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November 15, 2005

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U.S. Food and Drug Administration
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Dr. Brackett:

As the Food and Drug Administration and the US Environmental Protection Agency move forward with safety assessments for the Teflon-associated perfluorinated chemicals, we write to notify you that we have very strong reasons to believe that studies commissioned or performed by E. I. du Pont de Nemours (DuPont™), the sole manufacturer and a primary user of the perfluorochemical Zonyl, have been suppressed.

The failure by DuPont to submit these studies to a peer-reviewed journal or the relevant government agencies could have significantly altered the government's assessment of their safety. Specifically, suppression of this information would have mislead the FDA into thinking that levels of Zonyl and Zonyl breakdown-products in food were three times less than they actually were. The EPA would have been similarly mislead in its duty to ensure the safety of commercial chemicals under the Toxics Substances Control Act.

We have enclosed the documents in question for your review and request that you formally investigate whether or not DuPont™ in fact withheld them from the FDA. We further ask that you require full submission of all the relevant studies in DuPont's possession on Zonyl and related perfluorochemicals to the public record. We are submitting these documents under a separate cover to the US EPA docket #OPPT-2003-0012.

As you know, perfluorinated chemicals (PFCs) pollute the blood of over 90% of Americans, are widespread in the food supply, are some of the most persistent synthetic chemicals known, and have health risks ranging from increased cholesterol levels to reproductive and developmental effects to cancer (1-9). Zonyl products both degrade and are metabolized into PFOA, a Teflon-related chemical that was recommended for classification as a likely human carcinogen by the EPA's independent Science Advisory Board. The scientific community is increasingly focused on telomer exposure as the prime driver of PFCs in human blood due to the telomer breakdown into persistent PFCs such as PFOA in the body and environment (10, 11). Multiple agencies led by the US Environmental Protection Agency are currently investigating PFOA and other PFCs to determine the magnitude of the health hazard that they present.

The documents we are submitting (Exhibit A) show that as of 1987, DuPont™ knowingly produced Zonyl, a paper coating chemical allowed for food contact use, in a manner where the amount of Zonyl that migrated into foods (0.62 ppm) was over three times the FDA-agreed upon limits (Exhibit B). Zonyl was, and presumably still is, used as a grease and water barrier for paper food containers for hundreds of popular food items from French fry and pizza boxes to cookie and doughnut packages, candy wrappers, and microwave popcorn bags.

The allowable level (a.k.a. extraction limit) of Zonyl in food is 0.2 ppm, and this amount was the basis for the regulation set by FDA in 1967 that governs the amount of Zonyl that may be applied to papers used as food packaging and hot food containers: 0.17 lb/1000 sq ft. This is still the legal level today [21 CFR 176.170]. The enclosed document shows that DuPont knew that applying Zonyl to paper at this rate resulted in Zonyl in food at three times the level that FDA found safe in 1967 (0.62 found in 1987 vs. 0.2 established as the limit in 1967). We have very strong reasons to believe that DuPont never informed the FDA of this important finding even though it is clear that it could have had a major impact on the public health, and could have triggered a reevaluation of the safety of the Zonyl as a paper coating that leached into foods.

What makes this worse is that DuPont knew at that time that Zonyl breakdown-products, such as PFOA, in food were very persistent in the environment and were contaminating human blood, including the fetal cord blood of babies born to DuPont female employees.

DuPont has already been found guilty of withholding critical health information from the EPA, and is negotiating a settlement with the agency for violations of section 8e of the Toxic Substances Control Act. If the company withheld these critical internal company studies from the FDA it would not be surprising—it would simply be another example of a very bad pattern of behavior, where corporate hubris took precedent over fairness and protection of the public health.

We appreciate your prompt attention to the concerns we raise in this letter, and hope that the full record of PFC exposure to humans through food will soon be available to the public and other Agencies as you proceed with your assessment of human health risks posed by these chemicals.

Sincerely,

Richard Wiles
Senior Vice President

CC: 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

Andrew C. von Eschenbach, M.D., Acting Commissioner, U.S. Food and Drug Administration
Daniel R. Levinson, Inspector General, U.S. Office of Health and Human Services

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