DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0002]

Regulatory Procedures Manual; Chapter 9: Import Operations/Action, Subchapter: Secured Storage; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a new subchapter of the Regulatory Procedures Manual. The new subchapter is entitled ''Secured Storage.'' This subchapter has been provided to FDA's field offices to provide operational procedures for identifying those importers who should be referred to the U.S. Customs Service (U.S. Customs) so that U.S. Customs can require those importers to place their imported foods into secured storage under the control of U.S. Customs pending a decision by FDA of their admissibility. The subchapter is located in Chapter 9 of FDA's Regulatory Procedures Manual.

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies of the subchapter entitled ''Secured Storage'' to Joseph L. McCallion, Division of Import Operations and Policy (HFC–170), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request.

Submit written comments on the subchapter to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the subchapter.

FOR FURTHER INFORMATION CONTACT: Joseph L. McCallion, Division of Import Operations and Policy (HFC–170), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6553.

SUPPLEMENTARY INFORMATION:

I. Background

On July 3, 1999, the President announced an initiative to ensure the safety of imported food by directing the Secretary of the Department of Health and Human Services (DHHS) and the Secretary of the Treasury to develop new operational procedures to protect the public health. The initiative is geared to optimize the statutory authorities and resources available to the FDA, DHHS, and the U.S. Customs, Department of the Treasury, to protect consumers from unsafe imported foods. The President directed the agencies to target unscrupulous importers who violate the import laws and work to subvert the system by introducing unsafe foods into U.S. markets. Six specific objectives were emphasized in the directive.

On December 11, 1999, the President announced the plan developed by FDA and U.S. Customs in response to the directive of July 3, 1999. One element of the plan was to prevent distribution of imported unsafe food by requiring importers with a history of illegal distribution, misrepresentation, or substitution to hold future shipments in secure storage facilities until specifically released by FDA. The subchapter now being made available is setting out the procedures for accomplishing this objective.

The subchapter does not create or confer any rights, privileges, or benefits for, or on, any person and does not operate to bind FDA, U.S. Customs, or the public. The subchapter is being distributed in accordance the FDA's policy for Level 2 guidance documents as set out in the agency's good guidance practices, published in the **Federal Register** of September 19, 2000 (65 FR 56468).

II. Comments

Interested persons may, at any time, submit written comments to the Dockets Management Branch (address above) regarding this new subchapter. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the subchapter and any received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain a copy of this subchapter at http://www.fda.gov/ora.

Dated: January 12, 2001.

Dennis E. Baker,

Associate Commissioner for Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[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; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a 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.'' Cry9C is a pesticidal protein that was introduced into the StarLink™ variety of yellow corn using recombinant deoxyribonucleic acid (DNA) techniques to make the corn more resistant to certain types of insects. StarLink™ corn is lawful only for use in animal feed, not human food. However, some Cry9C-containing corn was commingled with yellow corn intended for human use. This document outlines the approach that FDA recommends to manufacturers of corn products for human food use for sampling and testing yellow corn (and milled yellow corn in certain situations) in order to minimize the production of human food products with corn containing the Cry9C protein.

DATES: Submit written comments concerning this guidance to the Dockets Management Branch (address below) by March 23, 2001. After March 23, 2001, submit written comments to the contact person (address below).

ADDRESSES: Submit written comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the guidance to Lauren M. Posnick, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5321. Send one self-adhesive address label to assist that office in processing your request. Comments and requests for copies should be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and comments received by March 23, 2001, are available for public