Washington, DC 20204–0002, 202–418–3098.

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 6B4491) has been filed by Ciba-Geigy Corp., 540 White Plains Road, P.O. Box 2005, Tarrytown, N.Y. 10591–4311. The petition proposes to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers* (21 CFR 178.2010) to expand the safe use of oxidized bis(hydrogenated tallow alkyl)amines as a process stabilizer for polypropylene homo- and copolymers and high-density polyethylene homo- and copolymers 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 25, 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: February 8, 1996.

Alan M. Rulis,

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

[FR Doc. 96–4063 Filed 2–22–96; 8:45 am]

BILLING CODE 4160–01–P

[Docket No. 91F–0264]

Stockhausen, Inc.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 9B4149), proposing that the food additive regulations be amended to provide for the safe use of N-((3-dimethylamino)propyl)-2-propenamide, polymer with 2-propenoic acid, sodium salt as a dispersing aid in paper and paper coatings intended for use in contact with food.

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: In a notice published in the Federal Register of August 1, 1991 (56 FR 36185), FDA announced that a food additive petition (FAP 9B4149) had been filed on behalf of Stockhausen, Inc., 2401 Doyle St. (formerly 2408 Doyle St.), Greensboro, NC 27406. The petition proposed to amend the food additive regulations in § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) to provide for the safe use of N-((3-dimethylamino)propyl)-2-propenamide, polymer with 2-propenoic acid, sodium salt as a dispersing aid in paper and paper coatings intended for use in contact with food.

Stockhausen, Inc., has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: February 8, 1996.

Alan M. Rulis,

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

[FR Doc. 96–4062 Filed 2–22–96; 8:45 am]

BILLING CODE 4160–01–P

[Docket No. 95D–0216]

International Conference on Harmonisation; Final Guideline on Quality of Biotechnological Products: Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration is publishing a final guideline on the quality of biotechnological products entitled ''Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products.'' The guideline was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guideline is intended to describe the types of information that are considered valuable in assessing the structure of the expression construct used to produce recombinant deoxyribonucleic acid (r-DNA) derived proteins.

DATES: Effective February 23, 1996. Submit written comments at any time.

ADDRESSES: Submit written comments on the guideline to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Copies of the guideline are available from the Division of Communications Management (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1012. An electronic version of this guideline is also available via Internet by connecting to the CDER file transfer protocol (FTP) server (CDVS2.CDER.FDA.GOV).

FOR FURTHER INFORMATION CONTACT:

Regarding the guideline: Elaine C. Esber, Center for Biologics Evaluation and Research (HFM–30), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0641.

Regarding ICH: Janet J. Showalter, Office of Health Affairs (HFY–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input