DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Draft Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled “Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds.” The purpose of this draft guidance is to identify for the industry recommended maximum fumonisin levels that FDA considers adequate to protect human and animal health and that are achievable in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.


SUPPLEMENTARY INFORMATION: FDA has developed a draft guidance document regarding the maximum recommended levels of fumonisins in corn used for production of human foods and animal feeds.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The purpose of the draft guidance is to identify for the industry recommended maximum fumonisin levels that FDA considers adequate to protect human and animal health and that are achievable in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.


Margaret M. Dotzel,
Associate Commissioner for Policy.

Health Care Financing Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration.

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