Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Hypertension, Thrombosis, Vascular Inflammation and Dysfunction.

Date: April 23–24, 2015.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Natalia Komissarova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5207, MSC 7846, Bethesda, MD 20892, 301–435–1206, *komissar@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS).

Dated: March 25, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–07256 Filed 3–30–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0815]

Electronic Study Data Submission; Data Standards; Recommending the Use of the World Health Organization Drug Dictionary

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing support for the World Health Organization (WHO) Drug Dictionary (available at *http://www.who-umc.org/*), which is maintained and updated by the Uppsala Monitoring Centre. FDA is encouraging sponsors and applicants to use WHO Drug Dictionary codes in investigational study data provided in regulatory submissions to the Center for Drug Evaluation and Research and to the Center for Biologics Evaluation and Research. The WHO Drug Dictionary contains unique codes for identifying drug names and evaluating medicinal product information, including active ingredients and therapeutic uses. Typically, WHO Drug Dictionary is used to code concomitant medications used by subjects during the course of a clinical trial. WHO Drug Dictionary will be listed in the FDA Data Standards Catalog posted to FDA's Study Data Standards Resources Web site at *http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm*

DATES: Although you can comment on this notice at any time, to ensure that the Agency considers your comments submit either electronic or written comments by May 5, 2015.

ADDRESSES: Submit written requests for single copies of the documents to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002 or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit electronic comments 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: Ron Fitzmartin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, rm. 1192, Silver Spring, MD 20993–002, *ronald.fitzmartin@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 71, Rm. 7301, Silver Spring, MD 20993, *stephen.ripley@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The use of a common dictionary to code concomitant medications is an important component of study data standardization. Generally, controlled terminology standards specify the key concepts that are represented as definitions, preferred terms, synonyms, codes, and code system. The analysis of study data is greatly facilitated by the use of controlled terms for clinical or scientific concepts that have standard, predefined meanings and representations. WHO Drug Dictionary contains unique codes as drug names and corresponding medicinal product information, including active ingredients and the Anatomical Therapeutic Chemical (ATC) classification system for the therapeutic uses. Typically, sponsors and applicants use WHO Drug Dictionary to code and analyze concomitant medications taken by subjects during the course of clinical trials.

Although use of WHO Drug Dictionary codes are not required at this time, FDA now supports and encourages the use of WHO Drug Dictionary coded concomitant medications used in clinical trials. For purposes of this notice, ''supported'' means the receiving Center has established processes and technology to support receiving, processing, reviewing, and archiving files in the specified standard.

FDA is now encouraging sponsors and applicants to provide WHO Drug Dictionary codes for concomitant medication data in investigational studies provided in regulatory submissions (*e.g.,* investigational new drug applications, new drug applications, abbreviated new drug applications, and biologics license applications). The codes should include the drug product trade name where available, the active ingredient(s) and the ATC class.

II. Comments

Interested persons may submit either electronic comments to *http://www.regulations.gov* or written comments regarding this notice to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. 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.*

Dated: March 23, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–07269 Filed 3–30–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–0839]

Target Animal Safety Data Presentation and Statistical Analysis; Draft 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 draft guidance for

industry #226 entitled ''Target Animal Safety Data Presentation and Statistical Analysis.'' The purpose of this document is to provide recommendations to industry regarding the presentation and statistical analyses of target animal safety (TAS) data submitted to the Center for Veterinary Medicine (CVM) as part of a study report to support approval of a new animal drug. These recommendations apply to TAS data generated from both TAS and field effectiveness studies conducted in companion animals (*e.g.,* dogs, cats, and horses) and food animals (*e.g.,* swine, ruminants, fish, and poultry).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by June 1, 2015.

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 requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft 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: Virginia Recta, Center for Veterinary Medicine (HFV–164), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0840, *virginia.recta@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry #226 entitled ''Target Animal Safety Data Presentation and Statistical Analysis.'' It is intended to provide recommendations to industry regarding the presentation and statistical analyses of TAS data submitted to CVM as part of a study report to support approval of a new animal drug. These recommendations apply to TAS data generated from both TAS and field effectiveness studies conducted in companion animals (*e.g.,* dogs, cats, and horses) and food animals (*e.g.,* swine, ruminants, fish, and poultry).

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 ''Target Animal Safety Data Presentation and Statistical Analysis.'' 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 21 CFR part 514 have been approved under OMB control number 0910–0032.

IV. Comments

Interested persons may submit either electronic comments regarding this document 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 the docket number found in brackets in the heading of this document. 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.*

V. 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: March 25, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–07264 Filed 3–30–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Same-sex relationships: Updates to Healthy Marriage and Relationship Education.

OMB No.: New Collection

Description: The Administration for Children and Families (ACF) will examine how healthy marriage programs currently approach, and could approach, serving sexual minority populations, that is, lesbian, gay, and bisexual populations. ACF expects to collect and analyze data from a range of information collection efforts—including interviews with program administrators, program managers, healthy marriage and relationship programming experts, and focus groups with program applicants and program attendees—to propose methods and practices for serving such couples/individuals/youth.

Respondents: Current healthy marriage program applicants and participants, program managers and facilitators, and experts in the field.

ANNUAL BURDEN ESTIMATES

Instrument	Total/annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Focus Group Guide for Program Applicants	30	1	1.5	45
Focus Group Guide for Program Attendees	60	1	1.5	90
Focus Group Guide for Program Attendees	60	1	1.5	90
Interview Guide for Program Managers	6	1	1	6
Interview Guide for Program Facilitators	12	1	1	12
Interview Guide for Program Experts	12	1	1	12