Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. HHS, with the HHS' NLCP contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

Upon finding a Canadian laboratory to be qualified, HHS will recommend that DOT certify the laboratory (**Federal Register**, July 16, 1996) as meeting the minimum standards of the Mandatory Guidelines published in the **Federal Register** on April 13, 2004 (69 FR 19644). After receiving DOT certification, the laboratory will be included in the monthly list of HHS-certified laboratories and participate in the NLCP certification maintenance program.

Dated: July 20, 2010.

Elaine Parry,

Director, Office of Program Services, SAMHSA.

[FR Doc. 2010–18636 Filed 7–30–10; 8:45 am]

BILLING CODE 4160–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0378]

Draft Compliance Policy Guide Sec. 690.800 *Salmonella* in Animal 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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for FDA staff entitled "Compliance Policy Guide Sec. 690.800 *Salmonella* in Animal Feed" (the draft CPG). The draft CPG, when finalized, is intended to provide guidance for FDA staff on regulatory policy relating to animal feed or feed ingredients that come in direct contact with humans, such as pet food and pet treats, contaminated with *Salmonella* and also on regulatory policy relating to animal feed or feed ingredients contaminated with a *Salmonella* serotype that is pathogenic to the target animal for the animal feed.

DATES: Although you can comment on any CPG at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on the draft CPG before it begins work on the final version of the CPG, submit either electronic or written comments on the draft CPG by November 1, 2010.

ADDRESSES: Submit written requests for single copies of the CPG to the Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft CPG.

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

FOR FURTHER INFORMATION CONTACT: Kim Young, Center for Veterinary Medicine (HFV–230), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–276–9200.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for FDA staff entitled "Compliance Policy Guide Sec. 690.800 *Salmonella* in Animal Feed." The draft CPG provides guidance for FDA staff regarding the contamination of animal feed and feed ingredients with *Salmonella*. The draft CPG proposes criteria that should be considered in recommending enforcement action against animal feed or feed ingredients that are adulterated due to the presence of *Salmonella*. In particular, the draft CPG proposes regulatory action guidance relating to animal feed or feed ingredients that are contaminated with *Salmonella* and (1) come in direct contact with humans, such as pet food and pet treats, or (2) are contaminated with a *Salmonella* serotype that is pathogenic to the target animal for which the animal feed is intended. The draft CPG also contains information that may be useful to regulated industry and the public.

FDA is issuing the draft CPG as Level 1 draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft CPG, when finalized, will represent the agency's current thinking on enforcement recommendations for certain circumstances where animal feed or feed ingredients are contaminated with *Salmonella*. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding the draft CPG. 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.

III. Electronic Access

Persons with access to the Internet may obtain the draft CPG at either *http://www.fda.gov/ora/compliance_ref/cpg/default.htm or http://www.regulations.gov*.

Dated: July 23, 2010.

Michael A. Chappell,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 2010–18873 Filed 7–30–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0125]

Guidance for Industry and Researchers on the Radioactive Drug Research Committee: Human Research Without an Investigational New Drug Application; 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 and researchers entitled "The Radioactive Drug Research Committee: Human Research Without an Investigational New Drug Application." This guidance provides information to those using radioactive drugs for certain research purposes to help determine whether research studies may be conducted under an FDA-approved radioactive drug research committee, or

whether research studies must be conducted under an investigational new drug application (IND). It also offers answers to frequently asked questions on conducting research with radioactive drugs, and provides information on the membership, functions, and reporting requirements of a radioactive drug research committee approved by FDA.

DATES: Submit either electronic or written comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this 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. 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: Orhan Suleiman, Center for Drug Evaluation and Research, Food and Drug Administration, 10901 New Hampshire Ave., Bldg. 22, rm. 2202, Silver Spring, MD 20993–0002, 301–796–1471.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and researchers entitled "The Radioactive Drug Research Committee: Human Research Without an Investigational New Drug Application."

In a document published in the **Federal Register** on July 25, 1975 (40 FR 31298), FDA changed the conditions under which new radioactive drug and biological products could be used. First, the Agency terminated a 1963 order from the Commissioner of Food and Drugs (28 FR 183, January 8, 1963) that had exempted radioactive new drug and biological products for investigational use in humans from new drug requirements (21 CFR part 312), as long as they were shipped consistent with regulations issued by the then Atomic Energy Commission (AEC). FDA and AEC had agreed that all radioactive drugs and biological products should now become subject to the same requirements for investigational use as other new drugs under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and section 351 of the Public Health Service Act (42 U.S.C. 262). Simultaneously, the Agency issued regulations (§ 361.1 (21 CFR 361.1)) explaining when radioactive drugs for basic science and medical research would not be subject to the same requirements for investigational use as other new drugs.

Today, research studies with a radioactive drug or biological product may be conducted in a number of ways: (1) Under an IND (part 312), (2) exempt from IND requirements (§ 312.2), or (3) under certain conditions, with the supervision and approval of an FDA-approved Radioactive Drugs Research Committee (RDRC) (§ 361.1).

This guidance discusses the conditions under which research with a radioactive drug may be conducted under § 361.1. Appendices to the guidance answer frequently asked questions about those conditions and provide additional information on RDRCs. Appendix A of the guidance answers questions on basic science research with radioactive drugs. Appendix B addresses approval by the RDRC and the information that must be submitted by investigators to the RDRC. Appendix C discusses the limits on the pharmacological dose, and Appendix D discusses the limits on the radiation dose. Each of these appendices also includes a summary of the regulations. Appendix E provides information on the membership, functions, and reports of an RDRC. The final appendix, Appendix F, is an RDRC review criteria checklist, indicating the areas on which the RDRC will focus when considering a proposed research study.

In the **Federal Register** of June 3, 2009 (74 FR 26703), FDA announced the availability of a draft guidance for industry and researchers entitled "The Radioactive Drug Research Committee: Human Research Without an Investigational New Drug Application." The notice gave interested persons an opportunity to comment by September 1, 2009. We received comments from seven institutions, organizations, and individuals. We have carefully considered the comments and, where appropriate, have made corrections, added information, or clarified the information in the guidance in response to the comments or on our own initiative.

This 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 determining whether human research with a radioactive drug can be conducted under a radioactive drug research committee. 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

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.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: July 27, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–18853 Filed 7–30–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel Member Conflict: AIDS Molecular Biology and Opportunistic Infections.

Date: August 12–13, 2010.

Time: 8 a.m.to 5 p.m.

Agenda: To review and evaluate grant applications.