bill the Medicaid program rather than the recipient, and accept the State's payment, including a payment of zero dollars, as payment in full. (See 42 CFR 447.15.)

• Would payments under the proposed SPA that are made directly to Medicaid recipients for services furnished after the recipients have been determined eligible (and not during a retroactive eligibility period) be within the regulatory exception at 42 CFR 431.246 and 431.250(b) to the vendor payment principle? Those sections provide for corrective payments based on a successful appeal by a recipient who, pending the appeal decision, sought and paid for covered services. Such a circumstance in the context of SPA 06–019B would exist where a recipient appealed the State's determination of the amount of the recipient's ''share of cost'' for covered services. But, SPA 06–019B does not appear to limit such payment to these exceptions to the vendor payment rule.

• Is there any binding judicial decision that would permit the Federal Government to participate in the payments contemplated in the proposed SPA? The United States was not a party to a California State Court case that apparently addressed the issues and is not bound by that decision. Moreover, under regulations at 42 CFR 431.250 that provide for Federal participation in payments made under court order, the services must be provided within the scope of the Medicaid program under Federal law. Services that are billed directly to the recipient (and not part of a retroactive eligibility period) are outside of the Federal definition of medical assistance, and thus are not within the scope of the Federal Medicaid program.

• Is there any statutory or regulatory conflict providing a basis to conclude that the express statutory provisions establishing the vendor payment principle could not practically be applied? CMS has recognized such a conflict as the basis for permitting an exception to the vendor payment principle during a retroactive period, but such a conflict does not appear to be present in this instance.

• Are direct payments to recipients who have been determined eligible consistent with accuracy, efficiency, and effectiveness of the State Medicaid program in serving those recipients?

I am scheduling a hearing on your request for reconsideration to be held on February 15, 2008, at the CMS San Francisco Regional Office, 90 7th Street, 5th Floor, Room 5A, San Francisco, California 94103, to reconsider the decision to disapprove SPA 06–019B. If this date is not acceptable, we would be glad to set another date that is mutually agreeable to the parties. The hearing will be governed by the procedures prescribed by Federal regulations at 42 CFR Part 430.

I am designating Ms. Kathleen Scully-Hayes as the presiding officer. If these arrangements present any problems, please contact the presiding officer at (410) 786–2055. In order to facilitate any communication which may be necessary between the parties to the hearing, please notify the presiding officer to indicate acceptability of the hearing date that has been scheduled and provide names of the individuals who will represent the State at the hearing.

Sincerely,

Kerry Weems,

Acting Administrator.

(Section 1116 of the Social Security Act (42 U.S.C. 1316); 42 CFR 430.18)

(Catalog of Federal Domestic Assistance program No. 13.714, Medicaid Assistance Program.)

Dated: January 2, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E8–109 Filed 1–7–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0462]

Compliance Policy Guide Sec. 555.700 Revocation of Tolerances for Cancelled Pesticides (CPG 7120.29); Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (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). CPG Sec. 555.700 is no longer necessary because the policy stated in the CPG is obsolete. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft revision of CPG Sec. 575.100 Pesticide Chemical Residues in Food and Feed—Enforcement Criteria (CPG 7141.01) (CPG Sec 575.100).

DATES: The withdrawal is effective January 8, 2008.

ADDRESSES: Submit written requests for single copies of CPG Sec. 555.700 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.

A copy of the CPG may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Michael E. Kashtock, Center for Food Safety and Applied Nutrition, Food and Drug Administration, College Park, MD 20740–3835, 301–436–2022, FAX 301–436–2651.

SUPPLEMENTARY INFORMATION: CPG Sec. 555.700 stated FDA's policy to routinely establish action levels for pesticide chemical residues to replace tolerances that are revoked when the Environmental Protection Agency (EPA) cancels registration for the pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act. Such residues may persist in the environment for many years. Section 408(l)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a(l)(4)), as amended by the Food Quality Protection Act of 1996, authorizes EPA to establish tolerances for pesticide chemical residues that will unavoidably persist in the environment. Therefore, because EPA may establish tolerances for such pesticide chemical residues, the policy set forth in CPG Sec. 555.700 is obsolete. Consequently, FDA is withdrawing CPG Sec. 555.700, in its entirety, to eliminate this obsolete policy.

Previously established action levels are listed in FDA's CPG Sec. 575.100 Pesticide Chemical Residues in Food and Feed—Enforcement Criteria (CPG 7141.01). A notice announcing availability of a draft revision of CPG Sec. 575.100 is published elsewhere in this issue of the **Federal Register**.

Dated: December 31, 2007.

Margaret O'K. Glavin,

Associate Commissioner for Regulatory Affairs.

[FR Doc. E8–127 Filed 1–7–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0463]

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 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

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.