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TO: All Members of:

SPI Food, Drug and Cosmetic
Packaging Materials Committee;
General Polyvinyl Chloride
Interest Mailing List;
Ad Hoc Liquor Bottle Committee;
Plastic Pipe Institute
(Executive Board);
Plastic Bottle Division
(Voting Representatives);
SPI Executive Committee;
SPI Public Affairs Committee;
VCM and PVC Producers Committee

Ladies and Gentlemen:

The October 7, 1974 issue of Food Chemical News carried an article which we have confirmed as being essentially correct noting that the Food and Drug Administration is evaluating a significant revision of its draft proposal concerning the use of polyvinyl chloride food contact plastics. The revision, as it has been described to us, since, obviously, we cannot obtain any copies of FDA's working papers, would seem to signal an important shift in the Agency's current thinking. Unfortunately, FDA appears to be moving towards a much harder line, possibly because of the type of public acceptance it has seen of OSHA's approach and a concern that it not evidence a less anti-industry or "pro-consumer" image.

In any event, we are told that the Food and Drug Administration Staff is now considering eliminating the end use test which would establish a maximum of 50 ppb of vinyl chloride in the test solvents. Instead, it is

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considering limiting single use PVC materials to 1 ppm of residual monomer, and repeated use materials such as pipe and tubing to 10 ppm residual monomer. The rationale advanced for this change in FDA thinking is that no oral toxicity exists to justify the safety of any VCM in food. Consequently, current FDA thinking is that even a level as low as the 50 ppb maximum cannot be justified by any evidence in its files with respect to safety.

Hopefully, this lack of information may be rectified to a degree by a report prepared by the Centraal Instituut voor Voedingsonderzoek (The Central Institute for Nutrition and Food Research) in Holland. This organization conducted a subchronic (90-day) oral toxicity study with vinyl chloride monomer in rats at the request of the German Verband der Kunststoffherzeugende Industrie e.V. (the German plastics industry trade association). Copies of this report have been obtained through the cooperation and courtesy of Dr. Karl Hochschwender, American Hoechst Corporation, and have been submitted to the Food and Drug Administration. We are enclosing a copy of our letter of transmittal to Dr. Schaffner; reproductions of the toxicological report sent with the letter may become available in the near future but we are not enclosing one with this letter because we have not yet received permission to duplicate to this degree. The letter to Dr. Schaffner contains a reprint from Food Chemical News which is being distributed to you with permission of the publisher.

The report indicates that vinyl chloride monomer, administered by gavage as a solution in soy oil, had a no-effect level of 20 mg/kg, and had no clearly toxic effects at levels as high as 300 mg/kg dosage levels. The difference between these two figures reflects effects noted at the higher levels in factors such as blood chemistry, liver weight, and minimal liver changes evident under microscopic examination; but the significance of these findings is not clear.

Most importantly, no evidence of carcinogenicity was detected nor were there any histopathological changes to the auditory sebaceous gland (Zymbal's gland) which is known to be one of the target organs of vinyl chloride monomer administered by inhalation.

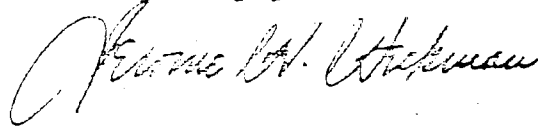
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We hope the information we have submitted to the Food and Drug Administration will be helpful in causing it to reconsider the present form of the draft proposal and perhaps revert to the form in which it had previously been cast. In any event, we shall try to follow the matter closely and keep you fully informed.

Cordially yours,

Enclosure

A handwritten signature in cursive script, appearing to read "Jerome W. Friedman".

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