

DEC 6 1973

JOSEPH E. KELLER
JEROME H. HECKMAN
CHARLES M. MEEHAN
WILLIAM H. BORGHESE, JR.
ROBERT R. TIERNAN
WAYNE V. BLACK
DAVID L. HILL
MARTIN W. BERCOVICI
EDWIN B. SPIEVACK
PETER M. NEMKOV
JOSEPH E. HADLEY
CAROLE C. HARRIS
WILLIAM W. PUGH

LAW OFFICES
KELLER AND HECKMAN
1150 17TH STREET, N. W.
SUITE 1000
WASHINGTON, D. C. 20036

TELEPHONE
202 296-2700
CABLE ADDRESS "KELMAN"

December 3, 1973

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:

Firstly, so that your files will be as completely up to date as seems reasonable and necessary to us, we are herewith enclosing a copy of a supplementary letter we filed with the Hearing Clerk of the Food and Drug Administration today. The letter was hand-delivered and included copies of the gas chromatograms and other information referenced therein. We are not sending each of you copies of the technical data since this would involve a more massive mailing than we believe justified. If any of you feel that you need to see the chromatograms or other data, they can be obtained from us or the Office of the Hearing Clerk; in either case reproduction and mailing charges will be involved.

More importantly, at the end of last week my office was contacted by the office of Mr. Richard Ronk, Division of Food and Color Additives, of the Food and Drug Administration and a suggestion was made that a meeting would be in order to discuss the overall PVC situation. This morning I had a number of telephone conversations with FDA personnel but was only able to learn that the Staff, including especially those working on chemistry and toxicology problems, would like to explain to me and Dr. Dixler in my office the current trend of FDA thinking. We were unable to obtain any

ASI-PR 0001853

December 3, 1973

Page Two

details. On the contrary, the Staff advised that it wanted to have such a meeting simply so that we could be informed of what additional data might be desired. In light of this fact, and contrary to the advance notice I gave a few of you at the Plastic Bottle Division meeting last week, we do not believe it would be appropriate for an industry group to sit in on this first session with the Food and Drug Administration Staff.

Instead, and largely at the suggestion of Gerry McCowin in Mr. Ronk's office, we have now made a date to meet with the Staff on Thursday, December 20. Attempts were made, primarily by us, to set an earlier date but this proved impossible, or at least, unacceptable to FDA because some of its Staffers who are most concerned will not be on hand at the same time until the date indicated. Our understanding is that the Staff members who will be present to advise us on an informal basis will be Mr. McCowin, Drs. Kokowski and Misra of the toxicology group, and Messrs. Holtz and Lakata of the chemistry group. There is a chance that Mr. Ronk will also be present and past experience leads me to believe that still others might be at the session.

In any case, at this stage our strategy will be to listen to the Staff's inquiries, react to the degree possible, and then advise you as to what takes place. We have been assured that there will then be an adequate opportunity for follow-up action along whatever lines might be deemed necessary.

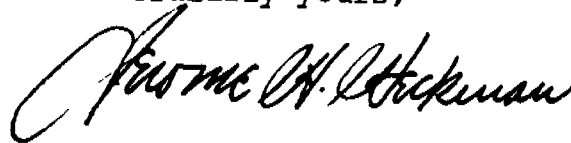
My feeling at the moment is that there may well come a time when we will want some of you to consult with the FDA Staff and us in another session but we do not believe this would be appropriate now, particularly because the Staff has not been specific in any way on what its thinking and concerns are. We realize that this letter will probably leave many of you feeling quite "up in the air" about what is taking place. Nevertheless, we do not believe over-reaction of any type is called for so we will be counting upon you to be reasonably patient in waiting for a more complete report before you become unduly concerned.

ASI-PR 0001854

December 3, 1973
Page Three

The one thing you can be certain of is that we will report to you promptly on anything we learn and will then give you our recommendations as to how we believe we should proceed.

Cordially yours,

A handwritten signature in cursive script, reading "Thomas H. Hickman". The signature is written in dark ink and is positioned below the typed name "Thomas H. Hickman".

Enclosure