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January 29, 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) Resins; Proposed Rulemaking, 38 Fed. Reg. 12931, May 17, 1973.

Gentlemen:

Undoubtedly most of you have by now become aware of the January 23 Release made by the B. F. Goodrich Company relative to the cancer deaths of three employees involved in polyvinyl chloride operations at B. F. Goodrich's Louisville, Kentucky plant. The Release has been used as the basis for newspaper stories in the Wall Street Journal, the Washington Post, and perhaps elsewhere. It has also occasioned a considerable amount of interest on the part of the National Institute of Occupational Safety and Health (NIOSH), the Occupational Safety and Health Administration (OSHA), and the Food and Drug Administration (FDA).

Today we were advised by our contacts at the Food and Drug Administration that interest in the matter has also been expressed by Dr. Saffiotti of the National Cancer Institute. Obviously, this type of interest was to be expected and is not surprising.

For those of you who may not have seen some of the publicity on the matter, we are enclosing herewith what I am afraid are something less than completely satisfactory reproductions of the Goodrich Release, the

Wall Street Journal story, and the Washington Post report. We think you should also be advised that the Occupational Safety and Health Administration has now announced its intent to hold public hearings on this matter beginning on February 15, 1974. We are not entirely clear on OSHA's plans in this respect as of this writing but we shall probably be learning more about the matter in due course.

Actually, and as many of you know, there is a special Manufacturing Chemists Association Committee which has been dealing with the industrial hygiene aspects of the vinyl monomer problem so the likelihood is that this group will be deemed the more appropriate one for any activity relative to the OSHA hearings. The main point you might want to remember at this stage is that the problem presented is basically an industrial hygiene problem which should not, scientifically or legally speaking, carry direct implications as far as packaging materials or any other end products are concerned. This point has been emphasized to the Food and Drug Administration and we have been informed that (1) FDA realizes the true nature of the situation, and (2) has no plan to take any precipitous action unless present circumstances are changed in some way which we cannot predict.

To be a bit more blunt, it would appear that FDA will not allow the revelations of this new industrial hygiene problem to push it into untoward action with respect to the referenced rulemaking proposal now pending. To bring some of you further up to date on where we stand with the rulemaking matter--and this is something we thought should be done if for no other reason than to reduce the number of telephone inquiries to a reasonable level--we are presently awaiting receipt of the Minutes of the December 20 meeting we had with the FDA Staff, which Minutes you will recall are to be placed in the rulemaking proceeding docket so that they will be public. It has taken the Food and Drug Administration an unusual amount of time to prepare these Minutes for our review, especially since I understand that the draft we are supposed to receive in the next day or two will be brief. Nevertheless, we had no occasion to press the matter so we have been waiting patiently.

While awaiting, we have now had a meeting of the Ad Hoc Liquor Bottle Committee at which a Task Group was appointed to discuss the various toxicological questions posed by the Food and Drug Administration at the December 20 session. The Ad Hoc Liquor Bottle Committee (and please understand that this really has become a misnomer since it is PVC for packaging in general that is really at issue, not just liquor bottles) session was held on January 15 and the Task Group met in our offices on January 24. The latter Group's report is now being circulated internally and some form of it will be communicated to the Food and Drug Administration after certain clearance procedures now underway are completed. For the moment, we are not in a position to discuss with precision what is planned. All that we can really say is that the Task Group has outlined a proposed course of action which will require some time for completion if the plan is approved.

The Food and Drug Administration is generally aware of how we are proceeding and is thus far indicating its understanding of our concept, and a willingness to delay final action on the rulemaking until such time as it is advised of what more we plan to do. Moreover, we believe it is fair to say that FDA understands our efforts will probably require a reasonable amount of time (up to perhaps a year) and does not seem at all surprised or unwilling to wait for the further data that might be produced.

To summarize as best we can under these very difficult circumstances, the status of the Food and Drug Administration proceeding as of today is that FDA has no immediate plans to take action which would result in a change in the prior sanctioned status of PVC pending its receipt of further information and data. Obviously, there is no sensible way in which to anticipate Bureau of Alcohol, Tobacco and Firearm action to rescind its ban on PVC liquor bottles but the status of PVC for other packaging applications remains satisfactory for the time being.

We do want you to know that we are watching the entire problem very closely, maintaining our contacts

with FDA, and will do our best to try to make certain that scientific and legal principles govern any actions taken, instead of over-reaction to public relations considerations. Likewise, we will keep you as fully informed as we can of what is taking place. If you have specific questions pending your receipt of any further reports from us, do feel free to call or write.

Cordially yours,

Jerome H. Stickney

Enclosures