hours— Burden Information for the Care Provider Questionnaire—Number of Responses: 1680; Burden per Response: .95 hours; Burden: 1596 hours—Burden Information for Notification of Admission to an Inpatient Facility—Number of Responses: 1680; Burden per Response: 1.9 minutes; Burden: 54 hours—Burden Information for Care Provider Profile—Number of Responses: 280; Burden per Response: 2.5 minutes; Burden: 12 hours—Burden Information for Focus Groups—Number of Responses: 56; Burden per Response: 122.21 minutes; Burden: 114 hours—Burden Information for Case Studies—Number of Responses: 8; Burden per Response: 60 minutes; Burden: 8 hours—Total Burden: 1818 hours. OMB Desk Officer: Allison Eydt

Copies of the information collection packages listed above can be obtained by calling the OS Reports Clearance Officer on (202) 690–6207. Written comments and recommendations for the proposed information collection should be sent directly to the OMB desk officer designated above at the following address: Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street N.W., Washington, D.C. 20503.

Comments may also be sent to Cynthia Agens Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue S.W., Washington DC, 20201. Written comments should be received within 30 days of this notice.

Dated: September 16, 1998.

Dennis P. Williams,

Deputy Assistant Secretary, Budget.

[FR Doc. 98–25507 Filed 9–23–98; 8:45 am]

BILLING CODE 4150–04–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 84D–0141]

Compliance Policy Guide; Revocation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of Compliance Policy Guide (CPG) section 615.100 entitled ''Extralabel Use of New Animal Drugs in Food-Producing Animals (CPG 7125.06)'' to fulfill the commitment made by the agency in the preamble to the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA). The CPG was superseded by AMDUCA.

FOR FURTHER INFORMATION CONTACT: Judith A. Gushee, Center for Veterinary Medicine (HFV–236), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0150.

SUPPLEMENTARY INFORMATION: FDA is revoking CPG section 615.100 entitled ''Extralabel Use of New Animal Drugs in Food-Producing Animals (CPG 7125.06)'' to fulfill the commitment made by the agency in the preamble to AMDUCA, which published in the **Federal Register** of November 7, 1996 (61 FR 57732). The regulation eliminated the need for a broad CPG on the extralabel use of drugs in food-producing animals.

Dated: September 17, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–25571 Filed 9–23–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food And Drug Administration

[Docket No. 98F–0797]

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 expanded safe use of 5,7-bis(1,1-dimethylethyl)-3-hydroxy-2(3H)-benzofuranone, reaction products with o-xylene as an antioxidant and/or stabilizer for olefin polymers intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215),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 8B4625) 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 expanded safe use of 5,7-bis(1,1-dimethylethyl)-3-hydroxy-2(3H)-benzofuranone, reaction products with o-xylene as an antioxidant and/or stabilizer for olefin polymers intended for use in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of the 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: September 4, 1998.

Laura M. Tarantino,

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

[FR Doc. 98–25570 Filed 9–23–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96D–0058]

International Conference on Harmonisation; Guidance on Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a guidance entitled ''Q5A Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin.'' The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance describes the testing and evaluation of the viral safety of biotechnology products derived from characterized cell lines of human or animal origin, and outlines data that should be submitted in marketing applications.

DATES: Effective September 24, 1998. Submit written comments at any time.

ADDRESSES: 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. Copies of the guidance are available from the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane,