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TO: R. W. Seymour-Aberdeen

FROM: J. C. Ledvina

DATE: January 17, 1991

SUBJ: ABERDEEN PLANT FDA REVIEW

Interoffice
Communication

VISTA

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