

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by June 1, 2015.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to 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FDA is announcing the availability of a draft guidance for industry #226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This level 1 draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115).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

Estimated Total Annual Burden Hours: 255.

In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. Email address: OPREinfocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Karl Koerper,

Reports Clearance Officer.

[FR Doc. 2015-07316 Filed 3-30-15; 8:45 am]

BILLING CODE 4184-73-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract

proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel; NIH Loan Repayment Program (Clinical and Pediatric Researchers).

Date: April 24, 2015.

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

Agenda: To review and evaluate contract proposals.

Place: National Institute of Environmental Health Sciences, Keystone Building, 530 Davis Drive, Suite 3118, Research Triangle Park, NC 27709, (Virtual Meeting).

Contact Person: RoseAnne M McGee, Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences, P.O. Box 12233, MD EC-30, Research Triangle Park, NC 27709 (919) 541-0752, mcgee1@niehs.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: March 25, 2015.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-07249 Filed 3-30-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0563]

Odalys Fernandez: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The U.S. Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debaring Odalys Fernandez from providing services in any capacity to a person that has an approved or pending drug product application for a period of 6 years. FDA bases this order on a finding that Ms. Fernandez was convicted of five felony counts under Federal law for conduct involving health care fraud, and one count of conspiracy to commit health care fraud, and that this pattern of conduct is sufficient to find that there is reason to

believe she may violate requirements under the FD&C Act relating to drug products. Ms. Fernandez was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Ms. Fernandez failed to request a hearing. Ms. Fernandez's failure to request a hearing constitutes a waiver of her right to a hearing concerning this action.

DATES: This order is effective March 31, 2015.

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Kenny Shade, Division of Enforcement, Office of Enforcement and Import Operations, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr. (ELEM-4144), Rockville, MD 20857, 301-796-4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(2)(B)(ii)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(ii)(I)) permits debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct which involves bribery, payment of illegal gratuities, fraud, perjury, false statement, racketeering, blackmail, extortion, falsification or destruction of records, or interference with, obstruction of an investigation into, or prosecution of any criminal offense, and FDA finds, on the basis of the conviction and other information, that such individual has demonstrated a pattern of conduct sufficient to find that there is reason to believe the individual may violate requirements under the FD&C Act relating to drug products.

On November 9, 2012, the U.S. District Court for the Southern District of Florida entered judgment against Ms. Fernandez after a jury found her guilty of five counts of health care fraud in violation of 18 U.S.C. 1347, and one count of conspiracy to commit health care fraud in violation of 18 U.S.C. 1349.

FDA's finding that debarment is appropriate is based on the felony convictions referenced herein. The factual basis for these convictions is as follows: Ms. Fernandez was a registered nurse working for Ideal Home Health Inc. (Ideal), which was a business in Miami-Dade County, FL. Ideal purportedly provided skilled nursing services to Medicare beneficiaries who required home health services. As a