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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: **Blending & Mixing**

Nature of the proposed change: **Addition of Equipment**

Proposed class and subclass of the equipment

Class: Diffusion Mixers

Subclass: V- Blenders

Proposed equipment listing: **L.B. Bohle**

Drawing or picture of the equipment is included

See Description, Brochure.

Sincerely

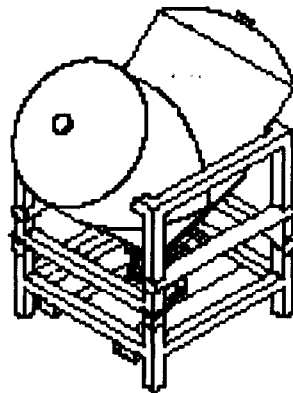
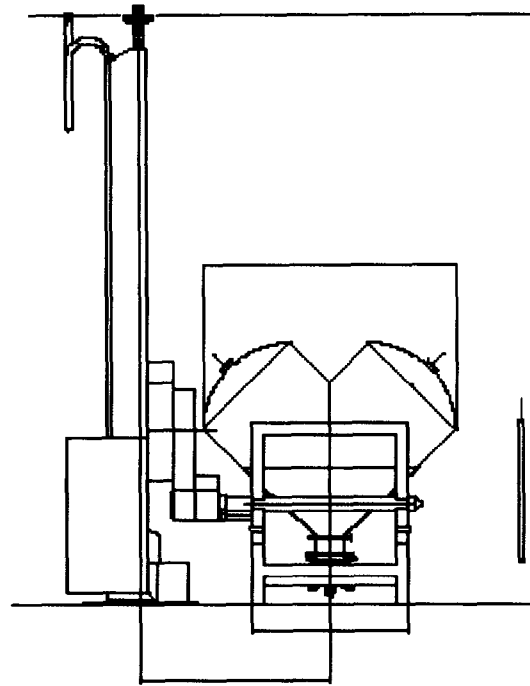
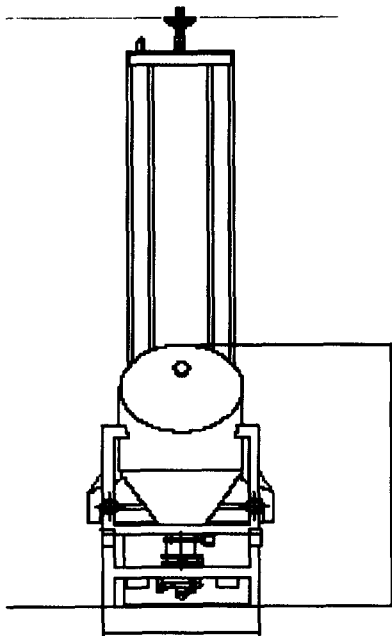
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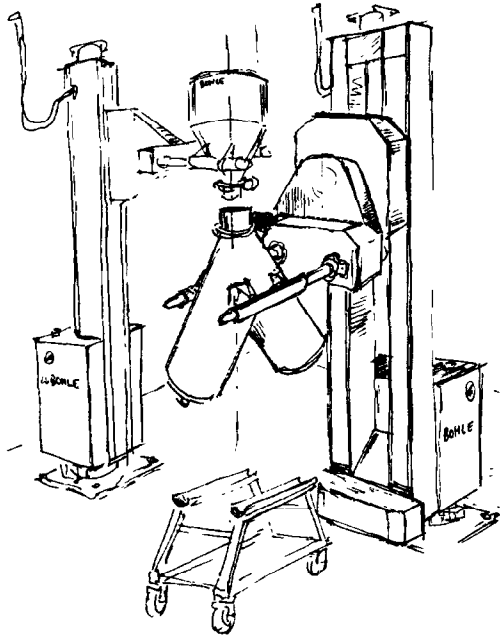
Project Manager

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RPT2

V-Shell Blending System





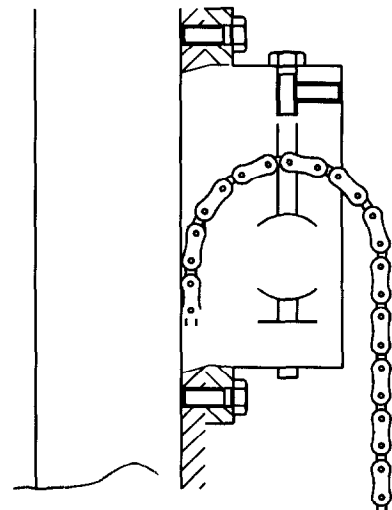
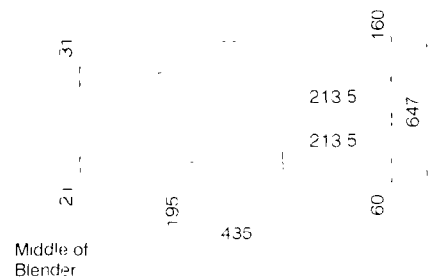
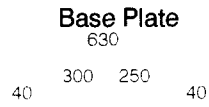
Technical Description:

The structural parts of the blender consist of:

