

The draft guidance indicates in section III.C.10 that, to meet the conditions of the guidance, outsourcing facilities compounding animal drug from bulk drug substances for office use in veterinary practices include on the label of any compounded drug these four statements:

- “Not for resale.”
- “For use only in [fill in species and any associated condition or limitation listed in Appendix A].”
- “Compounded by [name of outsourcing facility].”
- “Adverse events associated with this compounded drug should be reported to FDA on a Form FDA 1932a.”

We tentatively conclude that these four label statements are “public disclosures of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public” (5 CFR 1320.3(c)(2)) and are therefore not subject to review by OMB under the PRA. Thus, the time it would take to provide this information is not included in the burden estimate reported in table 2.

This draft guidance also refers to previously approved collections of information. A condition set forth in sections III.A.7., III.B.6, and III.C.5 is that any bulk drug substance used is manufactured by an establishment that is registered under section 510 of the FD&C Act (including a foreign establishment that is registered under section 360(i) of the FD&C Act) and is accompanied by a valid certificate of analysis. The information collection related to the disclosure of the certificate of analysis is approved under OMB control number 0910-0139.

Before the proposed information collection provisions contained in this draft guidance become effective, we will publish a notice in the **Federal Register** announcing OMB’s decision to approve, modify, or disapprove the proposed information collection provisions. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VI. Comments

Interested persons may submit either electronic comments regarding this draft guidance to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with Docket No. FDA-2015-D-1176. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday

through Friday, and will be posted to the docket at <http://www.regulations.gov>.

VII. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/AnimalVeterinary/GuidanceforIndustry/ucm042450.htm> or <http://www.regulations.gov>.

Dated: May 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS) Review Committee, pursuant to Section 1104(i) of the Patient Protection and Affordable Care Act (ACA).

Time and Date: June 16, 2015, 9:00 a.m.–5:00 p.m. EST; June 17, 2015, 8:00 a.m.–5:15 p.m. EST.

Place: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, 3311 Toledo Road, Auditorium B and C, Hyattsville, Maryland 20782, (301) 458-4524.

Status: Open.

Purpose: The purpose of this hearing is to obtain information from the health care industry on the currently adopted standards, operating rules, code sets and identifiers used in administrative simplification transactions.

The objectives of this hearing are as follows: (1) Review currently adopted standards, operating rules, code sets and identifiers used in each of the HIPAA-named administrative simplification transactions and evaluate the degree to which they meet current industry business needs; and (2) Identify transactions, standards, operating rules, code sets and identifiers used in administrative simplification that require changes, deletions or new versions in order to meet industry needs.

We invite the public to prepare and submit written testimony on any and all areas covered by this hearing. We also invite testifiers to prepare and submit more extensive written testimony, in addition to the oral testimony they will be providing during the hearing. Written testimonies should be sent to Marietta Squire, Committee Management Specialist, Centers for Disease Control and Prevention, National Center for Health Statistics, email msquire@cdc.gov.

Background on the Review Committee, including the Review Committee’s Charter can be accessed at <http://www.ncvhs.hhs.gov/subcommittees-work-groups/subcommittee-on-standards/review-committee/>.

Contact Person for More Information: Debbie M. Jackson, Acting Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 2339, Hyattsville, Maryland 20782, telephone (301) 458-4614 or Terri Deutsch, Centers for Medicare and Medicaid Services, Office of E-Health Standards and Services, 7500 Security Boulevard, Baltimore, Maryland 21244, telephone (410) 786-9462. Program information as well as summaries of meetings and a roster of committee members are available on the NCVHS home page of the HHS Web site: <http://ncvhs.us/>, where further information including an agenda will be posted when available.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (301) 458-4EEO (4336) as soon as possible.

Dated: May 13, 2015.

James Scanlon,

Deputy Assistant Secretary for Planning and Evaluation Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meetings of the Advisory Group on Prevention, Health Promotion, and Integrative and Public Health

AGENCY: Office of the Surgeon General of the United States Public Health Service, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In accordance with Section 10(a) of the Federal Advisory Committee Act, Public Law 92-463, as amended (5 U.S.C. App.), notice is hereby given that two meetings are scheduled for the Advisory Group on Prevention, Health Promotion, and Integrative and Public Health (the “Advisory Group”). The meetings will be open to the public. Information about the Advisory Group and the agendas for these meetings can be obtained by accessing the following Web site: <http://www.surgeongeneral.gov/initiatives/prevention/advisorygrp/index.html>.

DATES: The first meeting will be held on June 11, 2015, from 11:30 a.m. to 2:30 p.m. EST. The second meeting will be held on August 31 from 9:00 a.m. to