

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 94D-0147]

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**Guidance for Industry: Studies to Evaluate the Utility of Anti-*Salmonella*
Chemical Food Additives in Feeds; Availability**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry (#80) entitled "Guidance for Industry: Studies to Evaluate the Utility of Anti-*Salmonella* Chemical Food Additives in Feeds." The guidance explains the standards upon which studies to establish the utility of anti-*Salmonella* chemical food additives for maintaining feeds *Salmonella*-negative should be based. The intended effect of this guidance is to provide advice on study standards for the establishment of anti-*Salmonella* food additives that will maintain feeds *Salmonella*-negative.

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

ADDRESSES: Submit written requests for single copies of the final guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the final guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://>

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www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the final guidance document.

FOR FURTHER INFORMATION CONTACT: Henry E. Ekperigin, Center for Veterinary Medicine (HFV-222), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0174, e-mail: hekperig@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In April 1991, FDA publicly discussed its intention to adopt a policy requiring feeds and feed ingredients to be *Salmonella*-free (meeting of FDA's Veterinary Medicine Advisory Committee, April 11, 1991, Bethesda, MD). The agency later adopted a policy requiring feeds and feed ingredients to be *Salmonella*-negative (see 59 FR 33975, July 1, 1994). This reflected concerns that *Salmonella* infections cause a significant portion of foodborne illnesses, and that animal feeds are a significant source of *Salmonella* infections in food animals and thus in humans. After the issuance of the *Salmonella*-negative policy, development began on several products designed to achieve and maintain *Salmonella*-negative levels in animal feeds. Sponsors of these products may file food additive petitions to establish the safety and utility of the additives. Because sponsors have used a variety of research methods to support their petitions, FDA has found it difficult to evaluate the petitions in a uniform manner.

In an effort to achieve more consistency, FDA developed a draft guidance entitled "Utility Studies for Anti-*Salmonella* Chemical Food Additives in Animal Feeds." The availability of this draft guidance was announced in the **Federal Register** of June 23, 1994 (59 FR 32442). A public workshop on this

topic was held on August 8, 1994, in conjunction with the annual meeting of the Poultry Science Association in Starkville, MS. Comments at the public workshop and the written comments received on the draft guidance led FDA to revise the draft document. The agency clarified several statements that had caused confusion or had raised questions among the respondents. Further, following suggestions from the respondents, the agency made several changes in the testing methods.

The purpose of this final guidance is to support consistent evaluation of anti-*Salmonella* food additives and their ability to maintain a *Salmonella*-negative level in previously “clean” animal feeds through repeated exposure to various *Salmonella* serotypes. This guidance should help ensure that sponsors conduct appropriate studies to evaluate the utility of anti-*Salmonella* food additives, and that FDA accomplish uniform review and decisionmaking. In turn, this should facilitate the approval process for such food additives.

This final guidance explains the recommended experimental process in detail and references other FDA documents that pertain to general experimental practices and procedures recommended by FDA. The guidance provides details concerning recommended testing methods.

II. Significance of Guidance

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The final guidance represents the agency’s current thinking on anti-*Salmonella* food additives for keeping feeds *Salmonella*-negative. 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

There are nine or fewer respondents to the information collection described in this guidance and therefore no burden analysis is required under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Title: Guidance for Industry: Studies to Evaluate the Utility of Anti-*Salmonella* Chemical Food Additives in Feeds.

