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CC: J. Archuleta/OCC

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January 5, 1988

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TO: The SPI Vinyl Institute and The SPI Food,
Drug, and Cosmetic Packaging Materials Committee

RE: FDA to Request EPA's Current Views on
Environmental Issues in PVC Rulemaking

Ladies and Gentlemen:

In late October, we requested a meeting with Food and Drug's Commissioner Dr. Frank E. Young to discuss what more, if anything, needs to be done so that the Food and Drug Administration (FDA) can take final action on its 1986 proposed rule governing the use of polyvinyl chloride (PVC) food contact materials. Our request followed a lengthy delay in the rule-making proceedings during which FDA has been re-evaluating its original position that the rule does not warrant an environmental impact statement (EIS). The final decision on this matter is to be made by Commissioner Young.

On December 23, 1987, the Commissioner and his immediate staff met with members of FDA's Center for Food Safety and Applied Nutrition. At the conclusion of the briefing, Commissioner Young decided to seek the Environmental Protection Agency's (EPA) current views on whether significant environmental issues remain in light of all the data submitted by us to date. You will recall that it was EPA that first raised environmental impact questions in comments filed in June 1986 in response to the proposed rule. The EPA comments suggested that further study should be given to: (1) the increased use of plasticizers in PVC resins; and (2) the possibility of dioxin formation upon PVC incineration.

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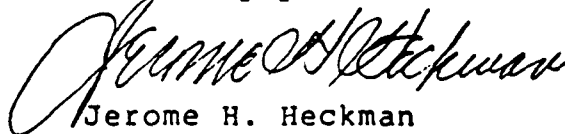
In July 1987, we met with the responsible EPA officials and presented them with data addressing those concerns. Although EPA was unwilling to commit itself in writing in the absence of a formal FDA request, it was our impression that EPA's environmental concerns were adequately settled by the information that SPI presented, including new studies on incineration of municipal solid waste and dioxin formation. Our October 23 letter to Commissioner Young included a discussion of recycling development and urged that FDA seek additional input from EPA on the environmental impact issue.

We understand that the Center for Food Safety is now preparing a letter that will formally request EPA's views. If EPA responds that its concerns have been adequately answered, this should substantially advance our position that no environmental impact statement (EIS) is required.

Please be assured that we share your frustration that the EIS issue remains unresolved at this point. Nor are we happy that the Agency took six months to decide to contact EPA after we first made that suggestion. Nonetheless, concurrence by EPA that no EIS is warranted may substantially bolster FDA's political courage to make the correct legal, scientific and socially sound decision.

We will forward copies of FDA's letter to EPA when it becomes available and will also continue pressing for prompt Agency action. In passing, I should note that we have been assured this is a matter the Commissioner's office (as distinguished from the Center for Food Safety and Nutrition personnel alone) is now addressing and that they will act expeditiously to obtain EPA's views and ultimately resolve the issue.

Cordially yours,



Jerome H. Heckman

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