

Submission” or “More Search Options” to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number \_\_\_\_\_, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of the following:

1. Access CMS’ Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).

3. Call the Reports Clearance Office at (410) 786-1326.

**FOR FURTHER INFORMATION CONTACT:** Reports Clearance Office at (410) 786-1326.

#### SUPPLEMENTARY INFORMATION:

##### Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection’s supporting statement and associated materials (see

ADDRESSES).

#### **CMS-10555 Small Business Health Options Program (SHOP) Effective Date and Termination Notice Requirements**

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

#### Information Collection

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Small Business Health Options Program (SHOP) Effective Date and Termination Notice Requirements; *Use:* We are requiring that for plan years beginning on or after January 1, 2017, the Small Business Health Options Program (SHOP) must ensure that a qualified health plan (QHP) issuer notifies qualified employees, enrollees, and new enrollees in a QHP through the SHOP of the effective date of coverage. As required by the Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameter for 2016 (CMS-9944-F), which published February 27, 2015, if any enrollee’s coverage through the SHOP is terminated due to non-payment of premiums or a loss of the enrollee’s or employer group’s eligibility to participate in the SHOP, the SHOP must notify the enrollee or the qualified employer of the termination of such coverage. In the termination of coverage the SHOP must include the termination date and reason for termination to the enrollee or qualified employer. *Form Number:* CMS-10555 (OMB Control Number: 0938-New); *Frequency:* Annually; *Affected Public:* Private sector (Business or other for profits and Not-for-profit institutions); *Number of Respondents:* 445; *Total Annual Responses:* 1,335; *Total Annual Hours:* 46,725. (For policy questions regarding this collection contact Christelle Jang at (410) 786-8438).

Dated: March 4, 2015.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2015-05420 Filed 3-6-15; 8:45 am]

**BILLING CODE 4120-01-P**

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Health Resources and Services Administration**

##### **Advisory Committee on Organ Transplantation (ACOT)**

**AGENCY:** Health Resources and Services Administration (HRSA), HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Health Resources and Services Administration published a notice in the **Federal Register**, FR 2015-03929 (February 26, 2015), announcing the meeting for the Advisory Committee

on Organ Transplantation (ACOT). This action is to add dial-in information.

**Correction:** In the **Federal Register**, FR 2015-03929 (February 26, 2015), please make the following addition:

Participants can also join this meeting via conference call by calling the toll-free phone number 888-324-4391 and providing the participant pass code 7744447.

**Jackie Painter,**

*Director, Division of the Executive Secretariat.*

[FR Doc. 2015-05415 Filed 3-6-15; 8:45 am]

**BILLING CODE 4165-15-P**

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **National Institutes of Health**

##### **National Institute of Diabetes and Digestive and Kidney Diseases; 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 of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Collaborative Interdisciplinary Team Science in NIDDK Research Areas (R24)—Hematopoiesis.

*Date:* March 20, 2015.

*Time:* 2:00 p.m. to 3:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Paul A. Rushing, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 747, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-8895, [rushingp@extra.niddk.nih.gov](mailto:rushingp@extra.niddk.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 of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; RFA-DK14-011 Chronic Kidney Disease Biomarkers Consortium (CKD BioCon) (U01).

*Date:* March 24, 2015.

*Time:* 11:30 a.m. to 3:30 p.m.

**Agenda:** To review and evaluate cooperative agreement applications.

**Place:** National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

**Contact Person:** Ann A. Jerkins, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 759, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, 301–594–2242, [jerkinsa@niddk.nih.gov](mailto:jerkinsa@niddk.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 of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; HIV-Associated Nephropathy Program Project.

**Date:** March 30, 2015.

**Time:** 10:00 a.m. to 1:00 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

**Contact Person:** Michele L. Barnard, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 753, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, (301) 594–8898, [barnardm@extra.niddk.nih.gov](mailto:barnardm@extra.niddk.nih.gov).

**Name of Committee:** National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK R24 Review.

**Date:** March 30, 2015.

**Time:** 2:00 p.m. to 4:00 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

**Contact Person:** Robert Wellner, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 706, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, 301–594–4721, [rw175w@nih.gov](mailto:rw175w@nih.gov).

**Name of Committee:** National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Building a Kidney: Cells to Organ.

**Date:** April 7, 2015.

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

**Agenda:** To review and evaluate grant applications.

**Place:** Washington Marriott at Metro Center, 775 12th St. NW., Washington, DC 20005.

**Contact Person:** Paul A. Rushing, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 747, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8895, [rushingp@extra.niddk.nih.gov](mailto:rushingp@extra.niddk.nih.gov).

**Name of Committee:** National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK R24 Grant Review.

**Date:** April 8, 2015.

**Time:** 12:00 p.m. to 2:00 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

**Contact Person:** Robert Wellner, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 706, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, 301–594–4721 [rw175w@nih.gov](mailto:rw175w@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

**Dated:** March 3, 2015.

**David Clary,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015–05306 Filed 3–6–15; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2010–D–0165]

#### International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Studies To Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Validation of Analytical Methods Used in Residue Depletion Studies; Revised Guidance for Industry; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a revised guidance for industry (GFI #208) entitled “Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Validation of Analytical Methods Used in Residue Depletion Studies” (VICH GL49(R)). This revised guidance, which provides minor updates to a final guidance on the same topic for which a notice of availability was published in the **Federal Register** of September 15, 2011, has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This revised VICH guidance document is intended to provide a general description of the criteria that have been found by the European Union, Japan, United States, Australia, New Zealand,

and Canada to be suitable for the validation of analytical methods used in veterinary drug residue depletion studies.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the revised guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Julia Oriani, Center for Veterinary Medicine (HFV–151), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0788, [julia.oriani@fda.hhs.gov](mailto:julia.oriani@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify, and then reduce, differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United