of the responsible party provided under section 415(a)(3) of the act; (2) the date on which the article of food was determined to be a reportable food; and (3) a description of the article of food including the quantity or amount.

Section 417(b)(2) of the act requires FDA to review promptly and assess information submitted via the electronic portal. Section 417(c)(1) requires FDA to issue, or cause to be issued, an alert or notification with respect to a reportable food using the information from the Registry as FDA deems necessary to protect the public health. In addition, following submission of a report via the Reportable Food electronic portal and after consultation with the responsible party that submitted a report, FDA may require the responsible party to provide a notification consistent with section 417(d)(6)(B) of the act. Section 1005(e) of FDAAA provides that the requirements of section 417(d) of the act are effective 1 year after the enactment date (i.e., on September 27, 2008). The failure to submit a report or provide a notification required by section 417(d) of the act is a prohibited act under section 301(mm) of the act (21 U.S.C. 331(mm)); persons who commit a prohibited act may be enjoined (21 U.S.C. 332) or prosecuted criminally (21 U.S.C. 333).

Under section 1005(f) of FDAAA, FDA is required to issue a guidance to industry about submitting reports to the electronic portal established under section 417(b)(1) of the act and providing notifications to other persons in the supply chain of an article of food. This guidance is required to be issued not later than 9 months after the date of enactment of FDAAA (i.e., by June 27, 2008).

II. Delay in Implementation of the Registry

FDA has determined that the most efficient and cost effective means of implementing the requirements of section 417 of the act relating to the Registry is to utilize the business enterprise system currently under development within the agency. This system will permit FDA to establish an electronic portal through which instances of reportable food may be submitted to the agency, and will be easy to use, for both those submitting reports to the agency and for FDA. However, the agency anticipates that FDA's business enterprise system will not be implemented in time to meet the statutory deadline of section 417(b)(1) of the act which, as stated, requires FDA to establish the Reportable Food electronic portal by September 27, 2008. Therefore, FDA is announcing a delay in the implementation of the requirements of section 417 of the act.

FDA expects that the agency's business enterprise system will be operational in spring 2009. In a future issue of the **Federal Register**, the agency will notify the public, including the industry, of the date the Reportable Food electronic portal becomes available to accept reports under section 417(d) of the act. After that date, FDA expects that responsible parties will comply with the requirements of section 417 of the act, including the requirement to submit instances of reportable food to the agency via the Reportable Food electronic portal. In the interim, FDA strongly encourages persons to continue to report instances of adulterated food through existing mechanisms, such as notifying the relevant FDA District office, until such time as the Registry and its associated electronic portal are fully implemented.

III. Request for Comments

FDA is seeking comments on the requirements contained in the Registry provisions of section 417 of the act. In addition to general information, data, and comments, we request comments on the following questions:

(1) What obstacles, if any, do responsible parties anticipate in complying with the requirements of section 417 of the act?

(2) How can FDA enhance the quality, utility, and clarity of the information to be submitted to the Registry?

(3) What would be an efficient and effective method for providing and receiving notifications to and from sources and recipients in the supply chain of instances of reportable food?

(4) In addition to the data elements set out in section 417 of the act, what other information, if any, would be important to provide in responsible party notifications to the immediate previous source and immediate subsequent recipient of the article of food?

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: May 16, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–11517 Filed 5–23–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 73 FR 22961–22964 dated April 28, 2008).

This notice reflects organizational changes in the Health Resources and Services Administration. Specifically, this notice updates the functional statement for the Office of Information Technology (RAG).

Chapter RA—Office of the Administrator

Section RA–10, Organization

The Office of the Administrator (RA) is headed by the Administrator, Health Resources and Services Administration, who reports directly to the Secretary. The OA includes the following components:

(1) Immediate Office of the Administrator (RA);

(2) Office of Equal Opportunity and Civil Rights (RA2);

(3) Office of Planning and Evaluation (RA5);

(4) Office of Communications (RA6);

(5) Office of Minority Health and Health Disparities (RA9);

(6) Office of Legislation (RAE);

(7) Office of Information Technology (RAG);

(8) Office of International Health Affairs (RAH); and

(9) Office of Management (RAM).

Section RAG–20, Functions

Delete the current functional statement for the Office of Information

Technology (RAG) in its entirety and replace with the following:

Office of Information Technology (RAG)

The Chief Information Officer (CIO) is responsible for the organization, management, and administrative functions necessary to carry out the responsibilities of the CIO including: organizational development, investment control, budget formulation and execution, policy development, strategic and tactical planning, and performance monitoring. The CIO provides leadership in the development, review and implementation of policies and procedures to promote improved information technology management capabilities and best practices throughout HRSA. The OCIO coordinates IT workforce issues and works closely with the departmental Office of Human Resources Management on IT recruitment and training issues.

