

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.

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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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for FDA staff entitled "Compliance Policy Guide Sec. 690.800 *Salmonella* in Animal Feed" (the draft CPG).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.

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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