdictions that have voluntarily elected to use the National Standards.

Utilization of the National Standards by local, State, and tribal regulatory agencies is an important step to further the goals of the President's Council on Food Safety and FDA program goals. All regulatory agencies are encouraged to voluntarily utilize the National Standards as a guide for the design and management of a retail food safety program. There is no reporting or recordkeeping requirement for those jurisdictions that wish to utilize part or all of the National Standards to enhance or measure program performance. Reporting is only a requirement for those jurisdictions that request to be listed in the FDA National Registry.

Jurisdictions that request listing in the FDA National Registry of participating regulatory agencies will be expected to perform certain management tasks and periodically report the results to FDA. Voluntary listing in the FDA National Registry requires that the following tasks be performed by State, local, and tribal program managers: (1) Conduct a program self assessment, (2) conduct a baseline survey of the regulated industry, and (3) obtain an independent outside audit. All three tasks must be completed within a 3-year timespan. The tasks must be performed in accordance with the guidance provided in the National Standards and the results reported to FDA.

FDA based its estimate on the number of State agencies (100) involved in Food Code related regulatory programs, 300 local agencies with local ordinance authority that may consider Food Code adoption in any one year and 100 tribal agencies. The presumption being that those agencies most likely to utilize the National Standards are also those agencies with authority to adopt and enforce the model FDA Food Code. There is only one required report, the FDA National Registry Report (Appendix I), which is used to report program self assessment, baseline surveys of industry, and outside audits. The time required to complete the actual reporting document is minimal, however, additional time is required to analyze and review existing records, conduct baseline inspections, and secure an outside audit. The hour burden estimate includes the time required to review the instructions in the National Standards, search existing data sources, gather and maintain the data needed, complete worksheets, and review the collected information. The estimate of 92 hours to complete a program self assessment is based on the average time reported by the four State and three local jurisdictions that participated in the National Standards Pilot. The amount of time expended by individual jurisdictions ranged from 40 to 215 hours. This range is reflective of the difference in size between jurisdictions. The baseline survey of industry and the outside audit are expected to require a similar amount of time to complete.

Because only one of the three tasks is required per year, the average annual reporting burden is estimated to be 92 hours per year for each participating jurisdiction. Because the records of establishment inspections, investigations, and enforcement activities are routinely maintained and accepted management practices already necessitate the collection of some required information and maintenance of records, the recordkeeping burden is minimal.

In the **Federal Register** of May 9, 2001 (66 FR 23715), the agency requested comments on the proposed collections