be used if they contain all of the required information and are retained for the required time period.

Section 101 of the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) amended section 414(a) of the FD&C Act and expanded our access to records. Specifically, FSMA expanded our access to records beyond records relating to the specific suspect article of food to records relating to any other article of food that we reasonably believe is likely to be affected in a similar manner. In addition, we can access records if we believe that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that we reasonably believe is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals. To gain access to these records, our officer or employee must present appropriate credentials and a written notice, at reasonable times and within reasonable limits and in a reasonable manner.

On February 23, 2012, we issued an interim final rule in the **Federal Register** (77 FR 10658) (the 2012 IFR) amending § 1.361 to be consistent with the current statutory language in section 414(a) of the FD&C Act, as amended by section 101 of FSMA. In the 2012 IFR, we concluded that the information collection provisions of § 1.361 were exempt from OMB review under 44 U.S.C. 3518(c)(1)(B)(ii) and 5 CFR 1320.4(a)(2) as collections of information obtained during the conduct of a civil action to which the United States or any official or agency thereof is a party, or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities (77 FR 10658 at 10661). The interim final rule was made final, without change, on April 4, 2014 (79 FR 18799). The regulations at 5 CFR 1320.3(c) provide that the exception in 5 CFR 1320.4(a)(2) applies during the entire course of the investigation, audit, or action, but only after a case file or equivalent is opened with respect to a particular party. Such a case file would be opened as part of the request to access records under § 1.361. Accordingly, we have not included an estimate of burden hours associated with § 1.361 in table 1.

Description of Respondents: Persons that manufacture, process, pack, hold, receive, distribute, transport, or import food in the United States are required to establish and maintain records, including persons that engage in both interstate and intrastate commerce.

In the **Federal Register** of June 14, 2017 (82 FR 27263), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment. The comment was supportive of the information collection but requested that FDA coordinate with the U.S. Department of Agriculture. FDA addresses issues regarding duplication of information collection in question 4 of the Agency's supporting statement.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
1.337, 1.345, and 1.352 (Records maintenance)	379,493	1	379,493	13.228	5,020,000
1.337, 1.345, and 1.352 (Learning for new firms)	18,975	1	18,975	4.790	90,890
Total					5,110,890

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

This estimate is based on our estimate of the number of facilities affected by the final rule entitled ''Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002,'' published in the **Federal Register** of December 9, 2004 (69 FR 71562 at 71650). With regard to records maintenance, we estimate that approximately 379,493 facilities will spend 13.228 hours collecting, recording, and checking for accuracy the limited amount of additional information required by the regulations, for a total of 5,020,000 hours annually. In addition, we estimate that new firms entering the affected businesses will incur a burden from learning the regulatory requirements and understanding the records required for compliance. In this regard, we estimate the number of new firms entering the affected businesses to be 5 percent of 379,493, or 18,975 firms. Thus, we estimate that approximately 18,975 facilities will spend 4.790 hours learning about the recordkeeping and records access requirements, for a total of 90,890 hours annually. We estimate that approximately the same number of firms (18,975) will exit the affected businesses in any given year, resulting in no growth in the number of total firms reported on line 1 of table 1. Therefore, the total annual recordkeeping burden is estimated to be 5,110,890 hours.

Dated: September 15, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–20239 Filed 9–21–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing 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.

FOR FURTHER INFORMATION CONTACT: Chris Kornak, 240–627–3705, *chris.kornak@nih.gov.* Licensing

information and copies of the U.S. patent applications listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office (TTIPO), 5601 Fishers Lane, Suite 6D, MSC 9804, Rockville, MD 20892, tel: 301–496–2644, fax: 240–627–3117. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology descriptions follow.

Research Material: A Potent, Broadly-Neutralizing, Anti-HIV Antibody (35O22) That Binds a Novel Epitope

Description of Technology: Millions of people are infected with HIV–1 worldwide. In the U.S., there are about 30,000 new cases of HIV infection reported annually. Researchers at NIAID are actively investigating broadly neutralizing anti-HIV–1 antibodies which can be used as therapeutics or prophylactics for HIV infection.

NIAID and Scripps researchers have discovered a potent anti-HIV antibody (35O22) that binds a novel HIV epitope. This antibody neutralizes at least 80% of HIV isolates tested so far. The unique binding of 35O22 makes it an attractive candidate to combine with other HIV antibodies or antivirals in treating or preventing HIV infection.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications:

- HIV–1 therapeutics
- HIV–1 prophylactics

Competitive Advantages:

- Unique epitope
- Broad neutralization of HIV isolates

Development Stage: Pre-Clinical.

Inventors: Mark Connors, John Mascola, Peter Kwong, Tongqing Zhou, Jinghe Huang, Byong Ha Kang, all of NIAID, NIH; Andrew Ward, Scripps Research Institute.

Publications: Huang, J et al., Broad and potent HIV–1 neutralization by a human antibody that binds the gp41–gp120 interface. *Nature* 515, 138–142.

Intellectual Property: Not applicable.

Licensing Contact: Chris Kornak, 240–627–3705, *chris.kornak@nih.gov.*

Collaborative Research Opportunity: The Technology Transfer and Intellectual Property Office (TTIPO) is seeking parties interested in collaborative research to further develop 35O22 in combination with other NIAID antibodies. For collaboration opportunities, please contact Chris Kornak, 240–627–3705, *chris.kornak@nih.gov*.

Dated: September 12, 2017.

Suzanne Frisbie,

Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

[FR Doc. 2017–20232 Filed 9–21–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Drug Repurposing for Alzheimer's Disease.

Date: October 17, 2017.

Time: 10:30 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, Suite 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20814 (Telephone Conference Call).

Contact Person: Anita H. Undale, Ph.D., MD, Scientific Review Branch, National Institute on Aging, Gateway Building, Suite 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892, 240–747–7825, *anita.undale@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: September 18, 2017.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–20230 Filed 9–21–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Eye Institute Special Emphasis Panel NEI; Institutional Training Grant Applications.

Date: October 16, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn Bethesda, 7301 Waverly Street, Bethesda, MD 20814.

Contact Person: Jeanette M. Hosseini, Ph.D., Scientific Review Officer, NEI/DEA/SRB, National Institutes of Health, 5635 Fishers Lane, Suite 1300, Bethesda, MD 20892, 301–451–2020, *jeanetteh@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: September 18, 2017.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–20178 Filed 9–21–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material,