

more rapidly and with greater frequency (Core Studies) and serve as a vehicle for studying more complex issues and topics in greater detail and with increased efficiency (Plus Studies). In fall 2014 and spring 2015, FACES will assess the school readiness skills of 2,400 Head Start children, survey their parents, and ask their Head Start teachers to rate children's social and emotional skills. In spring 2015 and again in spring 2017, the number of programs in the FACES sample will increase from the 60 that are used to collect data on children's school readiness outcomes to 180 for the purpose of conducting observations in 720 Head Start classrooms. Program director, center director, and teacher surveys will also be conducted in the spring. Plus features include additional survey content of policy or programmatic interest, which may

include more programs being sampled. This notice is specific to the data collection activities needed to recruit Head Start programs and centers into FACES 2014–2018. A future notice will provide information about data collection for the Core and Plus studies.

A total of 230 Head Start programs and 460 Head Start centers will be selected to participate in FACES 2014–2018. The Core Study will include a nationally representative sample of 180 programs, with up to 50 additional programs potentially selected for Plus studies. For the Core, the 60 programs participating in the Core child-level data collection will be contacted and recruited for the study in spring 2014. In fall 2014, the remaining 120 programs will be contacted. All 180 programs will be contacted a second time in fall 2016 to confirm their continued participation in the Core spring 2017 data collection. The 50 Plus study programs would be

recruited at a similar time as the Core study programs (i.e., spring 2014 or fall 2014/2016) depending on the nature of the study being conducted.

The method of data collection for recruitment of all programs will include telephone conversations with program directors and on-site coordinators who serve as liaisons between the FACES study team and the Head Start centers. These calls will inform program staff about the purpose of the study and will gather lists of centers in each program in order to compile the center sampling frame.

The purpose of this data collection is to support the 2007 reauthorization of the Head Start program (Pub. L. 110–134), which calls for periodic assessments of Head Start's quality and effectiveness.

*Respondents:* Head Start Program Directors and Staff.

**ANNUAL BURDEN ESTIMATES**

Instrument	Total number of respondents	Number of responses per respondent	Average burden hour per response	Estimated total burden hours	Estimated annual burden hours
Telephone script for program directors .....	230	2	1	460	154
Telephone script for on-site coordinators .....	230	2	.75	345	115
Total .....	.....	.....	.....	805	269

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](mailto: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,**  
*OPRE Reports Clearance Officer.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2011–D–0889]

**Guidance for Industry on New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions With Guidance for Industry #209; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry #213 entitled “New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions With Guidance for Industry #209.” The purpose of this document is to provide information to sponsors of certain antimicrobial new animal drug products who are interested in revising conditions of use for those products consistent with FDA's Guidance for Industry (GFI) #209, “The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals,” and to set timelines for stakeholders wishing to comply voluntarily with this guidance.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**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 guidance document.

Submit electronic comments on the 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:** William T. Flynn, Center for Veterinary Medicine (HVF-1), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9084, email: [william.flynn@fda.hhs.gov](mailto:william.flynn@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

In the **Federal Register** of April 13, 2012 (77 FR 22327), FDA published the notice of availability for a draft guidance entitled “New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions With GFI #209,” giving interested persons until July 12, 2012, to comment on the draft guidance. FDA received numerous comments on the draft guidance and those comments were considered as the guidance was finalized. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated April 13, 2012.

The purpose of this guidance document is to provide information to sponsors of certain antimicrobial new animal drug products who are interested in revising conditions of use for those products consistent with FDA’s Guidance for Industry (GFI) #209, “The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals,” and to set timelines for stakeholders wishing to comply voluntarily with this guidance. FDA intends to work with affected drug sponsors to help them to voluntarily implement the principles described above through modifications to the approved conditions of use of their new animal drug products. FDA believes a voluntary approach, conducted in a cooperative and timely manner, is the most effective approach to achieve the common goal of more judicious use of medically important antimicrobials in animal agriculture.

FDA recognizes that it is important to identify ways to assess the effect of GFI #209 and GFI #213 over time. FDA

currently collects data on the sale and distribution of antimicrobial drugs intended for use in food-producing animals, as well as data on antimicrobial resistance among foodborne pathogens as part of the National Antimicrobial Resistance Monitoring System. FDA is currently working in collaboration with other agencies, including United States Department of Agriculture and the Centers for Disease Control, to explore approaches for enhancing current data collection efforts in order to measure the effectiveness of the strategy. FDA anticipates seeking additional public input as it develops these enhancements.

##### **II. Significance of Guidance**

This level 1 guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency’s current thinking on the 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**

This 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 numbers 0910-0032 and 0910-0669.

##### **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 guidance at either <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <http://www.regulations.gov>.

Dated: December 9, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. FDA–2013–N–1504]

#### **Independent Assessment of the Process for the Review of Device Submissions; High Priority Recommendations**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is presenting Booz Allen Hamilton’s high priority recommendations submitted as part of their independent assessment of the process for the review of medical device submissions. The assessment is part of the FDA performance commitments relating to the Medical Device User Fee Amendments of 2012 (MDUFA III), which reauthorized device user fees for fiscal years 2013 to 2017. The assessment is described in section V, “Independent Assessment of Review Process Management”, of the commitment letter entitled “MDUFA Performance Goals and Procedures”<sup>1</sup> (MDUFA III Commitment Letter). The assessment is being conducted in two phases. The high priority recommendations are the first of a series of deliverables, as outlined in the contract statement of work,<sup>2</sup> to be published as part of Phase 1 of the assessment.

**FOR FURTHER INFORMATION CONTACT:** Amber Sligar, Office of Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 3291, Silver Spring, MD 20993–0002, 301–796–9384, [Amber.Sligar@fda.hhs.gov](mailto:Amber.Sligar@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

On July 9, 2012, President Obama signed into law the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) (FDASIA).<sup>3</sup> Title

<sup>1</sup> [www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM295454.pdf](http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM295454.pdf).

<sup>2</sup> <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/ucm314036.htm>.

<sup>3</sup> <http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf>.