

Interoffice
Communication

TO: Henrietta Lewis

TGG: JCL: FGJ: AC: AJO: RF
XF: _____

FROM: T. G. Grumbles

DATE: June 19, 1991

VISTA

SUBJ: FDA GMP FOR ALCOHOL FLAKING FACILITIES

There are no specific regulatory guidelines regarding the specifics of what is needed to comply with GMP. In general, the goal is to have practices, procedures, and, equipment that would prevent contamination of the product being processed. This would include some of the following:

1. Facility equipment that would allow segregated storage of the product.
2. Transfer lines that are free of contamination.
3. Procedures to assure handling equipment is free of contamination prior to handling the product.
4. Inspection procedures for storage equipment and product containers to detect contamination if it exists.
5. If the storage and handling equipment is to be used for other products, procedures must be in-place to assure the equipment is thoroughly cleaned and free of contamination prior to handling our product.

Let me know if you want to discuss this further.

T. G. Grumbles

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