

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No.        ]

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 draft 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 electronic or written comments on the draft CPG by [insert date 90 days after publication in the federal register].

ADDRESSES: 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. 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.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of draft 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, is intended to represent FDA's current thinking regarding 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) electronic or written comments regarding the draft CPG. 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.

## III. Electronic Access

Persons with access to the Internet may obtain the draft CPG from FDA's Office of Regulatory Affairs history page. It may be accessed at [http://www.fda.gov/ora/compliance\\_ref/cpg/default.htm](http://www.fda.gov/ora/compliance_ref/cpg/default.htm).

Dated: \_\_\_\_\_.

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