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 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: October 15, 1999. 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 Persons without internet access may submit written requests for single copies of the draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.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.

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: October 5, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–26886 Filed 10–14–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–4040]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection;

Title of Information Collection: Request for Enrollment in Supplementary Medical Insurance and Supporting Regulations in 42 CFR 407.10 and 407.11;

Form No.: HCFA–4040 (OMB #0938–0245);

Use: The HCFA–4040 is used to establish entitlement to Supplementary Medical Insurance by Beneficiaries not eligible under Part A of Title XVIII or Title II of the Social Security Act. The HCFA–4040SP is the Spanish edition of this form.;

Frequency: Other: One Time Only;

Affected Public: Individuals or Households, Federal Government, and State, Local or Tribal Government;

Number of Respondents: 10,000;

Total Annual Responses: 10,000;

Total Annual Hours: 2,500.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to

Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards; Attention: Dawn Willinghan, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: October 6, 1999.

John Parmigiani,

Manager, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–26996 Filed 10–14–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–5]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection;

Title of Information Collection: Physician Certifications/Recertifications in Skilled Nursing Facilities (SNFs) Manual Instructions and Supporting Regulations in 42 CFR 424.20;

Form No.: HCFA–R–5 (OMB #0938–0454);

Use: The Medicare program requires as a condition for Medicare Part A payment for post-hospital skilled nursing facility (SNF) services, that a physician must certify and periodically recertify that a beneficiary requires a SNF level of care. The physician certification and recertification is intended to ensure that the beneficiary's need for services has been established and then reviewed and updated at appropriate intervals. The documentation is a condition for Medicare Part A payment for post-hospital SNF care.;

Frequency: On occasion;

Affected Public: State, Local or Tribal Government, individuals or households, business or other for-profit, and not-for-profit institutions;

Number of Respondents: 2,038,248;

Total Annual Responses: 947,816;

Total Annual Hours: 417,239.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards; Attention: Dawn Willinghan, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: October 5, 1999.

John Parmigiani,

Manager, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–26997 Filed 10–14–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1091–N]

Medicare Program; Open Public Meeting on November 1, 1999 To Discuss Activities Related to the Collection of Encounter Data From Medicare+Choice Organizations for Risk Adjustment

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces a public meeting to provide Medicare+Choice Organizations (M+COs), providers, practitioners, and other interested parties an opportunity to ask questions and raise issues regarding encounter data collection for risk adjustment. The meeting will address the following topics:

- Collection of physician encounter data.
- Collection of hospital outpatient encounter data.
- Training and customer support services.

DATES: The meeting is scheduled for November 1, 1999 from 9 a.m. until 4 p.m., e.s.t.

ADDRESSES: The meeting will be held in the HCFA Auditorium, 7500 Security Boulevard, Baltimore, Maryland, 21244–1850.

FOR FURTHER INFORMATION CONTACT: Yvette Cooper-Williams, (410) 786–5644, ycooper@hcfa.gov.

SUPPLEMENTARY INFORMATION:

Background

The Balanced Budget Act of 1997 (BBA) (Public Law 105–33) established the Medicare+Choice program that significantly expanded the health care options available to Medicare beneficiaries. Under the BBA, the Secretary of the Department of Health and Human Services (the Secretary) must implement a risk adjustment methodology that accounts for variations in per capita costs based on health status and other demographic factors for payment to Medicare+Choice organizations (M+COs). Risk adjustment implementation must start no later than January 1, 2000. The BBA also gives the Secretary the authority to collect inpatient hospital data for discharges on or after July 1, 1997, and additional data for services occurring on or after July 1, 1998. The schedule for encounter data submission through June 30, 2001 is as follows:

- September 10, 1999: Deadline for submission of Year 2 data (dates of