- base plate
- column
- lifting and blending drive
- bin pick up
- control panel

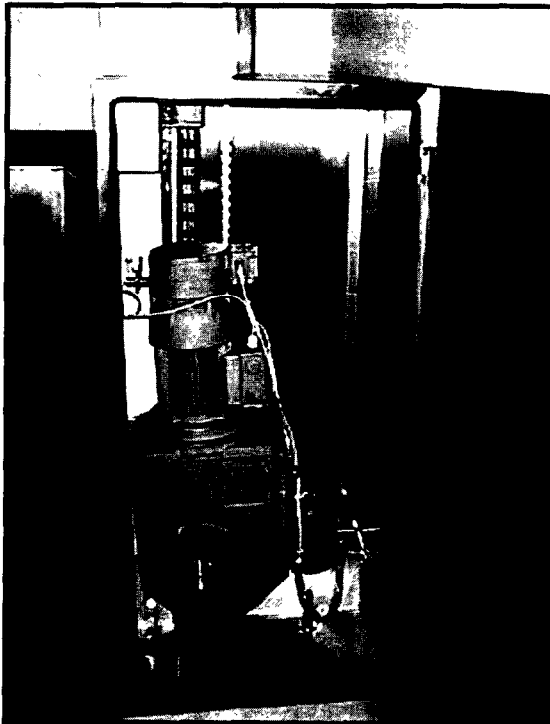
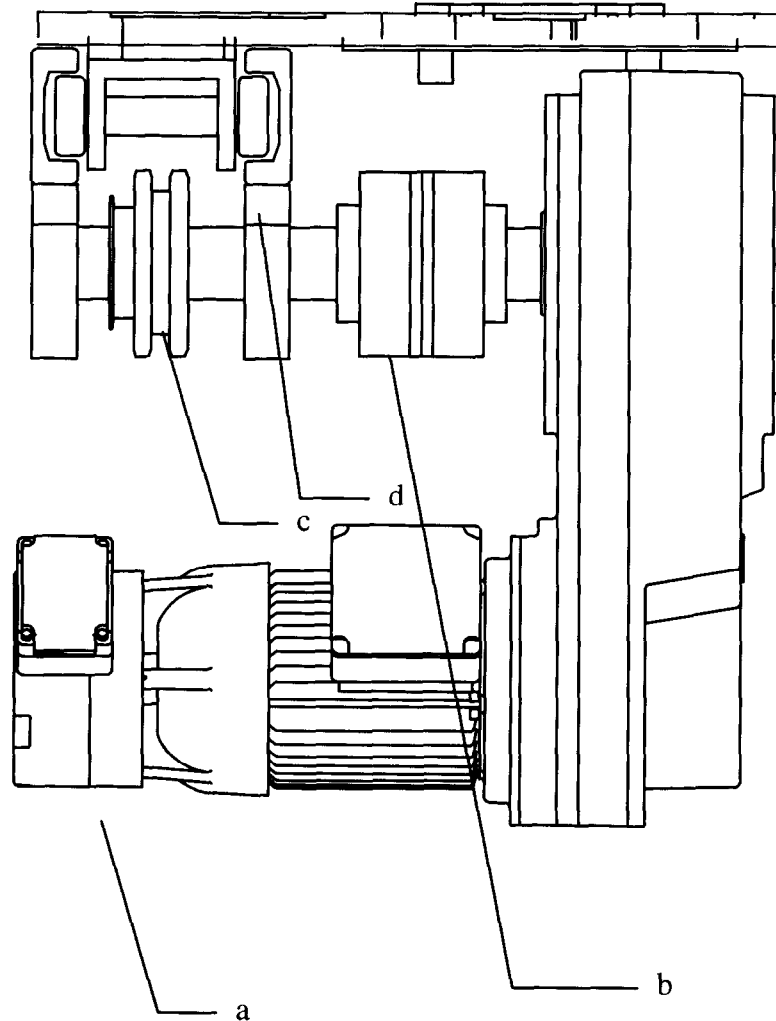
Base plate: The base plate is the main structural support of the blender. The parallel steel columns that support the blending arm are directly welded to the plate. The plate is bolted to the concrete floor via the hole pattern shown on the right. The compact structure of the blender allows for installations with minimal space requirements. The entire column can be placed on a swivel motor allowing 300 degree rotation of the column for docking the container to various other equipment. The swivel gear would be mounted directly to the base plate. (See Options)

Column: The column is a double profile construction with dual linked chains held by sprocket wheels at both top and bottom. The upper wheels are included in a tension adjustment bolts for the chain, the lower one is connected to the lifting drive. The chain is designed for (7) seven times rated load.



Lifting Drive: The lifting drive consists of an AC gear motor with electro-magnetic brake; the motor drives the shaft which is attached to the lower chain wheels. The motor, gear, and other parts of the lifting drive are completely shrouded in stainless steel. Please see the safety section for a description of the standard Bohle safety features.

- a) AC Motor
- b) Curved tooth coupling
- c) Chain Wheel
- d) Support Column



Safety: The blender should be protected by a physical barrier, such as a door or gate, that is interlocked back to the control system so if the door or gate is opened all functions in the blender cease immediately. This is the standard design and a safety relay circuit is provided to wire in a contact switch for the door or gate. As an option a light curtain can be provided to protect the blend zone. If the curtain is crossed by any object all functions of the blender cease.