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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D-0463]

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Draft, Revised Compliance Policy Guide Sec. 575.100 Pesticide Chemical Residues in Food—Enforcement Criteria (CPG 7141.01); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice

summary: The Food and Drug Administration (FDA) is announcing the availability of draft, revised Compliance Policy Guide (CPG) Sec. 575.100 Pesticide Chemical Residues in Food—Enforcement Criteria (CPG 7141.01) (the draft CPG). The draft CPG is intended to provide guidance to FDA staff on FDA's internal enforcement processes concerning pesticide chemical residues in food.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the withdrawal of Compliance Policy Guide Sec. 555.700 Revocation of Tolerances for Cancelled Pesticides (CPG 7120.29) (CPG Sec. 555.700).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the agency considers your comment on the draft CPG before it begins work on the final version of the CPG, submit written or electronic comments on the draft CPG by [insert date 60 days after date of publication in the Federal Register.]

ADDRESSES: Submit written requests for single copies of the draft CPG to the Division of Compliance Policy (HFC-230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane,

Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 240–632–6861.

Submit written comments on the draft CPG to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, room 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the SUPPLEMENTARY INFORMATION section for access to the draft CPG.

FOR FURTHER INFORMATION CONTACT: Michael E. Kashtock, Center for Food Safety and Applied Nutrition (HFS-317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301-436-2022, FAX 301-436-2651.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is revising CPG Sec. 575.100 Pesticide Chemical Residues in Food—Enforcement Criteria (CPG 7141.01) to reflect the changes in pesticide law, including the changes in the Federal Food, Drug, and Cosmetic Act (the Act) made by the Food Quality Protection Act of 1996 (FQPA). Subsequent to the FQPA, certain additional amendments related to pesticide provisions in the Act were made in the Antimicrobial Regulation Technical Corrections Act of 1998 (ARTCA) (Public Law 105–324). However, the ARTCA amendments do not affect the enforcement policy set forth in the draft CPG. The draft CPG is intended to provide clear policy and regulatory guidance to FDA's field and headquarters staff with regard to pesticide residue issues. It also contains information that may be useful to the regulated industry and to the public.

The draft CPG is being issued as a Level 1 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft CPG, when

finalized, will represent the agency's current thinking on enforcement policy relating to pesticide chemical residues. 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 statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments on the draft CPG. 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. A copy of the draft CPG and 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 draft CPG from the Office of Regulatory Affairs home page. It may be accessed at http://www.fda.gov/ora under "Compliance References."

Dated:

December 31, 2007.

Margaret O'K. Glavin

Associate Commissioner for Regulatory Affairs.

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