DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

December 20, 2005

Mr. Richard Wiles
Senior Vice President
Environmental Working Group
1436 U Street NW, Suite 100
Washington, DC 20009

Re: Environmental Working Group's request for comment on migration information concerning E. I. du Pont de Nemours' Zonyl® RP product

Dear Mr. Wiles:

This correspondence is in response to your letter of November 15, 2005, addressed to Dr. Robert Brackett, Ph.D., Director, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration. In that letter you requested that the Food and Drug Administration (FDA) comment on the possible suppression by E. I. du Pont de Nemours (DuPont) of migration information pertaining to the use of DuPont's Zonyl® RP product. It is your contention that suppression of this information misled FDA as to the amount of Zonyl® RP which could migrate to food during its use as a coating on paper products in contact with food and that this in turn could have altered the basis of safety used to regulate this product. Your letter has been referred to the Office of Food Additive Safety for response because it involves a past food additive safety assessment.

In your letter, you state that an "allowable level (a.k.a. extraction limit)" of 0.2 parts per million (ppm) of Zonyl® RP into food was used as the basis for regulating this material for food contact use. In support of this statement you have provided an internal 1966 DuPont memorandum of a meeting between FDA and DuPont officials where a migration level of Zonyl® RP into food is discussed. You also provide an internal 1987 DuPont memorandum where Zonyl® RP is reported to migrate to food simulant at a level of 0.62 ppm. You then contend that DuPont should have provided this information to FDA as it "could have triggered a reevaluation of the safety" of this product for use in food contact applications.

Zonyl® RP was originally regulated in 1967 for food contact use under room temperature and colder conditions. As part of the petition for this use, DuPont provided information which demonstrated that Zonyl® RP was extracted into food simulants at a concentration of 0.2 ppm under conditions appropriate for simulating the use under consideration. At that time, FDA equated migration into food simulants with the concentration that would be in all foods consumed. In essence, this approach assumes that all food is packaged in paper containing Zonyl® RP. No refinement was made to account for the percentage of the diet that consists of a particular type of food (food type distribution factor) or the percentage of food packaged in a particular type of packaging (consumption factor). As such, the safety of this substance was reviewed under the assumption (based on the above

approach) that 0.2 ppm of Zonyl® RP is present in a consumer's diet; in other words, that a person consumes 0.6 mg of Zonyl® RP /day. To ensure that future use would be consistent with what was tested, FDA applied a requirement for the amount of coating that would be applied to the paper but did not require extraction testing.

The regulated use conditions for Zonyl® RP were expanded in 1972 to include use in packaging that could also hold foods at higher temperatures, including reheating and boiling water sterilization. As part of the petition for this use, DuPont provided information that a concentration of 0.94 ppm of Zonyl® RP was found in food simulants under those use conditions (as testing for boiling water sterilization is more aggressive then testing for room temperature conditions, a higher migration level is expected). By 1972, FDA had started to apply food type distribution factors and packaging consumption factors to migration information in order to model the actual exposure of a consumer to a particular food contact substance more realistically. When these factors were applied to the migration level of 0.94 ppm, the concentration in the diet was estimated to be 0.0044 ppm, or 0.013 mg/day. This level is approximately 45 times lower than the 0.2 ppm (0.6 mg/day) concentration in the diet determined to be safe in 1967.

It should be noted that the DuPont test which you provided that reports a migration level of 0.62 ppm in water was performed in 1987, after both the 1967 and 1972 regulations for Zonyl® RP became effective. Furthermore, the test reported in this 1987 memo was performed in water at 150 °F for 2 hours, conditions which were more severe then those used to regulate Zonyl® RP in 1967 (those tests were performed in water at 150 °F for 0.5 hour and cottonseed oil at 100 °F for 0.5 hour). As such, this test would be expected to result in higher migration numbers then those reported to FDA prior to 1967 and would not have been comparable to the 0.2 ppm migration level nor applicable to the use conditions regulated in 1967. In addition, the 1987 test was less severe then those used to expand the regulated uses for Zonyl® RP in 1972 (water at 212 °F for 0.5 hour followed by 24 hours at 120 °F and in cottonseed oil at 212 °F for 1 hour followed by 24 hours at 120 °F).

In conclusion, DuPont's 1987 test was not comparable to any of the tests used to regulate Zonyl® RP. Therefore, the 1987 test performed by DuPont is irrelevant to the safety determination on the use of Zonyl® RP and the company would not have been required to provide this information to FDA.

If you have any further questions concerning this matter, please do not hesitate to contact us.

Sincerely,

Laura M. Tarantino, Ph.D.
Director
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

cc: Andrew C. von Eschenbach, M.D.; Acting Commissioner, U.S. Food and Drug Administration,
Daniel R. Levinson, Inspector General, U.S. Department of Health and Human Services
Stephen L. Johnson, Administrator, U.S. Environmental Protection Agency
Walker B. Smith, Director, Office of Civil Enforcement, U.S. Environmental Protection Agency
Charles Auer, U.S. Environmental Protection Agency
U.S. Environmental Protection Agency docket # OPPT-2003-0012