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).

The document announced FDA's determination of the regulatory review period for purposes of patent extension for Olean (olestra). The document was published with an error. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

In FR Doc. 97–138, appearing on page 763 in the Federal Register of Monday, January 6, 1997, the following correction is made: On page 763, in the third column, beginning in line 6, ''Olean (U.S. Patent No. 4,005,196)'' is corrected to read ''Olean (U.S. Patent No. Re. 34,617)''.

Dated: February 20, 1997.

Allen B. Duncan,

Acting Associate Commissioner for Health Affairs.

[FR Doc. 97–4960 Filed 2–27–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96E–0265]

Determination of Regulatory Review Period for Purposes of Patent Extension; REDUX™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for REDUX™ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

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

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product REDUX™ (dexfenfluramine hydrochloride). REDUX™ is indicated for the management of obesity including weight loss and maintenance of weight loss in patients on a reduced calorie diet. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for REDUX™ (U.S. Patent No. 4,309,445) from Interneuron Pharmaceuticals, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated November 21, 1996, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of REDUX™ represented the first permitted commercial marketing or use 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 REDUX™ is 1,613 days. Of this time, 541 days occurred during the testing phase of the regulatory review period, while 1,072 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: December 1, 1991. The applicant claims January 13, 1992, as the date the investigational new drug application (IND) for REDUX™ (IND 38,108) became effective. However, FDA records indicate that the effective date for IND 38,108 was December 1, 1991, which was 30 days after FDA receipt of the IND on November 1, 1991.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: May 24, 1993. The applicant claims May 23, 1993, as the date the new drug application (NDA) for REDUX™ (NDA 20–344) was initially submitted. However, FDA records indicate that NDA 20–344 was submitted on May 24, 1993.

3. *The date the application was approved*: April 29, 1996. FDA has verified the applicant's claim that NDA 20–344 was approved on April 29, 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 1,322 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 18, 1997.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 97–4961 Filed 2–27–97; 8:45 am]

BILLING CODE 4160–01–F