

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D-0263] (formerly Docket No. 03D-0263)

DDM

Display Date	5/17/05
Publication Date	5/18/05
Certifier	A. Corbin

Guidance for Industry on Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency Pursuant to Dietary Risk Considerations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency Pursuant to Dietary Risk Considerations." This guidance presents FDA's general policy for implementing the channels of trade provision in the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Food Quality Protection Act of 1996 (the FQPA), for food containing residues of pesticide chemicals, for which tolerances have been revoked, suspended, or modified pursuant to dietary risk considerations.

DATES: You may submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to Michael E. Kashtock, Office of Plant and Dairy Foods, Center for Food Safety and Applied Nutrition (HFS-305), Food and Drug Administration, 5100 Paint
cf058

NAD2

Branch Pkwy., College Park, MD 20740. Include a self-addressed adhesive label to assist that office in processing your request. Submit written comments on the guidance 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>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Michael E. Kashtock, Center for Food Safety and Applied Nutrition (HFS-305), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2022, e-mail: mkashtoc@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 23, 2003 (68 FR 43535), FDA announced the availability of a draft guidance document entitled "Guidance for Industry: Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency." This guidance presents FDA's general policy for implementing the channels of trade provision in the act, as amended by the FQPA. Interested persons were given until September 22, 2003, to comment on the draft guidance.

FDA received five written comments on the draft guidance document. The agency reviewed and evaluated these comments and has modified the guidance where appropriate. In particular, FDA has modified the guidance document, including its title, to make it clear that it applies solely to food commodities that contain residues of pesticide chemicals for which the applicable tolerance

was revoked, suspended, or modified by the Environmental Protection Agency (EPA) pursuant to dietary risk considerations as addressed under section 408(l)(2) of the FQPA. A comment pointed out that this condition was implied in the draft guidance document, but that it should be explicit in the final guidance.

FDA is issuing this guidance as a level 1 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on its planned enforcement approach to the channels of trade provision of the act and how that provision relates to FDA-regulated products with residues of pesticide chemicals for which tolerances have been revoked, suspended, or modified by EPA pursuant to dietary risk considerations. 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 it satisfies the requirements of the applicable statutes and regulations.

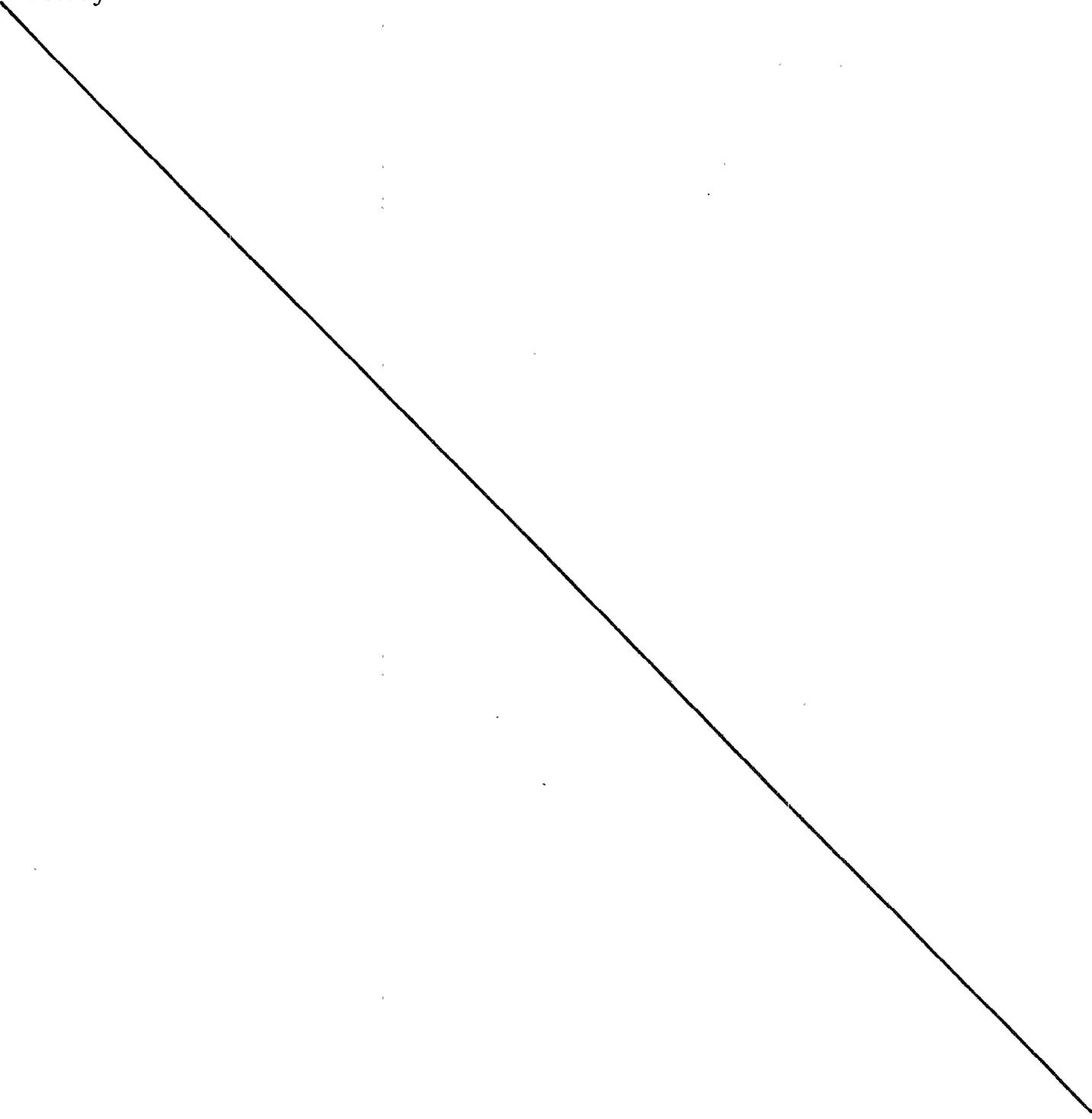
II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this guidance was approved under OMB Control No. 0910–0562. The approval expires on May 31, 2008. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding 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. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

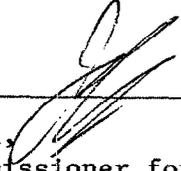


IV. Electronic Access

Interested persons may access the guidance document at <http://www.cfsan.fda.gov/guidance.html>.

Dated: 3/10/05
March ¹⁰~~8~~, 2005.

Ⓢ 3/12/05



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

BILLING CODE 4160-01-S

