IV. Electronic Access

Persons with access to the Internet may obtain the guidance document and the Version 1.2.0 Standard at http://www.fda.gov/cber/guidelines.htm.

Dated: May 25, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–14211 Filed 6–2–00; 11:16 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1277]

Draft Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds.'' The purpose of this draft guidance is to identify for the industry recommended maximum fumonisin levels that FDA considers adequate to protect human and animal health and that are achievable in human foods and animal feeds with the use of good agricultural and good manufacturing practices. FDA considers this guidance to be a prudent public health measure during the development of a better understanding of the human health risk associated with fumonisins and the development of a long-term risk management policy and program by the agency for the control of fumonisins in human foods and animal feeds.

DATES: Submit written comments by August 7, 2000.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled ''Draft Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds'' to Henry Kim, Center for Food Safety and Applied Nutrition (CFSAN) (address below), or Randall A. Lovell, Center for Veterinary Medicine (CVM) (address below). Send one self-addressed adhesive label to assist that office in processing your request. The draft guidance, CFSAN's ''Background Paper in Support of Fumonisin Levels in Corn and Corn Products Intended for Human Consumption,'' and CVM's ''Background Paper in Support of Fumonisin Levels in Animal Feed,'' may also be accessed at the CFSAN or CVM home page on the Internet at http://www.cfsan.fda.gov and http://www.fda.gov/cvm, respectively.

Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments and requests for copies should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Henry Kim, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–260–0631, FAX 202–205–4422, or

Randall A. Lovell, Center for Veterinary Medicine (HFV–222), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0176, FAX 301–827–1484.

SUPPLEMENTARY INFORMATION: FDA has developed a draft guidance document regarding the maximum recommended levels of fumonisins in corn used for production of human foods and animal feeds. Fumonisins are naturally occurring toxins produced by the molds *Fusarium moniliforme* (*F. verticillioides*), *F. proliferatum*, and other *Fusarium* species that are common contaminants of corn. Fumonisins have been linked to a variety of significant adverse health effects in livestock and experimental animals. Although human epidemiological studies are inconclusive at this time, based on a wide variety of significant adverse animal health effects, FDA believes that an association between fumonisins and human disease is possible.

The purpose of the draft guidance is to identify for the industry recommended maximum fumonisin levels that FDA considers adequate to protect human and animal health and that are achievable in human foods and animal feeds with the use of good agricultural and good manufacturing practices. FDA considers this guidance to be a prudent public health measure during the development of a better understanding of the human health risk associated with fumonisins and the development of a long-term risk management policy and program by the agency for the control of fumonisins in human foods and animal feeds. Based on information obtained from future national and international workshops on the risk from exposure to fumonisins, FDA will consider whether to establish tolerances, regulatory limits, or action levels, as appropriate, for fumonisins in human foods and animal feeds, respectively, under 21 CFR Part 109—Unavoidable Contaminants in Food for Human Consumption and Food-Packaging Material and under 21 CFR Part 509—Unavoidable Contaminants in Animal Food and Food-Packaging Material.

The agency has adopted good guidance practices (GGP's) that set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). The draft guidance document entitled ''Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds'' is being issued as a level 1 draft guidance consistent with GGP's. This draft guidance represents the agency's current thinking on the control of fumonisins in human foods and animal feeds as a prudent public health measure. 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 and regulations.

Interested persons may submit written comments to the Dockets Management Branch (address above) on the draft guidance by August 7, 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 found in brackets in the heading of this document. The draft guidance, CFSAN's ''Background Paper in Support of Fumonisin Levels in Corn and Corn Products Intended for Human Consumption,'' CVM's ''Background Paper in Support of Fumonisin Levels in Animal Feed,'' and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 26, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–14106 Filed 6–5–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–2540–96]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration.

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: Revision of a currently approved collection; *Title of Information Collection:* Skilled Nursing Facility Cost Report and Supporting Regulations in 42 CFR 413.20 and 413.24; *Form No.:* HCFA–2540 (OMB 0938–0463); *Use:* Form HCFA–2540–96 is the form used by skilled nursing facilities participating in the Medicare program. This form reports the health care costs used to determine the amount of reimbursable costs for services rendered to Medicare beneficiaries; *Frequency:* Annually; *Affected Public:* Businesses or other for-profit; Not-for-profit institutions; *Number of Respondents:* 15,700; *Total Annual Responses:* 15,706; *Total Annual Hours:* 2,943,200.

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: Julie Brown, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: May 25, 2000.

John P. Burke III,

Reports Clearance Officer, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 00–13987 Filed 6–5–00; 8:45 am]

BILLING CODE 4120–03–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–0280]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration.

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 Request: Extension of a currently approved collection; *Type of Information Collection:* Medigap Compare; *HCFA Form Number:* HCFA–R–0280 (OMB approval #:0938–0767); *Use:* HCFA collects plan-specific Medigap data, including but not limited to premiums charged and additional benefits offered, from each insurer offering Medigap plans. The data collection occurs electronically. The data are provided on www.medicare.gov to assist beneficiaries in obtaining accurate information on all their health care coverage options; *Frequency:* Annually, and semi-annually if needed; *Affected Public:* Business or other for-profit, Federal Government, State, Local, or Tribal Government, Not-for-profit institutions; *Number of Respondents:* 300; *Total annual Responses:* 450; *Total Annual Burden Hours:* 75.

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 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: May 25, 2000.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 00–14067 Filed 6–5–00; 8:45 am]

BILLING CODE 4120–03–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–10006]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Health Care Financing Administration.

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.

We are, however, requesting an emergency review of the information