examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: 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, FAX 202–205–4422, e–mail: lposnick@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing guidance for industry on sampling and testing for the presence of Cry9C protein residues in yellow corn (and milled yellow corn in certain situations) intended for human food use. Cry9C is a pesticidal protein that was introduced into the StarLink™ variety of yellow corn to make the corn more resistant to certain types of insects. The Environmental Protection Agency (EPA) authorized StarLink™ corn only for use in animal feed, not human food. EPA has not authorized the use of StarLink™ corn in human food because there is an unresolved question about the allergenic potential of the Cry9C protein.

Although restricted to animal food use, some StarLink™ corn was commingled with yellow corn intended for human use. In addition, in certain limited cases, the Cry9C protein has also been detected in corn seeds of a non-StarLink™ variety of corn or in corn from such seeds. Aventis S.A., the developer of StarLink™, in cooperation with the U.S. Department of Agriculture, has been buying back harvested StarLink™ corn from the year 2000 crop to prevent its introduction into the human food supply. Because some Cry9C-containing corn may have been missed in the buy-back program and because some StarLink™ corn from the 1999 crop may still be in some grain elevators, FDA is urging corn dry-milling and masa operations to screen yellow corn (and milled yellow corn in certain situations) to minimize the production of human food products with corn containing the Cry9C protein. Because corn containing the Cry9C pesticide is adulterated if intended for human food use (21 U.S.C. 342(a)(2)(B)), manufacturers who detect Cry9C-containing corn in any lot should divert the lot to animal feed or industrial use.

The guidance document contains FDA's recommendations to dry milling and masa operations for sampling and testing yellow corn shipments; the guidance recommends appropriate tests, representative sampling procedures, appropriate analytical procedures, and appropriate personnel training. FDA believes these recommendations will help manufacturers to identify those lots of corn that contain the StarLink™ variety commingled with other yellow corn and avoid the use of such corn in human food products.

This Level 1 guidance is being issued consistent with FDA's good guidance practices regulation (65 FR 56468, September 19, 2000). The guidance represents the agency's current thinking on sampling and testing yellow corn for residues of the Cry9C protein. 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. To the extent that use of this guidance helps millers and food manufacturers avoid the production of human food containing Cry9C residues, the guidance will help prevent human exposure to a potential food allergen and will otherwise help prevent adulteration of the food supply. Due to the urgent need to convey the sampling and testing recommendations to members of the food industry to help prevent the further introduction of Cry9C-containing corn into the human food supply, FDA conveyed the substance of this guidance to affected millers and food manufacturers in a letter dated December 27, 2000 (Ref. 1). Similarly, FDA is making this guidance document effective immediately because public participation prior to its implementation is not appropriate in these circumstances (21 CFR 10.115(g)(2); 65 FR 56478). However, in its letter of December 27, 2000, FDA recognized that some dry milling and masa operations may have inventories of stored grain or meal that have not been tested or have not been tested as described in the guidance document. Consistent with that advice, the agency is recommending that manufacturers that choose to follow this sampling guidance phase it in over a period of no more than 30 days dating from December 27, 2000.

Although the guidance document announced in this notice is being implemented immediately, FDA is requesting comments on the guidance. FDA will review all comments received, revise the guidance in response to the comments as appropriate, and publish a notice of availability of the revised guidance, if it is revised.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this immediately-in-effect guidance by March 23, 2001. After March 23, 2001, submit written comments regarding this guidance to the contact person (address above). FDA will consider such comments when determining whether to revise the current guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance document and comments received by March 23, 2001, may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. An electronic version of this guidance is available on the Internet at www.cfsan.fda.gov.

III. References

The following references have been placed on display at the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday

1. Letter and recommendations, dated December 27, 2000.

2. ''Sampling and testing plan, scientific basis,'' January, 2000.

Dated: January 12, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–1609 Filed 1–19–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–10027]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, DHHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality,

utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Request: New collection; Title of Information Collection: Ambulance Attachment Form; Form Number: HCFA–10027 (OMB approval #: 0938–NEW); Use: This form is used by ambulance suppliers in Missouri to report information needed to process their claims; it is an attachment to the HCFA form 1491, which is used to submit ambulance claims; Frequency: On occasion; Affected Public: Business or other for-profit, Not-for-profit institutions, State, local, or tribal gov; Number of Respondents: Total Annual Responses: 5,000; Total Annual Hours Requested: 167 hours.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Julie Brown, HCFA–10027; Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: January 10, 2001.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 01–1724 Filed 1–19–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–304 and 304a]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Reconciliation of State Invoice and Prior Quarter Adjustment Statement (Medicaid Drug Rebate Program—Labelers); *Form No.:* HCFA–304 and 304a (OMB# 0938–0676); *Use:* Section 1927 of the Social Security Act requires drug labelers to enter into and have in effect a rebate agreement with HCFA for States to receive funding for drugs dispensed to Medicaid recipients; *Frequency:* Quarterly; *Affected Public:* Business or other for-profit; *Number of Respondents:* 561; *Total Annual Responses:* 3,744; *Total Annual Hours:* 139,560. To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Wendy Taylor, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: January 10, 2001.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 01–1723 Filed 1–19–01; 8:45 am]

BILLING CODE 4120–03–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–0232]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Medicare Integrity Program Organizational Conflict of Interest Disclosure Certificate and Supporting Regulations at 42 CFR 421.300–421.318; *Form No.:* HCFA–R–0232 (OMB# 0938–0723); *Use:* HCFA needs this information to assess whether contractors who perform, or who seek to perform, Medicare Integrity Program functions, such as medical review, fraud review or cost audits, have organizational conflicts of interest and whether any conflicts have been resolved. The entities providing the information are organizations that have been awarded, or seek award of, a Medicare Integrity Program contract; *Frequency:* On occasion; *Affected Public:* Business or other for-profit; *Number of Respondents:* 10; *Total*