

TO: R. W. Seymour-Aberdeen

FGG: JCL: ERT: MTH: AJO: RF

XF: Aberdeen - C159

XXF: FDA-AVC - 0121

VISTA

FROM: J. C. Ledvina
DATE: January 17, 1991

SUBJ: ABERDEEN PLANT FDA REVIEW

Interoffice
Communication

On September 18, 1990, Bill McClain and I were at the Aberdeen Plant to review procedures and practices being used to assure production of FDA allowed PVC. Following are items noted during the review:

1. The Good Manufacturing Practices (GMP) manual was reviewed and found to be acceptable.
2. It was agreed that appropriate plant personnel should receive FDA training annually and that the training records will be kept in the Safety Department.
3. It was agreed that the Vinyl Operations Superintendent, currently John Olson, will be the person responsible to assure that changes in resin recipes or use of other substances in the resin area are adequately reviewed for FDA implications.
4. It was agreed that the resin recipes and GMP manual will be reviewed annually. The Vinyl Operations Superintendent will assure this happens.
5. EVC will be asked to provide a certificate of analysis for BUS-80. EVC should also be asked whether there are any SARA 313 chemicals in BUS-80.
6. Water and steam additives will be reviewed to assure they are FDA allowed.
7. Work will continue to assure that reactor agitator seal oil is FDA allowed or that the chance of leakage of seal oil into the reactors is negligible.
8. Storage in the current resin bag overflow storage area should be reviewed to assure there is minimal chance non-FDA resin will get shipped as FDA allowed resin.
9. The status of Isonox was discussed extensively. Isonox that is added as a reactor kill agent is part of the basic resin and can be used in sufficient quantity to accomplish its intended purpose. Isonox that is added as an antioxidant after the reaction is killed is subject to use limits as detailed in extraction studies performed on Vista rigid resin plaques by

Schenectady Chemical. Currently, all Isonox is added as a reactor kill agent. As a result, all resin, whether for rigid or flexible applications, is considered FDA allowed.

10. We discussed possible inspections of South Coast and D&S Terminals to assure practices there would not adulterate the resin. We have no reason to believe there is a problem and will consider visiting these locations.
11. It was pointed out that Vista is now selling Pacific Western PVC from the Pace, FL plant and that some of the resin may be represented as FDA allowed. JCL will contact Rick Smith and advise him of the effort at Aberdeen and ask what Pacific Western is doing.

The Plant looked great during the tour. Very clean and orderly. Give me a call if you would like to discuss any of this.



Joe Ledvina

cc: J. D. Olsen, D. C. Skokna, R. R. Smith, D. E. Knittig, J. M. Vinoski, R. B. Newton, F. G. Jeanson - Aber

D. L. Cohen, D. B. Fenton