DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB No.: 0970–0139]

Uniform Project Description (UPD) Project Narrative Format for Discretionary Grant Application Forms; Correction

AGENCY: Administration for Children and Families, HHS.

ACTION: Notice; correction.

SUMMARY: The Administration for Children and Families published a document in the Federal Register of February 17, 2015, concerning a request for comments on a proposed information collection. The document contained an incorrect citation.

FOR FURTHER INFORMATION CONTACT: Christopher Beach, Senior Grants Policy Specialist, Office of Administration, Administration for Children and Families, telephone (202) 401–1539.

Dated: February 18, 2015.

Christopher Beach, Senior Grants Policy Specialist, Office of Administration.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–0235]

Evaluating the Effectiveness of New Animal Drugs for the Reduction of Pathogenic Shiga Toxin–Producing Escherichia coli in Cattle; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (GFI #229) entitled “Evaluating the Effectiveness of New Animal Drugs for the Reduction of Pathogenic Shiga Toxin–Producing E. coli in Cattle.” The purpose of this document is to provide recommendations to industry relating to study design and describe criteria the Center for Veterinary Medicine (CVM) thinks are the most appropriate for the evaluation of the effectiveness of new animal drugs that are intended to reduce pathogenic Shiga toxin-producing E. coli (STEC) in cattle.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 27, 2015.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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.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: Joshua R. Hayes, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0651, Joshua.hayes@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry (GFI #229) entitled “Evaluating the Effectiveness of New Animal Drugs for the Reduction of Pathogenic Shiga Toxin–Producing E. coli in Cattle.” This draft guidance provides recommendations to industry relating to study design and describes criteria CVM thinks are the most appropriate for the evaluation of the effectiveness of new animal drugs that are intended to reduce pathogenic STEC in cattle. It discusses general considerations regarding the development of protocols, study conduct, animal welfare, substantial evidence of effectiveness, experimental parameters, nutritional content of experimental diets, and the assessment of drug concentrations in experimental diets. It also discusses the studies and analyses CVM recommends for sponsors
to substantiate the effectiveness of pathogenic STEC reduction drugs.

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 Agency’s current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

These collections of information are applicable statutes and regulations.

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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0595]

Environmental Protection Agency and Food and Drug Administration Advice About Eating Fish; Closure of the Public Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; closure of the public comment period.

SUMMARY: On June 11, 2014, the Food and Drug Administration (FDA), in coordination with the U.S. Environmental Protection Agency (EPA), (the Agencies), released for public comment draft fish consumption advice entitled “Fish: What Pregnant Women and Parents Should Know.” The draft advice would update the Agencies’ consumption advice and recommend that women who are pregnant (or might become pregnant) or nursing and anyone who prepares food for young children eat certain amounts and types of fish in order to improve health and developmental outcomes while minimizing risk from methylmercury in fish. The draft advice is consistent with recommendations in the Dietary Guidelines for Americans 2010, which are issued every 5 years by the U.S. Departments of Agriculture and Health and Human Services. FDA and EPA are now announcing the closure of the public comment period.

DATES: The comment period will close on March 26, 2015.

ADDRESSES: Comments may continue to be submitted until March 26, 2015. 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. FDA will share with EPA all comments submitted to the FDA docket.


SUPPLEMENTARY INFORMATION: In the Federal Register of June 11, 2014 (79 FR 33559), FDA, in coordination with EPA, announced the availability of the draft updated fish advice, entitled “Fish: What Pregnant Women and Parents Should Know,” for public comment (the notice). The draft advice is available electronically at http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm393070.htm. The notice stated that the comment period would be open until 30 days after the last transcript became available from either the FDA Risk Communication Advisory Committee (RCAC) meeting to be held on the draft advice or any other public meeting that the Agencies chose to hold on the draft advice (79 FR 33559). The notice also stated that the date for closure of public comment will be published in a future notice in the Federal Register (id.).

The RCAC meeting was held on November 3 and 4, 2014, and the transcript of the meeting became available on December 2, 2014. The meeting addressed the draft updated fish advice in great detail and included presentations by the Agencies on both the substance and the presentation of the draft advice, and included presentations by invited experts in risk communications. The meeting also provided members of the public with an opportunity to express their views to the RCAC and to members of the Agencies who were in attendance. A number of organizations and private citizens availed themselves of this opportunity. For these reasons, FDA and EPA have concluded that the thoroughness of this public meeting, in addition to the public comments received and still to be received, remove the need for additional public meetings and are hereby closing the public comment period on March 26, 2015. The transcript from the RCAC meeting is available electronically at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/RiskCommunicationAdvisoryCommittee/UCM425352.pdf and http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/RiskCommunicationAdvisoryCommittee/UCM425353.pdf.

Dated: February 18, 2015.

Leslie Kux,
Associate Commissioner for Policy.

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