piperidinyl)-1,3,5-triazine-2,4,6-triamine] as a light/thermal stabilizer in olefin polymers intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Ellen M. Waldron, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3089.

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 9B4639) 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 *N*,*N*‴-[1,2-ethanediylbis[[[4,6-bis[butyl(1,2,2,6,6-pentamethyl-4-piperidinyl)amino]-1,3,5-triazin-2-yl]imino]-3,1-propanediyl]]bis[*N*′,*N*″-dibutyl-*N*′,*N*″-bis(1,2,2,6,6-pentamethyl-4-piperidinyl)-1,3,5-triazine-2,4,6-triamine] as a light/thermal stabilizer in olefin polymers 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 20, 1999.

Laura M. Tarantino,

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

[FR Doc. 99–2506 Filed 2–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99F–0127]

GEO Specialty Chemicals; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that GEO Specialty Chemicals has filed a petition proposing that the food additive regulations be amended to provide for the safe use of trimethylolethane as a dispersant for pigments used as components of food-contact articles.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3091.

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 9B4635) has been filed by GEO Specialty Chemicals, C/O Keller and Heckman, 1001 G St., NW., suite 500 West, Washington, DC 20001. The petition proposes to amend the food additive regulations in § 178.3725 *Pigment dispersants* (21 CFR 178.3725) to provide for the safe use of trimethylolethane as a dispersant for pigments used as components of food-contact articles.

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 20, 1999.

Laura M. Tarantino,

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

[FR Doc. 99–2505 Filed 2–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 91N–0396]

Agency Information Collection Activities; Announcement of OMB Approval; Medical Devices; Reports of Corrections and Removals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing thata collection of information entitled ''Medical Devices; Reports of Corrections and Removals'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 25, 1998 (63 FR 65210), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–359. The approval expires on January 31, 2002. A copy of the supporting statement for this information collection is available on the Internet at ''http://www.fda.gov/ohrms/dockets''.

Dated: January 28, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–2563 Filed 2–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–1232]

Points To Consider Guidance Document on Assayed and Unassayed Quality Control Material; Draft; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Points To Consider Guidance Document on Assayed and Unassayed Quality Control Material.'' This draft guidance is neither final nor is it in effect at this time. This draft guidance is intended to provide assistance to manufacturers of in vitro diagnostic quality control materials. It complements the existing guidance on labeling of these devices entitled '' Points to Consider for Review of Calibration and Quality Control Labeling for In Vitro Diagnostic Device.''

DATES: Written comments concerning this draft guidance must be received by May 4, 1999.

ADDRESSES: Written comments concerning this draft guidance must be submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies on a 3.5″ diskette of the draft guidance

document entitled ''Points To Consider Guidance Document on Assayed and Unassayed Quality Control Material'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, 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. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Joseph L. Hackett, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3084.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance, entitled ''Points to Consider Guidance Document on Assayed and Unassayed Quality Control Materials,'' complements the existing guidance document published in February 1996, entitled ''Points to Consider for Review of Calibration and Quality Control Labeling for In Vitro Devices.'' FDA believes information in this draft guidance concerning unassayed quality control materials may be useful to manufacturers making these products, even though such materials are currently exempt from premarket review. For assayed quality control materials, the intent is for this draft guidance document to eventually be cited as the basis for abbreviated 510(k)'s for processing of assayed controls.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on assayed and unassayed quality control materials. 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 applicable statute, regulations, or both.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive ''Points To Consider Guidance Document on Assayed and Unassayed Quality Control Material'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (2231) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the World Wide Web (WWW). 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. Updated on a regular basis, the CDRH home page includes ''Points to Consider for Guidance Document on Assayed and Unassayed Quality Control Material,'' 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 CDRH home page may be accessed at ''http://www.fda.gov/cdrh''.

IV. Comments

Interested persons may, on or before May 4, 1999, submit to Docket Management Branch (address above) written comments regarding this draft 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 heading of this document. The draft guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 19, 1999.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 99–2508 Filed 2–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–1224]

Guidance for Industry on FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products.'' The guidance considers the quality and quantity of data that may be adequate to add a new use to the prescribing information for a product used in the treatment of cancer. The guidance is part of an agency effort to encourage the submission of supplemental applications for new uses for approved drug and biological products. This guidance is consistent with the Food and Drug Administration Modernization Act of 1997 (the Modernization Act), which specifies that the agency will continue its efforts to encourage sponsors to submit supplemental applications for new uses for their products.

DATES: Written comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm'' or ''http://www.fda.gov/cber/guidelines.htm''. Submit written requests for single copies of this guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Robert L. Justice, Center for Drug