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]

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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

literature may be the basis for approval of an original application. The draft guidance is intended to provide specific advice on when FDA may be able to rely on published literature, with or without the submission of underlying data, to support new animal drug approval.

DATES: Submit written comments on the draft guidance for industry by July 18, 2000.

ADDRESSES: 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. Submit written comments on this draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of the draft guidance may be obtained on the Internet at http://www.fda.gov/cvm/fda/TOCs/guideline.html.

FOR FURTHER INFORMATION CONTACT: Gail L. Schmerfeld, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20850, 301–594–1620, e-mail: gschmer1@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 403(b) of FDAMA (Public Law 105–115) requires FDA to issue guidances to clarify the requirements for, and facilitate the submission of data to support, the approval of supplemental applications for articles approved under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) or section 351 of the Public Health Service Act (42 U.S.C. 262). This provision includes a requirement that FDA publish guidance to clarify circumstances in which published matter may be the basis for approval of a supplemental application.

This draft guidance for industry clarifies the circumstances in which published literature may be the basis for approval of both original and supplemental new animal drug applications. Specifically, the draft guidance describes the circumstances under which FDA could rely on published literature without access to the underlying data and the circumstances under which the applicant should provide additional information about a published study.

II. Significance of Guidance

This draft guidance represents the agency's current thinking with regard to the use of published literature in support of new animal drug approval. 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. The agency has developed this draft guidance in accordance with the agency's good guidance practices (62 FR 8961, February 27, 1997), which set forth the policies and procedures for the development, issuance, and use of guidance documents.

III. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance by July 18, 2000. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft 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: April 10, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–9713 Filed 4–18–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources And Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: National Donor Sabbath Organ Procurement Organization Survey—New

November 10–12, 2000, will mark the fifth annual National Donor Sabbath (NDS), a time for clergy throughout the Nation to help increase awareness about the critical need for organs and tissues. In support of the 1999 NDS, the Health Resources and Services Administration, Office of Special Programs, Division of Transplantation (DoT) distributed to 61 Organ Procurement Organizations (OPO) in the U.S. more than 300,000 organ donor awareness lapel pins attached to paper backings containing NDS information. The OPOs were asked to distribute the pins to their local clergy to be used for further distribution and education of their congregation. DoT plans to replicate this activity for 2000 NDS.

While DoT believed the 1999 pin distribution to be a positive educational tool there exists a need to properly investigate the efficacy of the pins as an aid in promoting NDS. The Division wishes to examine the pin distribution in 2000 NDS in order to plan the most effective, efficient, and cost effective role for DoT in subsequent observances of NDS. Investigation will consist of requesting each OPO to complete a short survey concerning usage, distribution, and impact of the pins. This is a one-time survey.