review and evaluation of clinical testing and licensing. This document applies to monoclonal antibodies made by traditional hybridoma technology as well as by recombinant technologies. Some of the major changes in the revised PTC document include: (1) An updated definition of a monoclonal antibody; (2) modification of the quality control, product testing, and product comparability sections; and (3) clarification of the techniques for and necessity of retrovirus testing. The section of the draft 1994 PTC document dealing with changes to be reported after product approval is not included in the 1997 PTC document because this subject is addressed in a separate rulemaking (61 FR 2739, January 29, 1996).

A new section of the document discusses abbreviated product testing for feasibility trials in serious and immediately life-threatening conditions. Other important new concepts contained in the revised PTC document are those of generic and modular virus clearance studies and the acceptability of demonstrating the removal of some contaminants by means of clearance studies, as opposed to routine testing. The concepts of generic and modular virus clearance studies and of clearance studies for some contaminants apply not only to monoclonal antibodies but also to recombinant products, as appropriate. CBER intends to update other guidance documents to reflect these studies. New concepts on abbreviated product testing for feasibility trials in serious and immediately life-threatening conditions and on generic and modular virus clearance studies do not apply to products of entirely human origin or to products that have the potential to be contaminated by human pathogens.

As with other guidance documents, FDA does not intend the PTC document to be all inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements. Manufacturers may follow the document or may choose to use alternative procedures that are not provided in this document. If a manufacturer chooses to use alternative procedures, that manufacturer may wish to discuss the matter further with FDA to prevent expenditure of resources to generate data on activities that FDA may later determine to be unacceptable. Although this document does not create or confer any rights for or on any person and does not operate to bind FDA or the public, it does represent the agency's current thinking on the manufacture and testing of monoclonal antibody products for human use.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the PTC 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. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Received comments will be considered in determining whether further revision of the PTC document in warranted. Any revised version of the PTC document will be announced in the Federal Register.

Dated: February 20, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–5006 Filed 2–27–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 97F–0062]

General Electric Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that General Electric Co. has filed a petition proposing that the food additive regulations be amended to provide for the expanded safe use of triisopropanolamine as a component of phosphorous acid, cyclic butylethyl propanediol, 2,4,6-tri-*tert*-butylphenyl ester, a stabilizer for olefin polymers intended for use in contact with food.

DATES: Written comments on the petitioner's environmental assessment by March 31, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

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 7B4535) has been filed by General Electric Co., 1 Lexan Lane, Mt. Vernon, IN 47620–9364. 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 triisopropanolamine as a component of phosphorous acid, cyclic butylethyl propanediol, 2,4,6-tri-tert-butylphenyl ester, a stabilizer for olefin polymers intended for use in contact with food.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before March 31, 1997, submit to the Dockets Management Branch (address above) written comments. 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the Federal Register. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).

Dated: February 11, 1997.

George H. Pauli,

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

[FR Doc. 97–4962 Filed 2–27–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96E–0080]

Determination of Regulatory Review Period for Purposes of Patent Extension; Olean; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the Federal Register of January 6, 1997 (62 FR 763).