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January 31, 1974

TO: All members of:
SPI Ad Hoc Liquor Bottle Committee;
BATF Mailing List;
Plastic Bottle Division (Voting Representatives);
Food, Drug and Cosmetic Packaging Materials Committee

RE: Prior-Sanctioned Polyvinyl Chloride (PVC) Resin; Proposed Rulemaking, 38 Fed. Reg. 12931, May 17, 1973.

Gentlemen:

Following up on our letter of January 29, firstly we are enclosing herewith a reproduction of page 3874 from the January 30, 1974 edition of the Federal Register. As you will note, the portion of this page which has been reproduced relates to a "Request for Information and Notice of Fact-Finding Hearing" released by the Department of Labor and actually, more specifically, the Occupational Safety and Health Administration.

The Notice is clearly designed to indicate the Government's interest in the industrial hygiene problem relative to vinyl chloride monomer, this subject having been given considerable public attention in the aftermath of the B. F. Goodrich Company January 23 Press Release we sent to you. We think it entirely proper for OSHA to have instituted this proceeding and, indeed, hope that its action will be helpful in forestalling some type of emotional reaction by any other agency, particularly the Food and Drug Administration. As noted in our earlier letter, we believe, and feel that the Food and Drug Administration Staff agrees, that the problem presented thus far is an industrial hygiene problem occurring at monomer handling or polymerization stages which should not be related to polyvinyl chloride

end products, or others based on vinyl chloride monomer.

Thus far, it has been indicated to us that the Food and Drug Administration is not planning any action as a result of the Goodrich Release. All that it is doing is preparing itself to answer any questions aimed in its direction. We think it is fair to say that every effort will be made to let inquirers know that there is no present reason to believe that the vinyl chloride monomer industrial hygiene situation presents any particular problem as regards food packaging materials or food processing equipment.

We also want to report to you that we have been in touch with our contacts at the Manufacturing Chemists Association, primarily Dr. Ken Johnson, and have been advised that MCA is making plans to submit written data and make an oral presentation responsive to the enclosed Department of Labor Request and Notice. The MCA Committee which has been dealing with the vinyl monomer matter intends to adivse OSHA about MCA's role, and all of its activities in this field including the various toxicological studies now underway. This being the case, it is our opinion that there is no need for any presentation to OSHA by The Society of the Plastics Industry. Indeed, our feeling is that any such presentation might bring about an undue tying in of the industrial hygiene problem with the status of packaging materials and other end products. We hope you will agree with this view but if anyone is of a contrary opinion, we would appreciate being so advised immediately. If a presentation to OSHA needs to be made on behalf of the Society, special efforts would have to be instituted without delay in light of the tight time situation at hand.

Again, we note that we do not believe an SPI appearance at the OSHA hearings is called for or would be advisable, particularly since we know that MCA will be handling what we consider to be the only direct problem presented. On the other hand, it has certainly occurred to us that some of the companies receiving copies of this letter may well want to participate in

the OSHA proceedings in light of their particular interests. This is one of the reasons that we thought it would be best to send you copies of the Federal Register page, thereby bringing this collateral aspect of our PVC problem to your attention.

Turning now to the status of negotiations with the Food and Drug Administration, we have finally been supplied with the promised FDA draft of the Minutes of our December 20 meeting, have discussed the same with FDA, and now anticipate that the Minutes will be placed in the public comment file in the Office of the Hearing Clerk. This will probably lead to some trade press publicity.

For your information, a copy of the FDA draft is enclosed as retyped here. In general, we found the draft satisfactory and were particularly pleased to note the third sentence where it is stated that: "Purpose of the conference was to advise SPI of that data which is considered necessary before a final decision can be made concerning the subject proposal." [Emphasis supplied]. We think you will agree that this sentence at least tends to indicate that the Food and Drug Administration will await the data it has requested before it takes any action. In the absence of any change in this plan, this would mean that the present prior sanction for PVC would remain in effect and no current usage would have to be curtailed. Since it is likely that as much as a year might be required to give the Food and Drug Administration the data it desires, the fact that the Agency will delay making any status changes pending receipt of such information is most important.

There is one other point that should be made with respect to the draft. You will note that certain language in the document has been bracketed and underlined. The reason for this is that this language represents the changes we asked FDA to make in its draft. As of this writing, we cannot say that these changes will be made verbatim, or even in any form. However, we have been promised that due consideration

will be given to them. We will probably know very shortly whether the changes suggested will be accepted and, in any event, as soon as we have a final version of the Minutes, copies will be sent to you.

Finally, we are not yet in a position to supply you with a copy of the Ad Hoc Liquor Bottle Committee Task Group's recommendations because the clearance procedures mentioned in our last letter have not yet been completed. Normally we would have preferred to have delayed writing again until this situation had been handled. However, recognizing that a bit more in the way of a delay will be necessary here, we thought it would be best to provide you with this interim report in the meantime.

We will continue to keep you fully posted on all of these matters. If you do have questions while you are awaiting further information, please do not hesitate to call or write.

Cordially yours,

Jerome N. Jackson

Enclosures