SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry #233 entitled “Veterinary Feed Directive Common Format Questions and Answers.”

In 1996, Congress enacted the Animal Drug Availability Act (ADAA) to facilitate the approval and marketing of new animal drugs and medicated feeds. In passing the ADAA, Congress created a new regulatory category for certain animal drugs used in or on animal feed called VFD drugs. VFD drugs are new animal drugs intended for use in or on animal feed which are limited to use under the professional supervision of a licensed veterinarian. FDA published final regulations at § 558.6 (21 CFR 558.6) implementing the VFD-related provisions of the ADAA in 2000. On June 3, 2015 (80 FR 31707), FDA published a VFD final rule that revised those VFD regulations and introduced clarifying changes to specified definitions.

During the latest rulemaking process, FDA received a few comments requesting the Agency to require a uniform VFD format. We declined this request because we thought that requiring a specific format would be too prescriptive. However, we acknowledge that a common VFD format would help clients, veterinarians, and distributors (including feed mills) quickly identify relevant information on the VFD.

We are issuing this draft guidance to recommend a common VFD format. In the draft guidance, we use the term “VFD” to refer to the form used to convey the VFD order. This draft guidance describes the requirements in § 514.1(b)(9) (21 CFR 514.1(b)(9)) for sponsor submission of a VFD to FDA as part of the application process for approval of a new animal drug for use in or on animal feed as a VFD drug, as well as the required and optional information to be included on the VFD. This draft guidance provides examples that illustrate how a common VFD format might appear and how some of the information on the VFD may be prepopulated by a sponsor.

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Veterinary Feed Directive Common Format Questions and Answers.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in § 514.1 have been approved under OMB control number 0910–0032. The collections of information in § 558.6 have been approved under OMB control number 0910–0363.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm or http://www.regulations.gov.

Dated: November 25, 2015.

Leslie Kux,
Associate Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request: NIH Information Collection Forms To Support Genomic Data Sharing for Research Purposes (OD)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Office of the Director, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the
methodology and assumptions used; (3) the quality, utility, and clarity of the information to be collected; and (4) minimization of the burden of the collection of information from those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and For Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dina N. Baltz, Ph.D., MPH, Director, Genetics, Health, and Society Program, Office of Clinical Research and Bioethics Policy, Office of Science Policy, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892 or call non-toll-free number 301–496–9838 or Email your request, including your address to: GDS@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

DATES: Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.


Need and Use of Information Collection: Sharing research data supports the NIH mission and is essential to facilitate the translation of research results into knowledge, products, and procedures that improve human health. The NIH has longstanding policies to make a broad range of research data, including genomic data, publicly available in a timely manner from the research activities that it funds. Genomic research data sharing is an integral element of the NIH mission as it facilitates advances in our understanding of factors that influence health and disease, while also providing opportunities to accelerate research through the power of combining large and information-rich datasets. To promote robust sharing of human and non-human data from a wide range of large-scale genomic research and provide appropriate protections for research involving human data, the National Institutes of Health (NIH) issued the NIH Genomic Data Sharing Policy (GDS Policy). Human genomic data submissions and controlled-access are managed through a central data repository, the database of Genotypes and Phenotypes (dbGaP) which is administered by the National Center for Biotechnology Information (NCBI), part of the National Library of Medicine at NIH.

Under the GDS Policy, all investigators who receive NIH funding to conduct large-scale genomic research are expected to register studies with human genomic data in dbGaP; no matter which NIH-designated data repository will maintain the data. As part of the registration process, investigators must provide basic study information such as the type of data that will be submitted to dbGaP, a description of the study, and an institutional assurance (i.e. Institutional Certification) of the data submission which delineates any limitations on the secondary use of the data (e.g., data cannot be shared with for-profit companies, data can be used only for research of particular diseases).

Investigators interested in using controlled-access data for secondary research must apply through dbGaP and be granted permission from the relevant NIH Data Access Committee(s). As part of the application process, investigators and their institutions must provide information such as a description of the proposed research use of controlled-access datasets that conforms to any data use limitations, agree to the Genomic Data User Code of Conduct, and agree to the terms of access through a Data Use Certification agreement. Requests to renew data access and reports to close out data use are similar to the initial data access request, requiring sign-off by both the requestor and the institution, but also ask for information about how the data have been used, and about publications, presentations, or intellectual property based on the research conducted with the accessed data as well as any data security issues or other data management incidents.

The NIH has developed online forms, available through dbGaP, in an effort to reduce the burden for researchers and their institutional officials to complete the study registration, data submission, data access, and renewal and closeout processes.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 2,505.

### ESTIMATED ANNUALIZED BURDEN HOURS

<table>
<thead>
<tr>
<th>Type of form</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average time per response (in hours)</th>
<th>Total annual burden hour</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study Registration and Data Submission</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Investigator Submitting Data</td>
<td>150</td>
<td>1</td>
<td>1</td>
<td>150</td>
</tr>
<tr>
<td>Institutional Official to Certify</td>
<td>150</td>
<td>1</td>
<td>30/60</td>
<td>75</td>
</tr>
<tr>
<td><strong>Initial Data Access Request</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Investigator Requesting Data</td>
<td>633</td>
<td>2</td>
<td>45/60</td>
<td>950</td>
</tr>
<tr>
<td>Signing Official to Certify</td>
<td>633</td>
<td>2</td>
<td>30/60</td>
<td>633</td>
</tr>
<tr>
<td><strong>Renewal and Close-out of Data Access</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Investigator Requesting Data</td>
<td>633</td>
<td>2</td>
<td>15/60</td>
<td>317</td>
</tr>
<tr>
<td>Signing Official to Certify</td>
<td>633</td>
<td>2</td>
<td>18/60</td>
<td>380</td>
</tr>
</tbody>
</table>
DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel; Member Conflicts and Continuous Submissions.

Date: December 3, 2015.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Chee Lim, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4128, Bethesda, MD 20892, 301–435–1850, limc4@csr.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: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cardiovascular Sciences.

Date: December 9–10, 2015.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Kimm Hamann, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118A, MSC 7814, Bethesda, MD 20892, 301–435–5575, hamannk@csr.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: Center for Scientific Review Special Emphasis Panel; Neuropharmacology and Channels.

Date: December 11, 2015.

Time: 9:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Mary Custer, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4148, MSC 7850, Bethesda, MD 20892, (301) 435–1164, custerm@csr.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: Center for Scientific Review Special Emphasis Panel; Fellowship Review.

Date: December 11, 2015.

Time: 11:30 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Raj K Krishnaraj, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6190, Bethesda, MD 20892, 301–435–1047, kkrishna@csr.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.


Dated: November 24, 2015.

Natasha M. Copeland, Program Analyst, Office of Federal Advisory Committee Policy.

FOR FURTHER INFORMATION CONTACT:

Giselle Hersh, Division of Workplace Programs, SAMHSA/CSAP, Room 7–1051, One Choke Cherry Road, Rockville, Maryland 20857; 240–276–2600 (voice), 240–276–2610 (fax).

SUPPLEMENTARY INFORMATION:

The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Pub. L. 100–71. The “Mandatory Guidelines for Federal Workplace Drug Testing Programs,” as amended in the revisions listed above, requires strict standards that laboratories and IITFs must meet in order to conduct drug and specimen...