

before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques,

when appropriate, and other forms of information technology.

Animal Food Labeling; Declaration of Certifiable Color Additives—21 CFR 501.22(k) (OMB Control Number 0910-0721—Extension)

This information collection is associated with requirements under § 501.22(k) (21 CFR 501.22(k)) in which animal food manufacturers must declare the presence of certified and noncertified color additives in their animal food products on the product label. The Agency issued this regulation in response to the Nutrition Labeling and Education Act of 1990 to make animal food regulations consistent with the regulations regarding the declaration of color additives on human food labels and to provide animal owners with information on the colors used in animal food.

Respondents to this collection are manufacturers of pet food that contain color additives. Manufacturers of certain food or food ingredients do not have products that contain color additives requiring certification (*e.g.*, food for chickens, fish, and some other species, including some pet foods) and would thus be minimally affected by § 501.22(k)(1). However, since we cannot rule out the possibility that they may at some point use a color additive requiring certification, we have consolidated the burden estimates for § 501.22(k)(1) and (k)(2). Additionally, we believe that this burden is more accurately characterized as a third-party disclosure burden because FDA does not require routine submission of pet food labeling to the Agency.

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

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

21 CFR Section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
501.22(k); labeling of color additive or lack of color additive; labeling of color additives not subject to certification	3,120	0.83	2,587	0.25	647

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

Because § 501.22(k) became effective November 18, 2013, the Agency estimates that the burden associated with the labeling requirements under § 501.22(k) applies only to new product labels. Because the vast majority of animal food products that contain certified color additives are pet foods, we limit our burden estimate to reviewing labels for the use of certified color additives to pet food manufacturers subject to this regulation.

Based on A.C. Nielsen Data, FDA estimates that the number of animal food product units subject to § 501.22(k) for which sales of the products are greater than zero is 25,874. Assuming that the flow of new products is 10 percent per year, then 2,587 new animal food products subject to § 501.22(k) will come on the market each year. FDA also estimates that there are about 3,120 manufacturers of pet food subject to either § 501.22(k)(1) or (k)(2). Assuming the approximately 2,587 new products are split equally among the firms, then each firm would prepare labels for approximately 0.83 new products per year (2,587 new products/3,120 firms is approximately 0.83 labels per firm).

The Agency expects that firms prepare the required labeling for their products in a manner that takes into

account at one time all information required to be disclosed on their product labels. Based on our experience with reviewing pet food labeling, FDA estimates that firms would require less than 0.25 hour (15 minutes) per product to comply with the requirement to include the color additive information under § 501.22(k). The total burden of this activity is 647 hours (2,587 labels x 0.25 hour/label is approximately 647 hours).

Dated: March 25, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-07420 Filed 3-31-15; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 Alcohol Abuse and Alcoholism Special Emphasis Panel; Review of Alcohol Health Disparity Research Centers.

Date: April 28, 2015.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: NIAAA, NIH, 5635 Fishers Lane, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Ranga Srinivas, Ph.D., Chief, Extramural Project Review Branch, National Institute on Alcohol Abuse and Alcoholism, NIH, 5635 Fishers Lane, Room 2085, Rockville, MD 20852, (301) 443-2067, srinivar@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 92.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants;

93.701, ARRA Related Biomedical Research and Research Supports Awards, National Institutes of Health, HHS)

Dated: March 26, 2015.

Melanie J. Gray,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-07343 Filed 3-31-15; 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 Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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, 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; Immune System and Aging.

Date: April 15, 2015.

Time: 9:45 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, Suite 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892.

Contact Person: Alicja L. Markowska, Ph.D., DSC., Scientific Review Branch, National Institute on Aging, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301-496-9666, markowska@nia.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute on Aging Special Emphasis Panel; Neuromuscular Interactions.

Date: April 22, 2015.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, Suite 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Alicja L. Markowska, Ph.D., DSC., Scientific Review Branch, National Institute on Aging, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301-496-9666, markowska@nia.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

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

Dated: March 26, 2015.

Melanie J. Gray,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-07339 Filed 3-31-15; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Privacy Act of 1974; System of Records Notice

AGENCY: Office of the Secretary (OS), Department of Health and Human Services (HHS).

ACTION: Notice to establish a new system of records and delete an existing system of records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended (5 U.S.C. 552a), HHS is establishing a new department-wide system of records, "Records about Restricted Dataset Requesters," System Number 09-90-1401, to cover records about individuals within and outside HHS who request restricted datasets and software products from HHS (e.g., for health-related scientific research and study purposes), when HHS maintains the requester records in a system from which they are retrieved directly by an individual requester's name or other personal identifier. The System of Records Notice (SORN) previously published at 78 FR 32654 for "Online Application Ordering for Products from the Healthcare Cost and Utilization Project (HCUP)," System Number 09-35-0003, is being deleted and replaced by this new department-wide SORN.

DATES: *Effective Dates:* The department-wide SORN proposed in this Notice is effective upon publication, with the exception of the routine uses. The routine uses will be effective 30 days after publication of this Notice, unless comments are received that warrant revisions to this Notice. Written comments on the routine uses should be submitted within 30 days. The deletion of System Number 09-35-0003 will be effective 30 days after publication of this Notice.

ADDRESSES: The public should address written comments to: Beth Kramer, HHS Privacy Act Officer, Mary E. Switzer

Building—Room 2210, 330 C Street SW., Washington, DC 20201, beth.kramer@hhs.gov. Comments will be available for public viewing at the same location. To review comments in person, please contact Beth Kramer at beth.kramer@hhs.gov or (202) 690-6941.

FOR FURTHER INFORMATION CONTACT: Beth Kramer, HHS Privacy Act Officer, Mary E. Switzer Building—Room 2210, 330 C Street SW., Washington, DC 20201, beth.kramer@hhs.gov.

SUPPLEMENTARY INFORMATION: The new system of records will cover records about individuals within and outside HHS who request restricted datasets and software products from HHS, when HHS maintains the requester records in a system from which they are retrieved directly by an individual requester's name or other personal identifier. "Restricted" datasets and software products are those that HHS makes affirmatively available to qualified members of the public but provides subject to restrictions, because they contain identifiable data and/or anonymized data that has the potential, when combined with other data, to identify the particular individuals, such as patients or providers, whose information is represented in the data. The datasets and products are made available through an on-line or paper-based ordering and delivery system that provides them to qualified requesters electronically or by mail.

The restrictions are necessary to protect the privacy of individuals whose information is represented in the datasets or software products. The restrictions typically limit the data requester to using the data for research, analysis, study, and aggregate statistical reporting; prohibit any attempt to identify any individual or establishment represented in the data; and require specific security measures to safeguard the data from unauthorized access. HHS is required by law to impose, monitor, and enforce the restrictions (see, for example, provisions in the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA), 44 U.S.C. 3501 at note). To impose and enforce the restrictions, it is necessary to collect information about the data requesters.

Currently, this system of records covers data requester records in ordering and delivery systems administered by three HHS Operating Divisions, but only to the extent that the records pertain to requesters seeking *restricted* datasets. These ordering and delivery systems retrieve requester records directly by personal identifier: