requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive "Impact-Resistant Lenses: Questions and Answers," you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number (23) to identify the guidance you are requesting. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. Guidance documents are also available at *http://www.regulations.gov*.

IV. 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 801.109 have been approved under OMB Control No. 0910–0485; the collections of information in 21 CFR 807.87 have been approved under OMB Control No. 0910–0120; and the collections of information in 21 CFR Part 820 have been approved under OMB Control No. 0910–0073.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: August 27, 2010.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2010–21908 Filed 9–1–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0435]

Guidance for Industry; Small Entities Compliance Guide—The Index of Legally Marketed Unapproved New Animal Drugs for Minor Species; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a Level 2 guidance for industry #201 entitled "Small Entities Compliance Guide—The Index of Legally Marketed Unapproved New Animal Drugs for Minor Species." This small entities compliance guide aids industry in complying with the requirements of the final rule that published in the **Federal Register** of December 6, 2007. This regulation establishes administrative procedures and criteria for index listing a new animal drug for use in a minor species as provided by the Minor Use and Minor Species Animal Health Act of 2004 (MUMS).

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: Joan Gotthardt, Center for Veterinary Medicine (HFV–50), Food and Drug Administration, 7500 Standish Pl., MPN2, rm. N371, Rockville, MD 20855, 240–276–9090, email: *Joan.gotthardt@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a Level 2 guidance for industry #201 entitled "Small Entities Compliance Guide—The Index of Legally Marketed Unapproved New Animal Drugs for Minor Species." This guidance aids industry in complying with the requirements of the final rule published in the **Federal Register** of December 6, 2007 (72 FR 69108) (the indexing regulation).

FDA has prepared this guidance 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 section 572 of the MUMS act. Congress, in enacting MUMS, sought to encourage the development of animal drugs that are currently unavailable to minor species (species other than cattle, horses, swine, chickens, turkeys, dogs, and cats) in the United States or to major species afflicted with uncommon diseases or conditions (minor uses). The indexing regulation establishes procedures and criteria for index listing a new animal drug for use in a minor species.

II. Significance of Guidance

This level 2 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 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 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 section 572 of the MUMS act have been approved under OMB Control No. 0910–0620.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

V. Electronic Access

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

Dated: August 30, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–21981 Filed 9–1–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0432]

Guidance for Industry; Small Entities Compliance Guide—Designation of New Animal Drugs for Minor Uses or Minor Species; 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 #200 entitled "Small Entities Compliance Guide—Designation of New Animal Drugs for Minor Uses or Minor Species." This small entities compliance guide (SECG) aids industry in complying with the requirements of the final rule that published in the **Federal Register** of July 26, 2007. The Minor Use and Minor Species Animal Health Act of 2004 (MUMS act) establishes new regulatory procedures that provide incentives intended to make more drugs legally available to veterinarians and animal owners for the treatment of minor animal species and uncommon diseases in major animal species.

DATES: Submit either electronic or written comments on the SECG at any time.

ADDRESSES: Submit written requests for single copies of the SECG 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 SECG.

Submit electronic comments on the SECG 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: Meg Oeller, Center for Veterinary Medicine (HFV–50), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–9090, *Margaret.oeller@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of an SECG #200 entitled "Small Entities Compliance Guide—Designation of New Animal Drugs for Minor Uses or Minor Species." This SECG aids industry in complying with the requirements of the final rule published in the **Federal Register** of July 26, 2007 (72 FR 41010).

FDA has prepared this SECG 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 section 573 of the MUMS act. In enacting MUMS, Congress sought to encourage the development of animal drugs that are currently unavailable to minor species (species other than cattle, horses, swine, chickens, turkeys, dogs, and cats) in the United States or to major species afflicted with uncommon diseases or conditions (minor uses). These regulations describe the procedures for designating a new animal drug as a minor use or minor species drug. Such designation establishes eligibility for the incentives provided by the MUMS act.

II. Significance of Guidance

FDA is issuing this SECG as a level 2 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents 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 SECG 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 section 573 of the MUMS act have been approved under OMB control no. 0910–0605.

IV. Comments

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.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

V. Electronic Access

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

Dated: August 30, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–21980 Filed 9–1–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0574]

International Conference on Harmonisation; Guidance on Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; Annex 12 on Analytical Sieving General Chapter; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 12: Analytical Sieving General Chapter." The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance provides the results of the ICH Q4B evaluation of the Analytical Sieving General Chapter harmonized text from each of the three pharmacopoeias (United States, European, and Japanese) represented by