B.F.Goodrich INTER-ORGANIZATION CORRESPONDENCE

| TO | FIELD POINT OR DEPT. & BLDG. NO. | DATE YOUR LETTER |
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| C. Wilkes | Brecksville | |
| **FROM** | **FIELD POINT OR DEPT. & BLDG. NO.** | **DATE THIS LETTER** |
| W.C.Bachtel | Akron - D/0020, 5-H | 4/21/81 |

SUBJECT

PVC-FDA Status

Dr. Strassburg passed Al Berens' letter concerning the FDA status of PVC to me due to my responsibilities in the FDA area. I have attempted to keep abreast of the FDA-PVC situation through the Food, Drug and Cosmetic Packaging Materials committee of the SPA and other sources. There seems to be continued confusion about the FDA status of PVC, not only within BFG, but by customers also.

The current status of PVC is quite simple; PVC is prior sanctioned by the FDA for use in general food contact applications. This includes both flexible and rigid PVC. The prior sanction is based upon an article by A.J. Lehman of the FDA in the Journal of the Association of Food and Drug Officials of the United States, July 1951. The only specifications for "prior sanctioned" PVC is that it have a maximum volatility of 3.0% (1 hour @ 105°C) and an inherent viscosity not less than 0.35 by ASTM D-1243-66, Method A.. Good manufacturing practice would also dictate that the RVCM be as low as possible.

There have been no FDA bans or restrictions on the use of PVC, rigid or flexible, for food contact applications. The only so-called ban of PVC for food contact was the rescinding by the Bureau of Tobacco Alcohol and Firearms (BTAF) of their approval of the PVC liquor bottles. This was BTAF's decision, not FDA's.

The FDA did make certain proposals in 1975 concerning the use of PVC in contact with food; however, these were only proposals and have not been acted upon as yet.

As to the future, there have been several developments that indicate the FDA will not ban the use of PVC for general food contact applications.

1. In the Supreme Court acrylonitrile decision, the court told the FDA that they had some latitude to determine what constituted a "de minimus" amount of acrylonitrile which could migrate into food. That is, the FDA could determine what constituted a "safe" amount of AN. This decision has led the FDA to consider a "constituents" or "contaminants" policy for final food contact materials.

2. The recent FDA lead acetate hair coloring regulation takes into consideration the "de minimus" concept permitting the continued use of lead acetate (an animal carcinogen) for hair coloring.

3. In recent talks, various FDA spokesmen have discussed the "constituents policy"and its application to various materials.

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4. The recently issued report by the Interagency Regulatory Liasion Group (IRLG) included a regulatory schedule for action by the FDA on PVC. It was reported that "FDA plans to publish the withdrawal of the 1975 proposal to ban rigid and semi-rigid PVC in June 1981 and replace it with a new proposal based on the contaminants policy".

5. Last month in a meeting with FDA officials concerning further clearances for Goodrite 3114, it was suggested that we include rigid and/or plasticized PVC in our list of polymers for migration studies. This suggestion would not have been made if a PVC ban was imminent.

In summary, there are no current FDA bans or restrictions on the use of rigid or flexible PVC for food contact applications. The only so-called ban was the rescinding by the BTAF of the approval of PVC liquor bottles. Consequently, with the exception of the liquor bottle, flexible, semi-rigid and rigid PVC compounds are acceptable for general food contact applications.

It is unlikely that the FDA will ban PVC for food contact applications; rather it is more likely that FDA will set limits on RVCM in such resins.

W. C. Bachtel

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cc: R.W. Strassburg
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