example, pharmacist/veterinarian/client and VCPR. Rare instances of specialized compounding to meet emergency needs would not be considered disproportionate.

B. The following situations would indicate excessive risk to public health or to animals, or an otherwise adverse risk/benefit ratio, of high regulatory priority:

-Instances where illegal residues occur in meat, milk, eggs, honey, or aquaculture products and the residues were caused by the use of a compounded drug in association with the violation being investigated;

-Compounding of medicaments for food-producing animals, especially those used in lactating dairy animals, which cause a significant risk of illegal residues because, for example, withholding times have not been established by the veterinarian using adequate scientific information; and

-Preparation of drug products that are essentially similar to products that have been removed from the market due to regulatory concerns, for example, chloramphenicol, dimetridazole, DES in food animals.

C. The following activities would indicate compounding subject to regulatory action, and possibly of high regulatory priority. However, guidance from CVM should be solicited to assess the potential public health threat and/or animal safety (i. e., risk vs benefits).

-Instances where animals have been harmed or their safety unnecessarily compromised, such as compounding a nonsterile product for parenteral or ophthalmic administration where a sterile product is indicated, or other instances of not adhering to good compounding practices.

-Compounded substances that do not bear the required label information, including the name of the authorizing veterinarian, the active ingredients, directions for use, cautionary statements, and withdrawal times.

D. The following compounding situations would not ordinarily be considered for regulatory action. Appropriate state and local practice and pharmacy laws must be adhered to, however.

-Compounding for non-food animals and minor food animal uses where public health and animal safety have not been threatened, and are of great need and small risk. This would include such common practices as: veterinarians' combining agents for anesthesia, large volume parenterals, preparing appropriate dosage-forms for the size of the patient in question, ''animal-side'' compounding, and other similar common practices that are widely accepted in the day to day treatment of animal patients.

-Compounding from bulk drug substances for use in nonfood animals, including animals in public and private aquaria, when animal health is not threatened, and there is not a significant risk of diversion of the bulk drugs or compounded drugs for use in food animals. Bulk drug substances would ordinarily be expected to be in small packages that meet or exceed USP standards; see definition of ''bulk drugs'' above. Compounding should be performed in accordance with current standards of pharmaceutical practice (including referral to compendial monographs or established pharmacy textbooks).

If circumstances exist on a case-by-case basis that indicate otherwise, the Field should request guidance from CVM before considering regulatory action. The preceding is not intended to be a complete list of activities relating to compounding; there may be other factors which are appropriate when assessing an individual case.

Guidance for Charging Violations:

A warning letter is ordinarily the first choice of action, when referral to state authorities is not appropriate. Injunction would be the usual choice of court action, although seizure should be considered in the case of high priority drugs such as chloramphenicol or DES intended for use in food animals. Criminal action can be considered in egregious situations.

Compounded drugs subject to regulatory action under this policy will ordinarily be charged as unapproved new animal drugs, violative under Section 501(a)(5). Deviations from GCP, if not subject of state action will ordinarily be charged under Section 501(a)(2)(b). The tissue residue violations are covered under Section 402(a)(2)(D).

Dated: June 26, 1996.

Gary Dykstra,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 96–16973 Filed 7–2–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96F–0184]

Life Technologies, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Life Technologies, Inc., has filed a petition proposing that the food additive regulations be amended to provide for a change in the level of reactants for sulphopropyl cellulose ion-exchange resin for the recovery and purification of proteins for food use.

DATES: Written comments on the petitioner's environmental assessment by August 2, 1996.

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: Andrew D. Laumbach, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3071.

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 6A4500) has been filed by Life Technologies, Inc., 8400 Helgerman Ct., Gaithersburg, MD 20874. The petition proposes to amend the food additive regulations in § 173.25 *Ion-exchange resins* (21 CFR 173.25) to provide for a change in the level of the reactants for sulphopropyl cellulose ion-exchange resin for the recovery and purification of proteins for food use. The amendment proposes that the amount of epichlorohydrin plus propylene oxide employed does not exceed 250 percent by weight of the starting quantity of cellulose. The current regulation provides that the amount of epichlorohydrin plus propylene oxide employed does not exceed 61 percent by weight of the starting quantity of cellulose.

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 display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before August 2, 1996, 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: May 31, 1996.

Alan M. Rulis,

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

[FR Doc. 96–16975 Filed 7–2–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96F–0205]

Sumitomo Chemical America, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Sumitomo Chemical America, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the additional safe use of 3,9-bis{2-[3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propionyloxy]-1,1-dimethylethyl}-2,4,8,10-tetraoxaspiro[5.5]-undecane as an antioxidant and/or stabilizer in propylene homopolymer and high-propylene olefin copolymer articles intended for use in contact with food.

DATES: Written comments on the petitioner's environmental assessment by August 2, 1996.

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 6B4510) has been filed by Sumitomo Chemical America, Inc., 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 § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the additional safe use of 3,9-bis{2-[3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propionyloxy]-1,1-dimethylethyl}-2,4,8,10-tetraoxaspiro[5.5]-undecane as an antioxidant and/or stabilizer in propylene homopolymer and high-propylene olefin copolymer articles 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 display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before August 2, 1996, 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: June 17, 1996.

George H. Pauli,

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

[FR Doc. 96–16976 Filed 7–2–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95M–0195]

Ciba Corning Diagnostics Corp.; Premarket Approval of ACS™ AFP

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Ciba Corning Diagnostics Corp., Medfield, MA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of ACS™ AFP. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant by letter of September 29, 1995, of the approval of the application.

DATES: Petitions for administrative review by August 2, 1996.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Peter E. Maxim, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1293.

SUPPLEMENTARY INFORMATION: On October 18, 1993, Ciba Corning Diagnostics Corp., Medfield, MA 02052–1688, submitted to CDRH an application for premarket approval of ACS™ AFP. The device is a two-site chemiluminescence immunoassay and is indicated for the quantitative determination of alpha-fetoprotein (AFP) in human serum and in amniotic fluid from specimens obtained at 15 to 20 weeks gestation as an aid in detecting open neural tube defects (NTD's) when used in conjunction with ultrasonography and amniography; and in human serum, as an aid in managing nonseminomatous testicular cancer, when used in conjunction with physical examination, histology/pathology, and other clinical evaluation procedures, using the Ciba Corning ACS:180 automated chemiluminescence system.

In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this premarket approval application (PMA) was not referred to the Immunology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

On September 29, 1995, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or