The Chief Technology Officer (CTO), reporting to the CIO, is responsible for the HRSA emerging and advanced technology integration program consistent with HRSA missions and program objectives. The CTO manages technology planning and is responsible for coordinating the Agency's Enterprise Architecture (EA) efforts with the capital planning process, ensuring the suitability and consistency of technology investments with HRSA's EA and strategic objectives, and incorporating security standards as a component of the EA process. The CTO provides leadership for strategic planning that leverages information systems security, program strategies, and advanced technology integration to achieve program objectives through innovative technology use. The CTO also provides leadership and establishes policy to address legislative or regulatory requirements, such as Section 508 of the Rehabilitation Act, and provides oversight for Agency IT configuration management and control.

The Chief Information Security Officer (CISO), reporting to the CIO, provides leadership for, and collaborates with, Agency staff to oversee the implementation of security and privacy policy in the management of their IT systems, and plans all activities associated with the Federal Information Security Management Act (FISMA) or other agency security and privacy initiatives.

The CISO implements, coordinates, and administers security and privacy programs to protect the information resources of HRSA in compliance with legislation, Executive Orders, directives of the Office of Management and Budget (OMB), or other mandated requirements e.g., Presidential Decision Directive 63, OMB Circular A–130, the National Security Agency, the Privacy Act, and other Federal agencies. Further, the CISO is responsible for the execution of the Agency's Risk Management Program, and evaluates and assists with the implementation of safeguards to protect major information systems, and IT infrastructure. In close coordination with the Division of IT Operations and Customer Service, develops and implements HRSA level policies, procedures, guidelines, and standards for the incorporation of intrusion detection systems, vulnerability scanning, forensic and other security tools used to monitor automated systems and subsystems to safeguard HRSA's electronic information and data assets. The CISO manages the development, implementation, and evaluation of the HRSA information technology security and privacy training program to meet the requirements as mandated by OMB Circular A–130, the Computer Security Act, and Privacy Act.

Division of Business Information Management (RAG1)

The Division of Business Information Management (DBIM), provides consultation, assistance, and services to HRSA to promote and manage information dissemination and collaboration practices using appropriate electronic media. DBIM evaluates and integrates emerging technology to facilitate the translation of data and information from data repositories into electronic formats for internal and external dissemination. In collaboration with the Office of Communications, DBIM is responsible for the design, deployment, and maintenance of HRSA's Internet and Intranet Web sites including development and implementation of related policies and procedures. DBIM develops and maintains an overall data and information management strategy for HRSA that is integrated with HHS and Government-wide strategies. DBIM identifies information needs across HRSA and develops approaches for meeting those needs using appropriate technologies including development and maintenance of an enterprise reporting platform. DBIM provides for data quality and ensures that data required for enterprise information requirements are captured in appropriate enterprise applications and that necessary data repositories are built and maintained. DBIM enhances and expands use and utility of HRSA's data by providing basic analytic and user support; develops and maintains a range of information products for internal and external users; and demonstrates potential uses of information in supporting management decisions. DBIM provides leadership and establishes policy to address legislative or regulatory requirements in its areas of responsibility.

Division of Capital Planning and Project Management (RAG2)

The Division of Capital Planning and Project Management (DCPPM) coordinates the development and review of policies and procedures for IT Capital Planning and Investment Control, Earned Value Management, IT portfolio management, IT project management, and the enterprise performance lifecycle methodology. DCPPM administers the Department's multi-year strategic information resources planning process, including developing and administering the Department's Strategic IT Plan; supports the Budget Office in its evaluation of IT initiatives, and preparation of Agency, departmental and OMB Budget Exhibits and documents. DCPPM works to obtain required information and analyzes it as appropriate; coordinates control and evaluation review of ongoing IT projects, including support to the HRSA ITIRB in conducting such review; promotes and follows a consistent methodology for project management and improves agency-wide project management. DCPPM operates a Project Management Office to improve management, communications and functional user involvement, assists with project prioritization, and monitors progress and budget.

Division of Enterprise Solutions Development and Management (RAG3)

The Division of Enterprise Solutions Development and Management (DESDM) provides leadership, consultation, and IT project management services in the definition of Agency business applications architectures, the engineering of business processes, the building and deployment of applications, and the development, maintenance and management of enterprise systems and data collections efforts. DESDM is responsible for technology evaluation, application and data architecture definition, controlling software configuration management, data modeling, database design, development and management and stewardship services for business process owners. DESDM manages the systems development lifecycle by facilitating business process engineering efforts, systems requirements definition, and

provides oversight for application change management control. DESDM provides enterprise application user training, Tier-3 assistance, and is responsible for end-to-end application building, deployment, maintenance and data security assurance.

