DUPLICATE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

JAN 14 1997

Director, Office of Premarket Approval, HFS-200

Amendment to Section 176.170- Components of paper and paperboard in contact with aqueous and fatty foods - Food Additive Petition No. 6B4513 - ACTION

Director, Center for Food Safety and Applied Nutrition, HFS-1

OBJECTIVE

To publish the attached document (Tab A), which would amend Section 176.170 of the food additive regulations.

FACTS

The attached order (Tab A) would amend § 176.170 Components of paper and paperboard in contact with aqueous and fatty foods, to provide for the safe use of perfluoroalkyl substituted phosphate ester acids, ammonium salts formed by the reaction of 2,2-bis[(γ,ω-perfluoroC_{4-20}alkylthio)methyl]-1,3-propanediol, polyphosphoric acid and ammonium hydroxide, as an oil and water repellant for paper and paperboard intended for use in contact with food. The order is in response to a food additive petition (FAP 6B4513) submitted by Ciba-Geigy Corp. The notice of filing (Tab B) published in the **Federal Register** of July 18, 1996.

DISCUSSION

The petition was reviewed by the Special Project Team in accordance with the SOP established on November 8, 1994. The team consists of a Chairman and a CSO from the Indirect Additives Branch of the Division of Petition Control, a representative of the Chemistry Review Branch (CRB) of the Division of Product Manufacture and Use (DPMU), a representative of the Division of Health Effects Evaluation (DHEE), and a representative of the Environmental Impact Staff of DPMU.

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The CRB representative concludes that the additive is adequately identified in the attached order and will accomplish its intended technical effect. The CRB representative concludes that the migration of the additive into food from its petitioned use will result in a dietary

[redacted]

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OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFS-216		1/10/97	HFS24	Duncan	2/4/97	HFS-0		2/6/97
HFS200		1-13-97	HFS24	Lord	2/5/97	HFS1		2/5/97
LEF-1	Copy	1-27-97	HFS-22	Wheeler	2/6/97			

concentration of no greater than 0.04 parts per million (ppm), which equates to an estimated daily intake (EDI) of 0.12 mg per person per day (mg/p/d). The cumulative exposure to the additive from the current and previously regulated uses would be no greater than 0.13 mg/p/d.

The DHEE representative concludes that based on the "virtually nil" dietary exposure to the additive, the proposed use of the subject additive is supported by the available toxicity data presented in the petition.

The Environmental Impact Staff concludes that this action will not have a significant impact on the quality of the human environment and that an environmental impact statement is not required. The environmental review package consisting of their finding of no significant impact (FONSI) is attached (Tab C) for display at the Dockets Management Branch. No comments were received during the thirty day comment period specified in the filing notice for comments on the environmental assessment submitted with the petition.

The Special Project Team concludes that Regulatory Flexibility and Regulatory Impact Analyses are not necessary because this action is exempt from the Regulatory Flexibility Act and Executive Order 12866.

The Office of Premarket Approval concludes that the use of this additive is safe under the conditions of use prescribed in the final rule. This rule should be signed by the Director, Center for Food Safety and Applied Nutrition or a designee, because it does not include novel or controversial issues and does not involve the jurisdiction of two Centers.

RECOMMENDATION

We recommend that the attached order be signed and published in the **Federal Register**.

Alan M. Rulis

Alan M. Rulis, Ph.D.

Attachments
Tab A - Document
Tab B - Filing Notice
Tab C - Finding of No Significant Impact

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DECISION

Approved [signature] Disapproved _____ Date 2/7/97

Prepared by:HFS-216:VDAnand:10/7/96

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cc: HFS-216(2) HF-22 FAP 6B4513
R/D:HFS-216:VDAnand:10/7/96:418-3081 c:\spt\6B4513.am
INIT:HFS-247:MCVanDerveer:10/8/96
HFS-226:KPMisra:10/9/96
HFS-246:LIBatarseh:10/9/96
GCF-1:CLCopp:12/11/96
F/T:HFS-215:VDAnand:sdd:1/8/97

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