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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: 7/15/99

JUL 15 1999

Margaret M. Dotzel
Acting Associate Commisioner for Policy

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