Dated: February 4, 1998.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 98–3190 Filed 2–4–98; 12:45 pm]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F–0057]

Ciba Specialty Chemicals Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ciba Specialty Chemicals Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of calcium bis[monoethyl(3,5-di-*tert*-butyl-4-hydroxybenzyl)phosphonate] as a stabilizer for polyethylene phthalate polymers intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 8B4578) has been filed by Ciba Specialty Chemicals Corp., 540 White Plains Rd., Tarrytown, NY 10591–9005. The petition proposes to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the safe use of calcium bis[monoethyl (3,5-di-*tert*-butyl-4-hydroxybenzyl)phosphonate] as a stabilizer for polyethylene phthalate polymers, complying with 21 CFR 177.1630, intended for use in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: January 22, 1998.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–2909 Filed 2–5–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0003]

FDA Modernization Act of 1997: Guidance for the Device Industry on Implementation of Highest Priority Provisions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''FDA Modernization Act of 1997: Guidance for the Device Industry on Implementation of Highest Priority Provisions; Availability.'' This guidance, generally referred to as the ''Day-1 guidance'' summarizes FDA's strategy for implementing the highest priority provisions of the FDA Modernization Act of 1997 (FDAMA) as it relates to the regulation of medical devices. The agency requests comments on this guidance.

DATES: Submit written comments by May 7, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Submit written requests for single copies of the guidance entitled ''FDA Modernization Act of 1997: Guidance for the Device Industry on Implementation of the Highest Priority Provisions'' to the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–1), Food and Drug Administration, 1350 Picard Dr., Rockville, MD 20850, 301–443–4690.

SUPPLEMENTARY INFORMATION:

I. Background

The ''Day-1 guidance'' announced in this document summarizes FDA's strategy for implementing the highest priority provisions of the FDAMA (Pub. L. 105–115) as it relates to the regulation of medical devices. FDA identified these provisions as being of the highest priority for implementation because: (1) They become effective on or before February 19, 1998, the general effective date of the act; (2) they are expected to impact a large number of products/applications; or (3) they are of high interest to the device community. Unless an alternative method of implementation is specified in the statute, FDA generally plans to issue individual guidance documents to implement these provisions of the new law. The highest priority provisions of FDAMA identified in the guidance, and related sections in FDAMA, are:

(1) Early collaboration on data requirements for clinical studies (sections 201 and 205),

(2) Premarket approval application (PMA) collaborative review process (section 209),

(3) Scope of review: labeling claims for PMA's (section 205),

(4) PMA supplements for manufacturing changes (section 205),

(5) Premarket notification exemptions (section 206),

(6) Evaluation of automatic class III designation (section 207),

(7) Device standards (section 204),

(8) Scope of review: labeling claims for 510(k)'s (section 205),

(9) 90-Day review of 510(k)'s (section 209),

(10) Device tracking (section 211),

(11) Postmarket surveillance (section 212), and

(12) Dispute resolution (section 404).

The ''Day-1 guidance'' provides a section-by-section summary of each of these statutory provisions and describes FDA's general approach to implementing each such provision.

In accordance with FDA's Good Guidance Practices (62 FR 8961, February 27, 1997), this Level 1 guidance is being issued without prior public comment because it affects immediate implementation of new statutory requirements. Comments and suggestions regarding this guidance may be submitted by May 7, 1998. Unless specified otherwise, other guidances referenced in this guidance will also be issued as Level 1 guidances that become effective upon publication, with the opportunity to submit comments to the agency during the implementation stage.

This guidance represents the agency's current thinking on the implementation

of the FDAMA. 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 requirement of the applicable statute, regulations, or both.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so using the World Wide Web (WWW). The Center for Devices and Radiological health (CDRH) maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Web. The CDRH home page, which is updated on a regular basis, includes the guidance entitled ''FDA Modernization Act of 1997: Guidance for the Device Industry on Implementation of Highest Priority Provisions,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters and other device-oriented information. The guidance will be available on the CDRH home page at http://www.fda.gov/cdrh.

A text-only version of the CDRH Web site is also available from a computer or VT–100 compatible terminal by dialing 800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. From there follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA home page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH for general information, or arrow down for specific topics.

III. Comments

Interested persons may, on or before May 7, 1998, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments and requests for copies are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 13, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–3002 Filed 2–5–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4263–N–78]

Submission for OMB Review: Comment Request

AGENCY: Office of the Assistant Secretary for Administration HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been 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:* March 9, 1998.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments must be received within thirty (30) days from the date of this Notice. Comments should refer to the proposal by name and/or OMB approval number should be sent to: Joseph F. Lackey, Jr., HUD Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW, Washington, DC 20410, telephone (202) 708–0050. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB maybe obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35).

The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, an hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the names and telephone numbers of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: January 29, 1998.

David S. Cristy,

Director, Information Resources, Management Policy and Management Division.

Notice of Submission of Proposed Information Collection to OMB

Proposal: Mortgagee Letter: Revision to the Section 235(r) Refinancing Procedures.

Office: Housing.

OMB Approval Number: 2502–0456.

Description of the Need for the Information and its Proposed Use: The information is collected by the originating lender from the mortgage application and is used by the originating lender to process the applications for Section 235(r) mortgage insurance and assistance. The applications are underwritten and certified by the originating lender. The information is needed for the evaluation of the applications, the Department's financial management and accounting system(s), and the Department's monitoring of the origination and servicing activities of the lender.

Form Number: HUD–93114.

Respondents: Individuals or Households and Business or Other For-Profit.

Frequency of Submission: Annually.

Reporting Burden:

	Number of respondents	×	Requency of response	×	Hours per response	=	Burden hours
HUD–93114	23,000		1		.28		6,437