Dated: October 3, 2007.

James B. Gulliford,

Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2001D–0025 (formerly Docket No. 01D–0025)]

Guidance for Industry on FDA Recommendations for Sampling and Testing Yellow Corn and Dry-Milled Yellow Corn Shipments Intended for Human Food Use for Cry9C Protein Residues; Comments on Possible Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is seeking comment on whether to withdraw its guidance document entitled ''FDA Recommendations for Sampling and Testing Yellow Corn and Dry-Milled Yellow Corn Shipments Intended for Human Food Use for Cry9C Protein Residues.'' FDA is considering withdrawing its guidance in response to the release by the Environmental Protection Agency (EPA) of a draft ''White Paper Concerning Dietary Exposure to Cry9C Protein Produced by STARLINK Corn and the Potential Risks Associated with Such Exposure,'' the availability of which is announced elsewhere in this issue of the **Federal Register**.

DATES: Submit written or electronic comments by December 17, 2007.

ADDRESSES: Submit written comments on this notice to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Lauren Posnick Robin or Samir Assar, Center for Food Safety and Applied Nutrition (HFS–300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1639 or 301–436–1636, respectively.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 22, 2001 (66 FR 6627), FDA issued final guidance for industry entitled ''FDA Recommendations for Sampling and Testing Yellow Corn and Dry-Milled Yellow Corn Shipments Intended for Human Food Use for Cry9C Protein Residues.'' Cry9C is a pesticidal protein in the STARLINK variety of yellow corn that makes the corn more resistant to certain types of insects. EPA authorized STARLINK corn only for use in animal feed. EPA did not authorize the use of STARLINK corn in human food because of unresolved questions about the allergenic potential of the Cry9C protein. Although restricted to animal food use, some STARLINK corn was commingled with yellow corn intended for human use. In addition, in certain limited cases, the Cry9C protein was also detected in corn seeds of a non-STARLINK variety of corn or in corn from such seeds. In response to these findings, Aventis S.A. (the developer of STARLINK corn), EPA, FDA, the United States Department of Agriculture, and the food industry undertook efforts starting in 2000 to remove all STARLINK corn from the food supply. Among other measures, FDA issued guidance recommending that corn dry-milling and masa operations screen yellow corn (and milled yellow corn in certain situations) to minimize the production of human food products with corn containing the Cry9C protein. Corn containing the Cry9C pesticide is adulterated under section 402(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 342(a)(2)(B)) if such corn is for human food use because there is no tolerance or exemption from the need for a tolerance under section 408 of the act (21 U.S.C. 346a). Therefore, FDA recommended that manufacturers who detected Cry9C-containing corn in any lot should divert the lot to animal feed or industrial use.

EPA has developed a draft ''White Paper Concerning Dietary Exposure to Cry9C Protein Produced by STARLINK Corn and the Potential Risks Associated with Such Exposure'' (draft White Paper), which it is making available for comment elsewhere in this issue of the **Federal Register**. In the draft White Paper, EPA concludes that the Cry9C protein has been sufficiently removed from the human food supply to render the level of risk low enough that continued testing for the protein in yellow corn at dry mills and masa production facilities provides no additional human health protection. EPA reached that conclusion based on information including results from more than 4 million tests for Cry9C at corn handling operations over the past 7 years and an exposure assessment by Exponent, Inc., of the levels of Cry9C still present in the U.S. food supply. Based on its analysis, EPA recommends in its draft White Paper that FDA withdraw its guidance on the sampling and testing of yellow corn grain for Cry9C at dry mills and masa production facilities.

FDA is now seeking comment on whether to withdraw its guidance document entitled ''FDA Recommendations for Sampling and Testing Yellow Corn and Dry-Milled Yellow Corn Shipments Intended for Human Food Use for Cry9C Protein Residues.''

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the guidance document at *http://www.cfsan.fda.gov/guidance.html*.

Dated: September 6, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

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