0) or ''Healthy People 2000'' (Summary Report, Stock No. 017–001–00473–1) referenced in the **INTRODUCTION** may be obtained through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

Dated: April 24, 1995.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 95–10591 Filed 4–28–95; 8:45 am]

BILLING CODE 4163–18–P

Food and Drug Administration

[Docket No. 93F–0050]

E. I. du Pont de Nemours and Co.; 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 future filing, of a food additive petition (FAP 3B4360) proposing that the food additive regulations be amended to provide for the safe use of perfluoroalkylethyl acrylate copolymer, produced by the copolymerization of perfluoroalkylethyl acrylate, octadecyl methacrylate, vinylidene chloride, 2-hydroxyethyl methacrylate and polyoxyethylene methacrylate, as an oil and water repellant in paper and paperboard intended for food-contact use.

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3086.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of March 12, 1993 (58 FR 13603), FDA announced that a food additive petition (FAP 3B4360) had been filed by E. I. Du Pont de Nemours and Co., Du Pont Chemicals, Jackson Laboratory, Chamber Works, Deepwater, NJ 08023. 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 perfluoroalkylethyl acrylate copolymer, produced by the copolymerization of perfluoroalkylethyl acrylate, octadecyl methacrylate, vinylidene chloride, 2-hydroxyethyl methacrylate, and polyoxyethylene methacrylate, as an oil and water repellant in paper and paperboard intended for food-contact use. Du Pont has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: April 11, 1995.

Alan M. Rulis,

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

[FR Doc. 95–10645 Filed 4–28–95; 8:45 am]

BILLING CODE 4160–01–F

[FDA–225–94–3000]

Memorandum of Understanding Between the Food and Drug Administration and the National Institutes of Health

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA and the National Institutes of Health (NIH). The purpose of this MOU is to establish a relationship between the Center for Drug Evaluation and Research, FDA, and the Epilepsy Branch, National Institute of Neurological Diseases and Stroke, NIH, so that joint experiments can be conducted relating to drug metabolism and drug-drug interactions.

DATES: The agreement became effective December 13, 1993.

FOR FURTHER INFORMATION CONTACT: Jerry M. Collins, Center for Drug Evaluation and Research (HFD–400), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4750.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and memoranda of understanding between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of the memorandum of understanding.

Dated: April 25, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

Memorandum of Understanding Between the U.S. Department of Health and Human Services, National Institutes of Health, National Institute of Neurological Diseases and Stroke, Epilepsy Branch and the U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research

I. Purpose

The purpose of the proposed Memorandum of Understanding (MOU) is to establish a relationship between the Center for Drug Evaluation and Research (CDER), Food and Drug Administration, and the Epilepsy Branch, National Institute of Neurological Diseases and Stroke, so that joint experiments can be conducted relating to drug metabolism and drug-drug interactions.

II. Background

Drug metabolism and drug-drug interactions represent significant issues for the FDA's mission to ensure safe and effective drugs with adequate instructions for use. For both metabolism and interactions, studies in vitro can provide substantial information needed for drug development and regulation. Review and laboratory scientists in CDER have become increasingly involved in the development of the technology for testing in vitro, and its application to modern drug development and regulation.

The Antiepileptic Drug Development (ADD) Program of the National Institute of Neurological Disorders and Stroke (NINDS) was established to collaborate with the private sector and academia effective and safe drugs for the treatment of seizures in epileptic patients. The ADD Program includes preclinical pharmacodynamic and pharmacokinetic as well as clinical investigations. The Preclinical Pharmacology Section of the Epilepsy Branch is responsible for identifying potential compounds through a multistage screening program. At present, drug-drug interactions are found by chance, as new therapeutic agents proceed through the developmental process and enter clinical trials with comedicated epileptic patients. A critical need exists to establish possible drug-drug interactions prior to the initiation of clinical trials.

III. Substance of Agreement

Staff of both the FDA's Division of Clinical Pharmacology and the Preclinical Pharmacology Section, Epilepsy Branch, NINDS will collaborate in determining metabolic pathways and potential drug-drug interactions of ADD Program compounds. The basic technology for evaluating drug-drug interactions exists in the FDA's laboratory through the use of human liver slices and subcellular fractions. The division of labor for these studies are based on the expertise and equipment found in each laboratory. Analytical methods for the identification and quantification of metabolites of the experimental compounds and clinically effective antiepileptic drugs will be developed in both laboratories under a mutual agreement based on available resources. The compounds will be supplied by the Epilepsy Branch following an agreement with the pharmaceutical sponsor. All data from these studies will remain confidential as stipulated under the present NINDS ADD Program preclinical confidentiality agreement. Any information obtained or generated under this Memorandum of Understanding will not be disclosed by FDA staff to anyone outside FDA or NINDS without permission from NINDS or the pharmaceutical sponsor.