

January 7, 2003

To: Public Docket: #95D-0349. Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, rm. 1061 Rockville, MD 20852 Reference: SUPAC-IR/MR Equipment Addendum

We would like to be consider for the following:

SUPAC-IR/MR Equipment Addendum: Coating Equipment Nature of the proposed change: Addition of Equipment Proposed class and subclass of the equipment

Class: Pan Coating

Subclass: Conventional Coating Systems
Proposed equipment listing: L.B. Bohle
Pictures and descriptions of the equipment are included

See Description, Brochure.

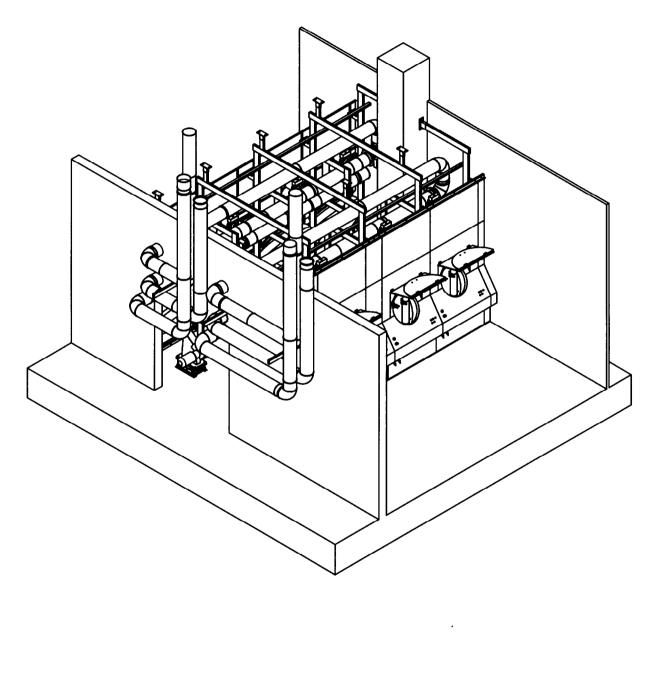
Sincerely

Rafael Navarro Project Manager

95-11-0349

RPT4





Bohle Conventional Coating System



Bohle Sugar Coating System

Description

The Bohle Sugar coating system can be build in various size banks of units. For the purpose of this quotation we design a bank of three coating panels that operate with a single air handling system. They also share a common PLC control system, but each pan has independent controls

The coaters have a strictly GMP design and are completely integrated into a stainless steel wall. All motors, gears, piping, instruments, and the pan itself are located in the Technical area behind the stainless steel wall. The coaters and air handler are designed for Class I, Division I & II environment.

The following are just some of the process parameters that are monitored and controlled by the system.

- Pan Speed
- Liquid Feed rate
- Solids Feed rate
- Air Flow
- Air Temperature
- Batch Time











Dosing unit



Technical specification, control unit

