

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-4201]

PMB

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Certifier	SN Reese

Guidance for Industry: Dioxin in Anti-caking Agents Used in Animal Feed and Feed Ingredients; 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 entitled "Dioxin in Anti-caking Agents Used in Animal Feed and Feed Ingredients." The guidance is intended to notify members of the feed industry of recent findings regarding the presence of dioxins in mined clays that may be used as anti-caking agents in animal feeds and to offer general advice regarding monitoring of these clays.

DATES: (*Insert date of publication in the Federal Register*). Submit written comments at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Copies of this guidance document may be obtained on the Internet from the CVM home page at <http://www.fda.gov/cvm/fda/TOCs/guideline.html>. Persons without internet access may submit written requests for single copies of the draft guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

FOR FURTHER INFORMATION CONTACT:

For general questions regarding the guidance document: Judy A. Gushee, Center for Veterinary Medicine (HFV-230), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0150, e-mail: jgushee@cvm.fda.gov.

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For scientific questions regarding the guidance document: Randall A. Lovell, Center for Veterinary Medicine (HFV-222), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0176, e-mail: rlovell@cvm.fda.gov.

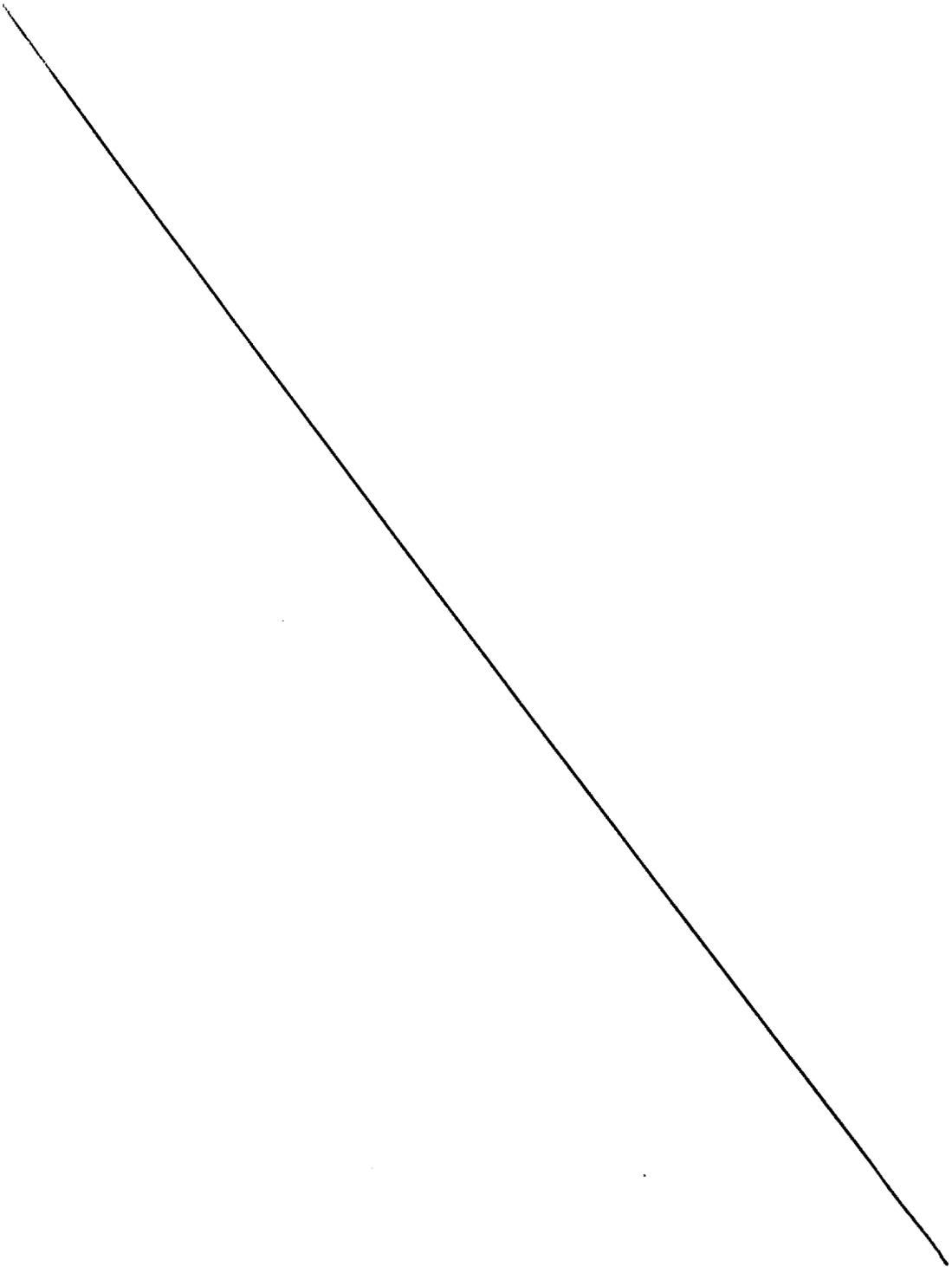
SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled "Dioxin in Anti-caking Agents Used in Animal Feed and Feed Ingredients." Nearly 2 years ago, a multiagency investigation tracked a previously unknown source of dioxins in the human food supply back to a mined clay anti-caking agent, called ball clay, used in animal feeds and feed ingredients. Together, industry and Government moved to swiftly eliminate the use of ball clay in the animal feeds, and thereby, removed a source of dioxins in the human food chain.

On October 7, 1997, FDA sent a letter regarding this issue to members of the feed industry. In that letter, we stated that the ultimate origin and the scope of dioxin presence in clay deposits were unknown and, for that reason, mined clay products of all types should be used with caution in the production of animal feeds. We advised companies offering mined clay products for animal feed uses to ensure that their products were not contaminated with dioxins.

Since that time, FDA has been collecting additional data. The information thus far indicates that dioxins can be present in mined clay products other than ball clay and that dioxin congeners other than 2,3,7,8-tetrachlorodibenzodioxin may be present in important amounts. The guidance that is the subject of this notice summarizes the data and suggests the need for increased caution in industry surveillance for dioxins in feed ingredients.

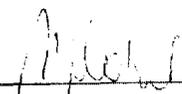
This guidance document is being issued as a Level 1 guidance consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It is being implemented immediately without prior public comment because of concern for public health. The guidance represents the agency's current thinking on the implications of dioxins in mined clays used in animal feeds and feed ingredients. 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 statute, regulations, or both.

Interested persons may submit written comments on the guidance to the Dockets Management Branch (address above). 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 examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 10/5/99
October 5, 1999



Margaret M. Dotzel
Acting Associate Commissioner for Policy

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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