DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2214]

Antimicrobial Food Additives—Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food And Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Antimicrobial Food Additives—Guidance.'' This document is intended to clarify FDA's jurisdiction over antimicrobials that are used in or on food, including those used in or on edible food, in water that contacts edible food, and those used in the manufacture of, or in or on, food-contact articles, subsequent to the enactment of the Food Quality Protection Act of 1996 (FQPA), and the Antimicrobial Regulation Technical Corrections Act of 1998 (ARTCA).

DATES: Written comments concerning this guidance may be submitted at any time.

ADDRESSES: Written comments concerning this guidance may be submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. Submit written requests for single copies of the guidance to the Office of Premarket Approval (HFS–200), Food and Drug Administration, 200 C St. SW., Washington DC 20204, or by telephone to the Office of Premarket Approval at 202–418–3100 (voice), or FAX 202–418–3131. All requests should identify the guidance by its title of ''Antimicrobial Food Additives—Guidance.'' See the **SUPPLEMENTARY INFORMATION** section for electronic access to this guidance.

FOR FURTHER INFORMATION CONTACT: Mark A. Hepp, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 200 C St. SW., Washington DC 20204–0001, 202–418–3098.

SUPPLEMENTARY INFORMATION:

I. Background

The FQPA, enacted on August 3, 1996, changed, among other things, the definitions of ''food additive'' and ''pesticide chemical'' in the Federal Food, Drug, and Cosmetic Act (the act) (section 201(s) and (q) respectively (21 U.S.C. 321(s) and (q)). These changes had a significant impact on the regulatory authority for many antimicrobial products that are used in food-contact applications. ARTCA, enacted on October 30, 1998, further amended the definition of a ''pesticide chemical,'' under section 201(q) of the act, and the transitional provisions under section 408(j) of the act (21 U.S.C. 340a(j)). ARTCA, in part, transferred authority for certain food-contact antimicrobials from the Environmental Protection Agency (EPA) back to FDA.

FDA is announcing availability of a guidance document entitled ''Antimicrobial Food Additives—Guidance'' that is intended to clarify FDA's jurisdiction over antimicrobials, subsequent to the passage of FQPA and ARTCA, that are used in food, or that may become components of food as a result of their intended use. The food-related uses of antimicrobial products that have been specifically excluded from FDA's regulatory authority by ARTCA are also discussed. In addition, this document provides guidance on the meaning of certain terms that are important in delineating the jurisdiction of FDA and EPA.

II. Significance of Guidance

This guidance document represents the agency's current thinking on the agency's regulatory authority over certain antimicrobials used in or on food, or as food-contact substances. 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, regulations, or both.

The guidance document entitled ''Antimicrobial Food Additives—Guidance'' is a level 1 guidance under the agency's good guidance practices (62 FR 8961, February 27, 1997). Level 1 guidance documents are generally subject to public comment prior to finalizing. However, public comment prior to implementation of this guidance document is not required because there is a new statutory requirement that requires immediate implementation.

III. Comments

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments regarding the guidance document. 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. The guidance document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Such comments will be considered when determining whether to amend the guidance.

IV. Electronic Access

The guidance may also be accessed at the Center for Food Safety and Applied Nutrition home page on the World Wide Web at ''http:// www.fda.gov/cfsan''.

Dated: July 15, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–19061 Filed 7–26–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–194]

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

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, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the 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 Disproportionate Share Adjustment Procedure and Criteria and Supporting Regulations in 42 CFR, Section 412.106;

Form No.: HCFA R–194;

Use: Regulation sets up an alternative process for hospitals that choose to have their disproportionate share adjustment statistics calculated based on their cost reporting periods rather than the Federal fiscal year.

Frequency: On occasion;

Affected Public: Business or other for-profit, and Not-for-profit institutions;

Number of Respondents: 100;

Total Annual Responses: 100;

Total Annual Hours Requested: 100.

To obtain copies of the supporting statement 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 and phone number, 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 designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: July 12, 1999.

John P. Burke III,

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

[FR Doc. 99–19050 Filed 7–26–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; Meeting

In accordance with section 10(a) (2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of September 1999.

Name: Advisory Committee on Infant Mortality (ACIM).

Date and Time: September 23, 1999; 9:00 a.m.–5:00 p.m.; September 24, 1999; 8:30 a.m.–3:00 p.m.

Place: Holiday Inn at Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814, (301) 652–2000.

The meeting is open to the public.

Agenda: Topics that will be discussed include: Early Postpartum Discharge; Low-Birth Weight; Disparities in Infant Mortality; and the Healthy Start Program.

Anyone requiring information regarding the Committee should contact Peter C. van Dyck, M.D., M.P.H., Executive Secretary, ACIM, Health Resources and Services Administration (HRSA), Room 18–05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, telephone: (301) 443–2170.

Agenda items are subject to change as priorities dictate.

Dated: July 21, 1999.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 99–19104 Filed 7–26–99; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4527–N–01]

Notice of Proposed Information Collection: Comment Request Forms for Large-Scale Computer Matching Income Verification

AGENCY: The Real Estate Assessment Center, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments Due Date: September 27, 1999.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to Wanda Funk, U.S. Department of Housing and Urban Development, Real Estate Assessment Center, 1280 Maryland Avenue, SW, Suite 800, Washington, DC 20224–2135; telephone Customer Service Center at 1–888–245–4860 (this is a toll-free number).

FOR FURTHER INFORMATION CONTACT: Additional information can be obtained from David Decker, U.S. Department of Housing and Urban Development, Real Estate Assessment Center, 451 Seventh Street, SW, Room 5156, Washington, DC 20410–5000.

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended). The Notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (1) evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond.

This notice also lists the following information:

Title of Proposal: Forms for Large-Scale Computer Matching Income Verification.

OMB Control Number, if applicable: Not Available.

Description of the need for information and proposed use: A notice, published December 9, 1998 (63 FR 68129), describes the computer matching program applicable to this information collection requirement. HUD has recently transferred the responsibility for the computer matching income verification program described in that notice to its Real Estate Assessment Center.

REAC has developed the Tenant Assessment Subsystem (TASS) to identify potential sources of income discrepancies between income reported by tenants and submitted by Public Housing Agencies and owners and agents (POAs) with Federal tax data provided by the Internal Revenue Service and the Social Security Administration. The process of comparing these two sources of income information is referred to as computer matching income verification (CMIV). TASS will be used to identify potential income discrepancies for tenants receiving assistance under HUD's Public Housing (Low Rent), Section 8 Tenant-Based, and Section 8 Project-Based programs. Through the use of CMIV, TASS will:

- Identify potential income discrepancies;
- Generate letters to be sent to tenants identifying possible income discrepancies;
- Prepare notifications of possible tenant income discrepancies for POA processing and resolution; and
- Track POA discrepancy resolution and recovery of excessive rental assistance provided to tenants due to underreported income.

POAs will be required to resolve potential discrepancies through the identification of both positive and false positive discrepancies, and to adjust or terminate tenant rental assistance for verified discrepancies. Recovery involves a prudent attempt by POAs to obtain full repayment of excess tenant rental assistance through repayment agreements or prospective adjustments to future rental assistance.

The REAC has developed three forms to help capture and summarize data concerning POA income discrepancy resolution and recovery of excessive