II. Electronic Access

In order to receive these guidance documents via your fax machine, call the CDRH FOD system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system and enter the document number listed above followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of these guidance documents may do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes these guidance documents, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. These guidance documents are also available at http://www.fda.gov/cdrh/ODE.

III. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding these guidance documents by July 18, 2000. 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 for each guidance document as listed in the table in the **SUPPLEMENTARY INFORMATION** section of this document. If you wish to comment on more than one guidance document, please submit your comments separately for each guidance document. The guidance documents and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 3, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–9710 Filed 4–18–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Industry Grassroots Meeting: Report on Partnership Activities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA), Office of Regulatory Affairs, San Francisco District Office is announcing the following meeting entitled ''Industry Grassroots Meeting: Report on Partnership Activities.'' The purpose of the meeting is to report the Partnership Among Industry and Regulators (PAIR) Committee activities and to solicit input from participants for future activities and projects for the PAIR Committee. The PAIR Committee was formed as a result of an action item coming out of a similar grassroots meeting held at the Oakland Federal Bldg. in January of 1997.

Date and Time: The meeting will be held on May 10, 2000, from 8 a.m. to 5 p.m.

Location: The meeting will be held at the Oakland Federal Bldg., North Tower, 3d Floor Auditorium, 1301 Clay St., Oakland, CA 94612.

Contact: Jake Pearson, San Francisco District Office (HFR–PA 160), 510–337–6877, FAX 510–337–6701, e-mail jpearson@ora.fda.gov, or Kathryn D. Macropol (HFR–PA 140), 510–337–6867, e-mail kmacropo@ora.fda.gov, Food and Drug Administration, 1431 Harbor Bay Pkwy., Alameda, CA 94502. Information is also available at the PAIR website at http://www.pair-ca.org.

Registration: There is no charge to attend the meeting; however, registration is required. The meeting is open to all interested in management and regulatory affairs activities of industries regulated by FDA. While attendance would most benefit those industries located in Northern California, all interested groups are encouraged to attend. You may register via the Internet at http://www.pair-ca.org and by completing the online registration form. Alternatively, you can register by sending your name, title, firm name, address, telephone, fax number, and e-mail address (if available) to the contacts listed above. Please include any topics of interest you would like to have included in the program.

If you need special accommodations due to a disability, please notify Jake Pearson at least 7 days in advance.

Dated: April 12, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–9712 Filed 4–18–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–4201]

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 revised guidance for industry (#98) 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 congeners that may be present in anti-caking agents in animal feeds and to offer general advice regarding monitoring of these products. This guidance has been revised in response to comments.

DATES: Submit written comments at any time.

ADDRESSES: Submit written comments on this guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of the guidance document entitled ''Dioxin in Anti-caking Agents Used in Animal Feed and Feed Ingredients'' 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 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.

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:

I. Background

In the**Federal Register** of October 15, 1999 (64 FR 55948), FDA published a notice of availability of a guidance entitled ''Dioxin in Anti-caking Agents Used in Animal Feed and Feed Ingredients.'' This guidance was issued as a Level 1 guidance consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It was implemented without prior public comment because of concern for the public health. The guidance was intended to notify 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. The agency received comments regarding this guidance and has revised the guidance in response to the comments. The following is a discussion of the issues raised by the comments.

II. Discussion of Comments

The agency received two comments on the guidance. One comment was from the feed industry objecting to the term ''mined clay products'' and one was from a company that produces limestone objecting to the term ''lime.''

(Comment 1) One comment noted that the term ''mined clay products'' was not appropriate because materials labeled as silicate and lime also tested positive to one or more of the dioxin congeners. We agree with the comment that the term was inappropriate for the scope of the affected product. FDA was attempting to use a generic term to describe the source of products of concern. FDA has revised the guidance document by replacing the term ''mined clay products'' with ''clay and non-clay anti-caking products.'' We have added the term ''anti-caking'' to emphasize that our primary concern is for the use of these products in feed and feed ingredients and not when used as litter or absorbents.

This comment also noted that of the terms montmorillonite, bentonite, and ground clay, only montmorillonite has a mineral definition. It was also noted that the animal feed industry and its suppliers do not follow scientific terminology for classification and description of these anti-caking animal feed ingredients. The comment recommended that FDA contact the U.S. Geological Survey (USGS) and the Clay Minerals Society (CMS) for assistance in mineral terminology. It was also suggested that the samples, which were analyzed for dioxin, be evaluated for their mineralogy and then properly classified based on the mineralogical components according to accepted scientific guidelines.

FDA was aware that many of the terms used by suppliers and the feed industry were only loosely based on mineralogy and were often more closely associated with some property (e.g., ball clay) of the product than mineralogical components. However, FDA did not fully understand the scope of the interchanging of the terms used by suppliers of these products. FDA agrees that classifying these products based upon the mineralogical components according to accepted scientific guidelines is preferred. FDA has contacted the USGS regarding analyzing the samples for their mineralogy. We have also contacted the USGS and the CMS for information on developing a scientifically accurate naming scheme based on mineralogy. We plan to seek the assistance of the feed industry and the Association of American Feed Control Officials (AAFCO) to implement a scientifically accurate naming scheme based on mineralogy.

(Comment 2) Another comment objected to the use of the term ''lime.'' The National Lime Association (NLA) noted that limestone is a naturally occurring mineral, while lime is not. Lime, according to the NLA, consists of either calcium oxide or calcium hydroxide and results from reacting ''limestone'' (calcium carbonate) and heat.

FDA does not dispute the NLA's definition of lime and, as mentioned above, has revised the terminology for the products of concern from ''mined clay products'' to ''clay and non-clay anti-caking products.'' FDA realizes that this does not directly address the NLA's concern that a product might have been incorrectly identified in the survey. FDA reported the findings based on what was on the label of the product sampled or by what the product was called by the company when the FDA investigator collected it.

In essence, the concern expressed by the NLA for the correct identification of the product is the same as that expressed by the other comment and is a concern shared by FDA. We encourage the NLA to work with its members, companies producing limestone, the feed industry, and AAFCO to ensure a scientifically accurate naming scheme is applied to the products supplied to the feed industry.

III. Status of this Guidance

This guidance represents the agency's current thinking on the presence of dioxin congeners in anti-caking agents. 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.

FDA plans to continue to sample regulated clay and non-clay anti-caking products for dioxin in conjunction with the Environmental Protection Agency and other Government agencies. Plans are also underway to sample other feed components for dioxin.

IV. Comments

As with all of FDA's guidances, the public is encouraged to submit to the Dockets Management Branch (address above) written comments with new data or other new information regarding this guidance. The comments will be periodically reviewed, and, where appropriate, the guidance will be amended. The public will be notified of any such amendments through a notice in the **Federal Register.**

Dated: April 11, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–9711 Filed 4–18–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–0790]

Draft Guidance for Industry: The Use of Published Literature in Support of New Animal Drug Approval; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comment of a draft guidance for industry entitled ''The Use of Published Literature in Support of New Animal Drug Approval.'' The draft guidance is intended to fulfill the section of the FDA Modernization Act of 1997 (FDAMA) that requires the agency to issue guidance to clarify the circumstances in which published matter may be the basis for approval of a supplemental application. The draft guidance also clarifies the circumstances in which published