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 March 10, 2008.

**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.*

[FR Doc. E8–123 Filed 1–7–08; 8:45 am]

**BILLING CODE 4160–01–S**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2006D–0063]**

### Guidance for Industry and Food and Drug Administration Staff; The Review and Inspection of Premarket Approval Application Manufacturing Information and Operations; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''The Review and Inspection of Premarket Approval Application Manufacturing Information and Operations.'' This guidance document explains for premarket approval application (PMA) applicants the process involved with the review of a PMA manufacturing section and inspection of the manufacturing operations described in the manufacturing section. This guidance is also generally applicable to the process involved with the review of manufacturing information in certain PMA supplements. The procedural information outlined in this document should help applicants and FDA schedule and complete their work in a timely manner.

**DATES:** Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance document entitled ''The Review and Inspection of Premarket Approval Application Manufacturing Information and Operations'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this 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* or *http://www.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Timothy A. Ulatowski, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–0100.

**SUPPLEMENTARY INFORMATION:**

## I. Background

On October 26, 2002, MDUFMA (Public Law 107–250), amended the Federal Food, Drug, and Cosmetic Act (the act). Among other things, MDUMFA authorized the collection of user fees to improve the performance and predictability of FDA's device premarket review process, which includes PMAs. FDA, in consultation with the regulated industry, agreed to dedicate user fees to help the agency achieve performance goals, including the predictability of scheduling and timeliness of preapproval inspections.

This final guidance document, ''The Review and Inspection of Premarket Approval Application Manufacturing Information and Operations,'' explains for PMA applicants the administrative process FDA intends to follow in its review of the PMA manufacturing section information and the inspection of the particular manufacturing facility and its manufacturing operations. This final guidance document supersedes the corresponding draft guidance issued on June 19, 2006 (71 FR 35275 through 35276).

The comment period for the draft guidance document closed on September 18, 2006. During the comment period, we received several comments and recommendations. Two comments recommended that the agency inspect pilot manufacturing operations or the manufacture of a surrogate product in lieu of inspecting the complete manufacturing operation described in the PMA manufacturing section. FDA disagrees with this recommendation as the statute does not provide such an alternative. The statute requires the agency to determine whether the manufacturing operations, as described in the PMA, conform to good manufacturing practice requirements.

Several comments recommended clarification of certain terms related to the process involved with scheduling inspections and factors that affect the PMA manufacturing section review process. The agency incorporated many of the suggested clarifications.

## II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on ''The Review and Inspection of Premarket Approval Application Manufacturing Information and Operations.'' 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.

## III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive ''The Review and Inspection of Premarket Approval Application Manufacturing Information and Operations,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1566 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

## IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 USC 3501–3520). The collections of information in 21 CFR part 814 have been approved under OMB Control Number 0910–0231; and the collections of information in 21 CFR part 820 have been approved under OMB Control Number 0910–0073.

## V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. 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.

Dated: December 20, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E8–126 Filed 1–7–08; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2006D–0228]**

### Guidance for Industry and Food and Drug Administration Staff; The Review and Inspection of Premarket Approval Applications Under the Bioresearch Monitoring Program; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''The Review and Inspection of Premarket Approval Applications Under the Bioresearch Monitoring Program.'' This guidance provides premarket approval application (PMA) applicants with information about the bioresearch monitoring (BIMO) review process. This includes a BIMO evaluation of clinical and nonclinical information in the PMA and certain PMA supplements as well as preapproval BIMO inspections. The procedural information outlined in this document should help applicants and FDA to better understand the BIMO review and inspection so it can proceed in a timely manner.

**DATES:** Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance document entitled ''The Review and Inspection of Premarket Approval Applications Under the Bioresearch Monitoring Program'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this 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* or *http://www.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Matthew J. Tarosky, Center for Devices