Division of IT Operations and Customer Services (RAG4)

The Division of IT Operations and Customer Services (ITOCS) provides leadership, consultation, training, and management services for HRSA's enterprise computing environment. ITOCS directs and manages the support and acquisition of HRSA network and desktop hardware, servers, wireless communication devices, and software licenses. ITOCS is responsible for the HRSA Data Center and the operation and maintenance of a complex, high-availability network infrastructure on which mission-critical applications are made available 24 hours per day, 7 days per week. ITOCS provides oversight for outsourced electronic mail, Internet and connectivity, web and video conferencing, and co-managed firewall and security monitoring services. ITOCS controls infrastructure configuration management, installations and upgrades, security perimeter protection, and system resource access. ITOCS coordinates IT activities for Continuity of Operations Planning (COOP) Agency-wide including provisioning and maintaining IT infrastructure and hardware at designated COOP locations to support emergency and COOP requirements. ITOCS is accountable for property life cycle management and tracking of Agency-wide IT capital equipment. ITOCS provides oversight for outsourced Tier-1 and Tier-2 Help Desk Call Center technical assistance; maintains workstation hardware and software configuration management controls; and provides oversight of outsourced network and desktop services to staff in HRSA Regional Offices (ROs).

Section RA–30, Delegations of Authority

All delegations and re-delegations of authority made to HRSA officials and employees of affected organizational components will continue in them or their successors pending further re-delegations, provided they are consistent with this reorganization.

This reorganization is effective upon the date of signature.

Dated: May 15, 2008.

Elizabeth M. Duke,

Administrator.

[FR Doc. E8–11800 Filed 5–23–08; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency 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.

C4′-Substituted-2-Deoxyadenosine Analogs and Methods of Treating HIV

Description of Technology: The invention describes a new use for C4′-methyl-2-deoxyadenosine, a nucleoside analog that has significant activity against HIV–1 and most strains of HIV previously shown to be resistant to other reverse transcriptase nucleoside inhibitor treatments. In vitro experimental results show substantial anti-HIV activity (blocked infectivity) with no observable cytotoxicity in cell culture. Mechanistic studies indicate that this compound blocks DNA synthesis by reverse transcriptase.

Applications: Treatment and prevention of HIV infection.

Advantages: Nucleoside analog against HIV–1 reverse transcriptase with no observable cytotoxicity in cell culture.

Potential new treatment for HIV–1 infections including infections by strains of HIV–1 that are resistant to nucleoside reverse transcriptase inhibitors.

Development Status: In vitro data can be provided upon request.

Market: Therapeutic for the treatment and/or prevention of HIV infection.

Inventors: Bao-Han Christie Vu, Stephen H. Hughes, Maqbool Siddiqui, and Victor E. Marquez (NCI).

Publication: Meeting Abstract: 8th Annual Symposium for Antiviral Resistance in Richmond, VA, November 11–14, 2007 (Can be provided upon request).

Patent Status: U.S. Provisional Application No. 61/002,711 filed 09 Nov 2007 (HHS Reference No. E–012–2008/0–US–01).

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Sally Hu, Ph.D.; 301–435–5606, *HuS@mail.nih.gov*.

Collaborative Research Opportunity: The National Cancer Institute HIV Drug Resistance Program is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize C4′-methyl- and C4′-ethyl-substituted-2-deoxyadenosine analogs. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Method of Treating Infectious and Inflammatory Lung Disease With Suppressive Oligonucleotides

Description of Technology: Lung disease is the number three killer in America, responsible for one in seven deaths, and lung disease and other breathing problems are the number one killer of babies younger than one year old. Today, more than thirty (30) million Americans are living with chronic inflammatory lung diseases such as emphysema and chronic bronchitis. In addition, approximately one hundred and fifty thousand (150,000) Americans are affected by acute respiratory distress syndrome (ARDS) each year.

Many lung diseases are associated with lung inflammation. For example, ARDS involves the rapid onset of progressive malfunction of the lungs, and is usually associated with the malfunction of other organs due to the inability to take up oxygen. The condition is associated with extensive lung inflammation and small blood vessel injury in all affected organs. ARDS is commonly precipitated by trauma, sepsis (systemic infection), diffuse pneumonia, and shock. It also may be associated with extensive surgery, and certain blood abnormalities. In many cases of ARDS and other inflammatory lung diseases, the inflammatory response that accompanies the underlying disease state is much more dangerous than the underlying infection or trauma.