III. Commentsuidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments regarding the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.regulations.gov*.

Dated: January 13, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–919 Filed 1–15–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0510]

Draft Guidance for Industry: Submission of Laboratory Packages by Accredited Laboratories; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Submission of Laboratory Packages by Accredited Laboratories.'' The draft guidance document provides information and recommendations about accreditation standards for laboratories and the quality and type of data that accredited laboratories produce to support testing results submitted to FDA about the admissibility of detained articles offered for import. We are taking this action under a recommendation made by the President's Interagency Working Group on Import Safety (Working Group).

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by April 16, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Executive Operations (HFC–2), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Donna Porter, Division of Field Science (HFA–141), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7605.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Submission of Laboratory Packages by Accredited Laboratories.'' The draft guidance is about accreditation standards for laboratories and about the quality and type of data that accredited laboratories should produce in support of testing results submitted to FDA pertaining to the admissibility of detained articles offered for import of all product types (i.e., biological products, drugs, devices, and food) that we regulate. FDA is taking this action under a recommendation made by the President's Interagency Working Group on Import Safety (Working Group). The Working Group was to conduct a comprehensive review of the U.S. import system and identify ways to further increase the safety of imports entering the country, and it presented its initial findings to the President on September 10, 2007, in a report entitled ''Protecting American Consumers Every Step of the Way: A Strategic Framework for Continual Improvement in Import Safety.''

On November 6, 2007, the Working Group presented to the President its Import Safety Action Plan (Action Plan), which contains short- and long-term recommendations for continuing to improve the safety of imports entering the United States. The Action Plan recommended that FDA issue guidance that ''would set standards for the sampling and testing of imported products, including the use of accredited laboratories submitting data to FDA to assist in evaluating whether an appearance of a violation may be resolved.''

The issuance of the draft guidance is, therefore, consistent with the Action Plan and also consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA'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.

II. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/ora* or *http://www.regulations.gov*.

Dated: January 9, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–837 Filed 1–15–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0394]

Guidance for Industry on Regulation of Genetically Engineered Animals Containing Heritable recombinant DNA Constructs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the agency) is announcing the availability of a guidance for industry #187 entitled ''Regulation of Genetically Engineered Animals Containing Heritable recombinant DNA Constructs.'' This guidance is intended to clarify FDA's requirements and recommendations for producers and developers of genetically engineered (GE) animals and their products. The guidance describes how the new animal drug provisions of the Federal Food, Drug, and Cosmetic Act (the act) apply with respect to GE animals, including FDA's intent to exercise enforcement discretion regarding requirements for certain GE animals.

DATES: Submit written or electronic 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. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Larisa Rudenko, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8247, e-mail: *larisa.rudenko@hhs.fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 19, 2008 (73 FR 54407), FDA published the notice of availability for a draft guidance entitled ''Regulation of Genetically Engineered Animals Containing Heritable rDNA Constructs'' giving interested persons until November 18, 2008, to comment on the draft guidance. FDA received numerous comments on the draft guidance. FDA reviewed and considered all comments and, in response, made several changes. In response to requests for greater transparency, the agency clarified its intent to hold public advisory committee meetings for GE animal-related approvals and its intent to post statements of intent to exercise enforcement discretion over certain GE animals. In response to other comments, FDA clarified the scope of new animal drug application (NADA) approvals for GE animals and clarified its intent to work with other agencies should it receive a request for investigation or approval of a new animal drug in a GE wildlife animal ultimately intended for release into the wild.

The guidance announced in this notice finalizes the draft guidance dated September 19, 2008.

For the purpose of this guidance, FDA defines ''genetically engineered (GE) animals'' as those animals modified by recombinant DNA (rDNA) techniques, including progeny that contain the modification. The term GE animal can refer to both animals with heritable rDNA constructs and animals with non-heritable rDNA constructs (e.g., those modifications intended to be used as gene therapy). Although much of this guidance will be relevant to non-heritable rDNA constructs, and FDA intends to regulate non-heritable constructs in much the same way as described in this guidance for heritable constructs, this guidance only pertains to GE animals containing heritable rDNA constructs. We may issue a separate guidance on the regulation of GE animals bearing non-heritable constructs to discuss when those constructs would be under FDA jurisdiction and the kinds of information that would be relevant for FDA's review. In this guidance, we will use the term ''GE animal'' to refer to GE animals with heritable rDNA constructs. For ease of reference, we sometimes refer to regulation of the article (the rDNA construct) in such GE animals as regulation of the GE animal.

The Center for Veterinary Medicine (''CVM'', ''we'', ''us'', ''our'') has been working on applications submitted by developers of GE animals under the New Animal Drug provisions of the act (21 U.S.C. 321 *et seq.*). This guidance is intended to clarify these requirements and our recommendations for producers and developers (''sponsors,'' ''you'') of GE animals and their products. CVM will work closely with the other Centers at FDA that regulate pharmaceuticals or other medical products derived from biopharm animals to ensure that our oversight is complementary and not unnecessarily duplicative. Developers of GE animals should contact CVM early in the development of their GE animal; developers whose animals are already well under development also should contact CVM. We intend to issue additional guidance to describe more fully how various components of the New Animal Drug provisions of the act apply to biopharm animals and how CVM will implement them, the division of responsibilities between CVM and the other Centers regarding biopharm animals and products derived from them, and, more generally, how CVM and the other Centers will work interactively to regulate biopharm animals and their products. Developers of GE animals should come to CVM early in the process.

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 have been approved under OMB Control Nos. 0910–0032, 0910–0045, 0910–0117, and 0910–0284.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any