Acculturation: A Systematic Review of Public Health Studies With Hispanic Population in the United States," *Social Science & Medicine,* 69: 983–991, 2009.

Dated: March 4, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–5736 Filed 3–11–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0112]

Draft Guidance for Industry on Chemistry, Manufacturing, and Controls Information—Fermentation-Derived Intermediates, Drug Substances, and Related Drug Products for Veterinary Medicinal Use; 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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry #216 entitled "Chemistry, Manufacturing, and Controls (CMC) Information—Fermentation-Derived Intermediates, Drug Substances, and Related Drug Products for Veterinary Medicinal Use". The purpose of this document is to provide recommendations on what documentation to submit to support the CMC information for fermentation-derived intermediates, drug substances, and related drug products for veterinary medicinal use.

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on any guidance at any time (*see* 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 30, 2011.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), 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 *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm.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: Michael J. Popek, Center for Veterinary Medicine (HFV–144), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8269, *e-mail: michael.popek@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry #216 entitled "Chemistry, Manufacturing, and Controls (CMC) Information—Fermentation-Derived Intermediates, Drug Substances, and Related Drug Products for Veterinary Medicinal Use." This draft guidance provides recommendations on what documentation to submit to support the CMC information for fermentation-derived intermediates, drug substances, and related drug products for veterinary medicinal use. This information is filed to CVM in a new animal drug application (NADA), conditional NADA, investigational new animal drug file, abbreviated NADA, generic investigational new animal drug file, drug master file, or veterinary master file.

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

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 this draft guidance have been approved under OMB control number 0910–0032 (expiration date April 30, 2011).

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

Dated: March 8, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–5816 Filed 3–11–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0108]

Revised Draft Guidance for Industry on User Fee Waivers, Reductions, and Refunds for Drug and Biological Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised draft guidance for industry entitled "User Fee Waivers, Reductions, and Refunds for Drug and Biological Products." This revised draft guidance provides recommendations to applicants considering whether to request a waiver or reduction in user fees. This guidance is a revision of the draft guidance entitled "Draft Interim Guidance Document for Waivers of and Reductions in User Fees," issued July 16, 1993.

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 June 13, 2011.

Submit written comments on the proposed collection of information by May 13, 2011.

ADDRESSES: Submit written requests for single copies of the revised draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring,