commercial marketing of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for EXCENEL® Sterile Suspension is 900 days. Of this time, 881 days occurred during the testing phase of the regulatory review period, while 19 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act became effective*: November 10, 1993. FDA has verified the applicant's claim that November 10, 1993, was the date that the investigational new animal drug application became effective.

2. *The date the application was initially submitted with respect to the animal drug product under section 512(b) of the Federal Food, Drug, and Cosmetic Act*: April 8, 1996. The applicant claims April 3, 1996, as the date the new animal drug application (NADA) for EXCENEL® Sterile Suspension (NADA 140–890) was initially submitted. However, a review of FDA records reveals that FDA's official acknowledgment that the NADA was sufficiently complete to begin review was a telephone call requesting that certain additional information be added to the NADA on April 8, 1996, which is considered to be the initially submitted date for the NADA.

3. *The date the application was approved*: April 26, 1996. FDA has verified the applicant's claim that NADA 140–890 was approved on April 26, 1996.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,151 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before April 29, 1997, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before August 27, 1997, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 20, 1997.

Allen B. Duncan,

Acting Associate Commissioner for Health Affairs.

[FR Doc. 97–4954 Filed 2–27–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 94D–0259]

"Points to Consider in the Manufacture and Testing of Monoclonal Antibody Products for Human Use (1997);" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a points to consider (PTC) document entitled "Points to Consider in the Manufacture and Testing of Monoclonal Antibody Products for Human Use (1997)." This PTC document is intended to assist sponsors and investigators engaged in monoclonal antibody product development and it includes information to submit when filing investigational new drug applications and product license applications. The document revises a 1994 document entitled "Draft Points to Consider in the Manufacture and Testing of Monoclonal Antibody Products for Human Use."

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the document entitled "Points to Consider in the Manufacture and Testing of Monoclonal Antibody Products for Human Use (1997)" to the Manufacturers Assistance and Communication Staff (HFM–42), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The document may also be obtained by mail or fax by calling the CBER Fax Information System at 1–888–CBER–FAX or 301–827–3844.

Persons with access to the Internet may obtain the document using the World Wide Web (WWW) or bounce-back e-mail. For WWW access, connect to CBER at "http://www.fda.gov/cber/cberftp.html." For bounce back e-mail send a message to "ptc__mab@al.cber.fda.gov."

Submit written comments on the PTC document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the PTC document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Sharon A. Carayiannis, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a PTC document entitled "Points to Consider in the Manufacture and Testing of Monoclonal Antibody Products for Human Use (1997)." This PTC document supersedes the document entitled "Draft Points to Consider in the Manufacture and Testing of Monoclonal Antibody Products for Human Use" announced in the Federal Register of August 3, 1994 (59 FR 39571), and is designed to assist sponsors and investigators engaged in monoclonal antibody product development.

The PTC revision was undertaken for reasons that include but are not limited to: (1) Facilitating initial development of monoclonal antibodies for serious and immediately life-threatening indications; (2) updating and streamlining information from the 1994 PTC document; and (3) assuring consistency with current CBER policy and International Conference on Harmonisation documents dealing with this category of products. In the revision of this document, CBER reviewed and considered all comments submitted to the docket.

The PTC document details an approach for sponsors and investigators to follow in product manufacturing and testing, preclinical and clinical studies, and the information to be provided for

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).