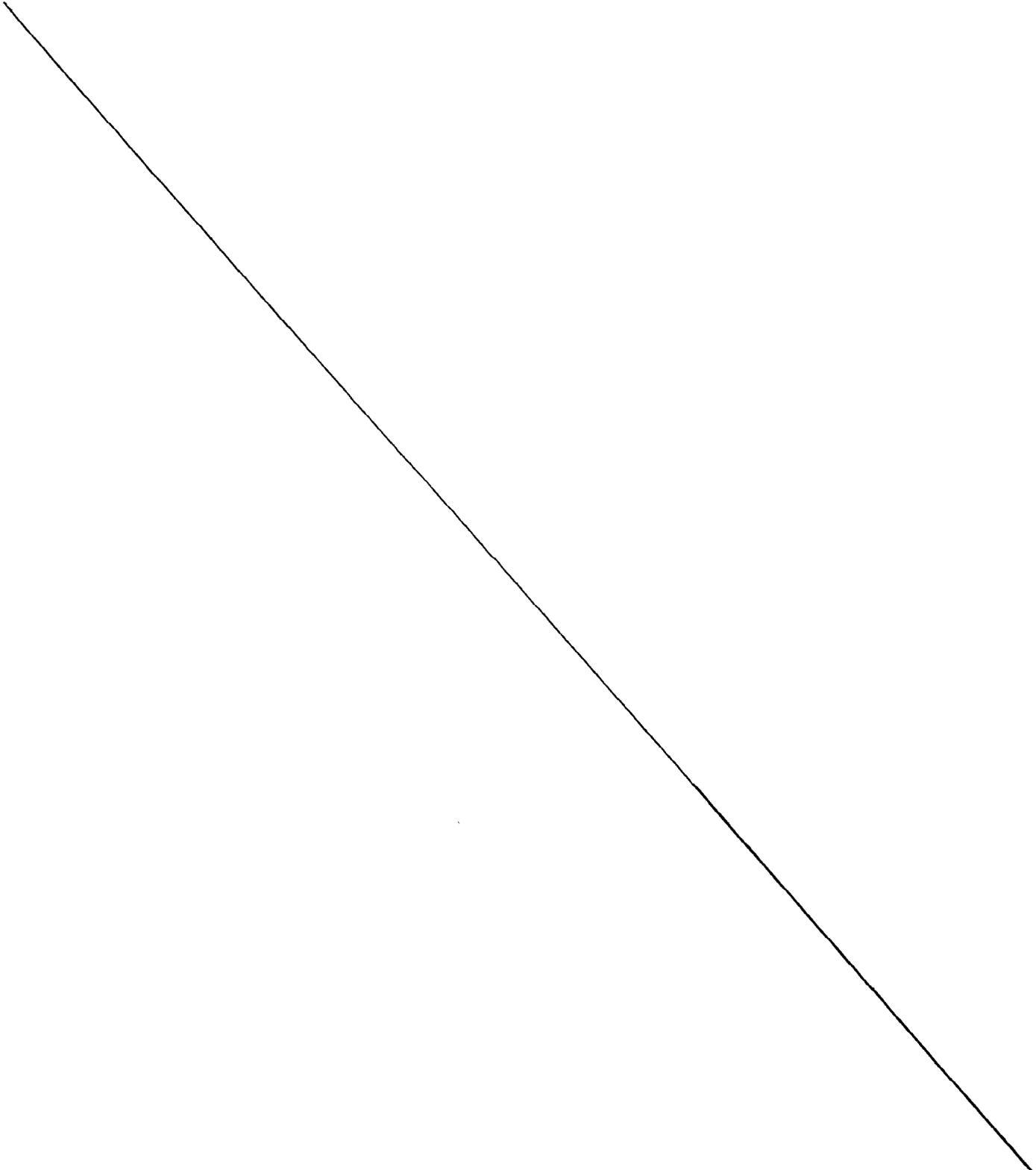
Description: In 1990, FDA announced its goal of *Salmonella*-negative animal feed and feed ingredients (see 59 FR 33975, July 1, 1994). The policy responds to concerns that *Salmonella* infections cause a significant portion of foodborne illnesses, and that animal feeds serve as a significant source of *Salmonella* infections in food animals and consequently in humans. In response, sponsors have developed several products designed to achieve and maintain *Salmonella*-negative levels in animal feeds. The sponsors also have filed the requisite food additive petitions that prove both the safety and utility of the additive products. However, up to this point, it has been difficult for FDA to evaluate the petitions in a consistent manner, as the research methods supporting the petitions have varied to a significant degree.

This final guidance document describes standards upon which studies to establish the utility of anti-*Salmonella* chemical food additives for maintaining feeds *Salmonella*-negative should be based. Certain types of information should be collected in these studies, as described in the final guidance.

IV. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this final guidance at any time. Two copies of any comments are to be submitted, except that individuals

may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public inspection in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

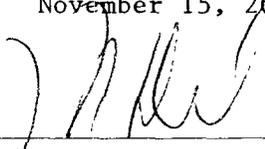


V. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cvm>.

Dated: 11-15-02

November 15, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

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