TGG: JCL: ERT: MJH: AJO: RF

XF: _____

TO: Distribution

FROM: J. C. Ledvina
DATE: November 6, 1989

nteroffice
:ommunication

SUBJ: MEETING NOTES - PVC/FDA

VISTA

On October 20, 1989 a meeting was held to discuss the FDA status of Vista PVC. Attendees were Bill McClain, Mike Horowitz, Ken Birck, Bruce Borsuk, Rick Smith, Diana Fenton, and Joe Ledvina.

About three years ago, Vista began a effort to secure resin business from American Hoechst. In order to get the business, Vista needed to assure Hoechst that its resin was FDA allowed. After numerous internal meetings, consultations with the law firm of Keller and Heckman, testing, and ingredient standardization at Aberdeen, it appeared that Aberdeen could supply FDA allowed resin to Hoechst. Vista began supplying Hoechst resin approximately two years ago.

During the meeting on October 20 we reviewed the rational on why Vista resin was FDA allowed. Qualifying specific ingredients, the Basic Resin Doctrine, and Good Manufacturing Practices (GMP) were discussed in detail. It was generally agreed after the discussion that Vista was producing FDA allowed resin at Aberdeen for use in rigid applications. We also agreed that there was a need to document the manufacturing practices used at the Plant to assure that the resin was not adulterated. We agreed to develop a GMP Manual as a step toward improving documentation.

Action items agreed to in the meeting were:

1. Determine if there are any residual VCM specifications for any PVC/FDA applications.

   Responsibility: JCL by 12/15

2. Ask Keller and Heckman whether there is any pending regulation on residual VCM at FDA. Also ask K&H whether steam used in steam stripping is covered by the Basic Resin Doctrine.

   Responsibility: WLM by 12/15

3. Send a letter to S&T alerting them to the need for GMP on transportation equipment and at ex-plant operations.

   Responsibility: JCL by 12/31

TO: Ken Birck-Aber

TGG: JCL FOR [illegible] RF

XF: _____

FROM: J. C. Ledvina
DATE: November 3, 1989

VISTA

interoffice communication

SUBJ: GMP GUIDANCE

As discussed in the 10/20/89 PVC/FDA meeting, following are questions Bill McClain and I believe should be addressed by the Good Manufacturing Practices Manual.

J. C. Ledvina

J. C. Ledvina

dlj

cc: T. H. Huffman, M. J. Horowitz, E. J. Meyer
R. W. Seymour, D. Skokna-Aber
D. Fenton-Austin

A

5. How do you keep lead out of the air transfer system?

Storage/Packaging

1. How do we ensure that silos and hopper cars/trucks don't contaminate or adulterate the product (e.g. didn't last contain compound/dryblend or other non-FDA materials)?

2. How are you sure we don't inappropriately label containers (e.g. labeling resin as dryblend)?

3. What procedures are used to ensure proper segregation of non-FDA allowed resins (e.g. Debox, sifter overflow, pond resin)?

4. How do you ensure that compound/dryblend additives do not contaminate the resin during packaging operations?

5. What procedures are used to segregate FDA allowed products from non-FDA allowed in the warehouse?

Shipping

1. What procedures are used to assure the product is not adulterated due to contaminated shipping containers?

2. If FDA resin is contaminated, what procedure is used to keep it segregated from FDA resin?

3. How is tampering of shipping containers in transit prevented or detected.?