through community-based organizations, Tribes and Village governments. The purpose of ANA is to promote the goal of economic and social self-sufficiency for American Indians, Native Hawaiians, Alaskan Natives and other Native American Pacific Islanders, including American Samoa Natives.

2. Priority Area Description for Economic Development

The FY2009 PA Priority Area Description for Economic Development Projects adds the following bullet:

• Projects to promote traditional energy activities and practices that support conservation and help to mitigate the high costs associated with the purchase, transportation, and storage of fuel in remote Alaskan Villages.

3. Priority Area Description for Social Development

The FY 2009 PA Priority Area Description for Social Development Projects removes the following bullets:

• Projects to reduce child/infant abuse and neglect and family domestic violence.

• Projects that address the needs of grandparents raising grandchildren.

• Projects to recruit, train and certify new Native American foster parents or promote appropriate extended family placements or to assist abused, neglected and abandoned Native American children, youth and their families.

(D) *ANA ERE:* The FY 2009 PA includes an additional instruction in the Approach evaluation criterion, Project Strategy sub-criterion. This change reflects the need for additional information related to the land area and natural resources over which the applicant has jurisdiction. (Legal authority: Section 803(a) and (d) and 803C of the Native American Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b–3 and Pub. L. 109–394.)

The FY 2009 PA Approach evaluation criterion, Project Strategy sub-criterion will have the following statement added:

Applicants are required to describe a land base or other resources, e.g., river or body of water, over which they exercise jurisdiction to implement Tribal regulation of environmental quality. Maps and photos of the area are encouraged.

Dated: September 30, 2008.

Quanah Crossland Stamps,

Commissioner, Administration for Native Americans.

[FR Doc. E8–23662 Filed 10–6–08; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–F–0518]

Anitox; Filing of Food Additive Petition (Animal Use); Formaldehyde

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Anitox has filed a petition proposing that the food additive regulations be amended to provide for the safe use of formaldehyde to retard the growth of *Clostridium perfringens* in animal feeds.

DATES: Submit written or electronic comments on the petitioner's environmental assessment December 8, 2008.

ADDRESSES: Submit written comments 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*.

FOR FURTHER INFORMATION CONTACT: Isabel W. Pocurull, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–453–6853, e-mail: *isabel.pocurull@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5)), notice is given that a food additive petition (FAP 2259) has been filed by Anitox, 1055 Progress Circle, Lawrenceville, GA 30043. The petition proposes to amend the food additive regulations in part 573—Food Additives Permitted in Feed and Drinking Water of Animals (21 CFR part 573) to provide for the safe use of formaldehyde to retard the growth of *Clostridium perfringens* in animal feeds.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations issued under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Division of Dockets Management (see **DATES** and **ADDRESSES**) for public review and comment.

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. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.51(b).

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*.

Dated: September 29, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8–23723 Filed 10–6–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0038]

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice that appeared in the **Federal Register** of September 24, 2008 (73 FR 55114). The document announced a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). A portion of the meeting will be closed to the public. This document corrects the error.

FOR FURTHER INFORMATION CONTACT: Theresa Green, Office of the Commissioner, Food and Drug

Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1220.

SUPPLEMENTARY INFORMATION: In FR Doc. E8–22437, appearing on page 55114 in the **Federal Register** of Wednesday, September 24, 2008, the following correction is made:

1. On page 55114, in the third column, in the *Procedure* section, the fourth sentence is corrected to read ''Oral presentations from the public will be scheduled between approximately 2 p.m. and 3 p.m.''

There are no other changes to the document.

Dated: October 1, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–23718 Filed 10–6–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0525]

Draft Guidance for Industry on New Contrast Imaging Indication Considerations for Devices and Approved 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 draft guidance for industry entitled ''New Contrast Imaging Indication Considerations for Devices and Approved Drug and Biological Products.'' As part of the Medical Device User Fee Amendments of 2007 (MDUFA) Commitment for the Performance Goals and Procedures, FDA agreed to publish draft guidance by September 30, 2008, for medical imaging devices with ''contrast agents or radiopharmaceuticals.'' FDA intends this draft guidance to assist developers of medical imaging devices and imaging drug/biological products that provide image contrast enhancement. Particularly this guidance focuses on approaches in developing new contrast indications for imaging devices for use with already approved imaging products. FDA intends for the recommendations in this guidance to promote timely and effective review of, and consistent and appropriate regulation and labeling for imaging drugs and devices.

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 January 5, 2009.

ADDRESSES: Submit written requests for single copies of this 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, MD 20993–0002. 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: Patricia Y. Love, Office of Combination Products (HFG–3), Office of the Commissioner, Food and Drug Administration, 15800 Crabbs Branch Way, Rockville, MD 20855, 301–427–1934.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''New Contrast Imaging Indication Considerations for Devices and Approved Drug and Biological Products.'' This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on New Contrast Imaging Indication Considerations for Devices and Approved Drug and Biological Products. 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.

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 part 807 have been approved under 0910–0120. The collections of information in 21 CFR part 814 have been approved under 0910–0231. The collections of information in 21 CFR part 314 have been approved under 0910–0001.

II. 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*.

III. Electronic Access

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

Dated: September 29, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–23712 Filed 10–6–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0281]

Pilot Program To Evaluate Proposed Name Submissions; Concept Paper

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a concept paper entitled ''PDUFA Pilot Project Proprietary Name Review.'' The concept paper provides information to pharmaceutical firms about how to evaluate proposed propriety names and submit the data generated from those evaluations to FDA for review under an anticipated pilot program. FDA plans to begin enrollment in the pilot program in fiscal year (FY) 2009.