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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier A. Corbin

[Docket No. FDA–2008–D–0597]

Draft Guidance for Industry: Small Entities Compliance Guide for Renderers—Substances Prohibited From Use in Animal Food or Feed; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry #195, entitled "Draft Guidance for Industry: Small Entities Compliance Guide for Renderers—Substances Prohibited From Use in Animal Food or Feed." This small entities compliance guide aids renderers in complying with the requirements of the final rule published in the **Federal Register** of April 25, 2008 (73 FR 22720). FDA's goal is to strengthen existing safeguards to prevent the spread of bovine spongiform encephalopathy (BSE) in U.S. cattle and to reduce the risk of human exposure to the BSE agent.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by [*insert date 60 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and

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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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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: Shannon Jordre, Division of Compliance, Center for Veterinary Medicine (HFV–230), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9229, *Shannon.jordre@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry #195, entitled "Draft Guidance for Industry: Small Entities Compliance Guide for Renderers—Substances Prohibited From Use in Animal Food or Feed." In the **Federal Register** of April 25, 2008 (73 FR 22720), FDA published a final rule entitled "Substances Prohibited From Use in Animal Food or Feed." This regulation is designed to further strengthen existing safeguards against the establishment and amplification of BSE, sometimes referred to as "Mad Cow Disease," through animal feed. The regulation prohibits the use of certain cattle origin materials in the food or feed of all animals.

FDA has prepared this draft Small Entities Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121). This document is intended to provide

guidance to small businesses on the requirements of Title 21, Code of Federal Regulations, new § 589.2001 and amended § 589.2000.

II. Significance of Guidance

FDA is issuing this small entities compliance guide as a 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

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 589.2001 have been approved under OMB Control Number 0910–0627.

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 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. Received comments may be seen 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/cvm* or *http://www.regulations.gov.*

Dated: 11/20/08

November 20, 2008.

Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

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