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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: Conventional Mixers
Subclass: Diffusion Mixers with Intensifier
Proposed equipment listing: **L.B. Bohle**
Drawing or picture of the equipment is included
See Description, Brochure.

Sincerely

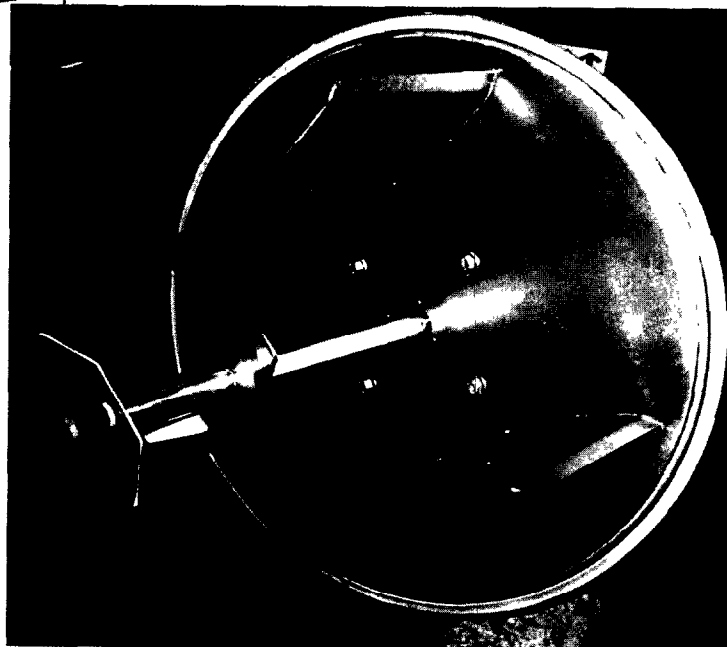
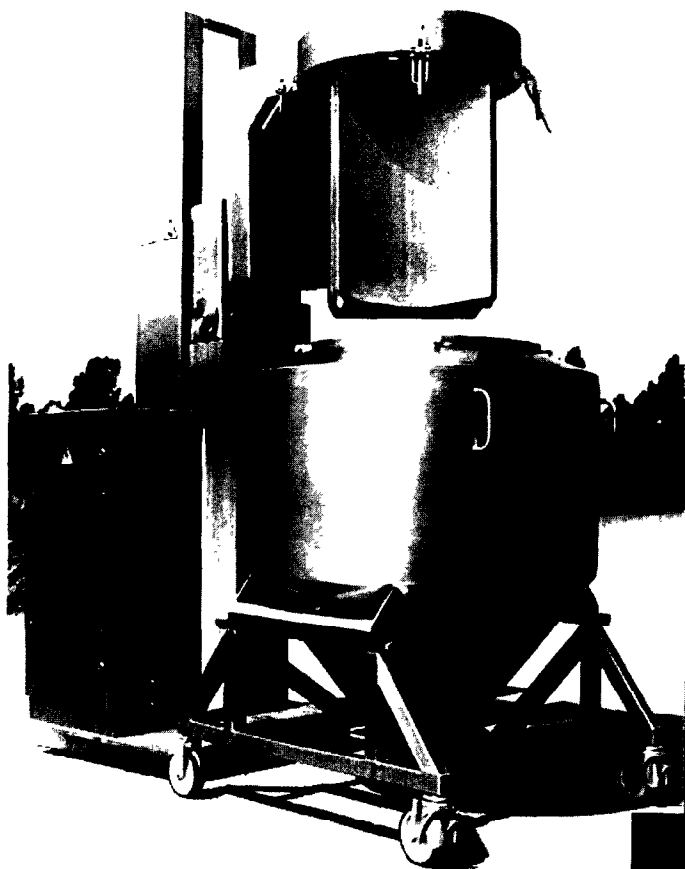
Rafael Navarro
Project Manager

95-D-0349

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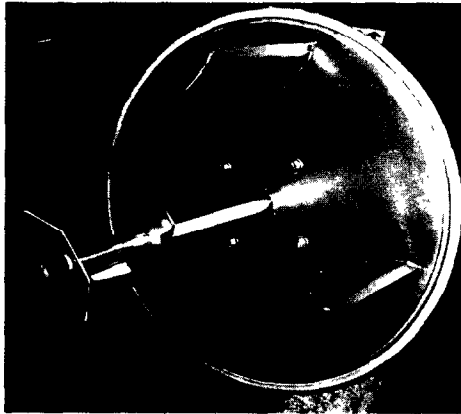
LS BOHLE

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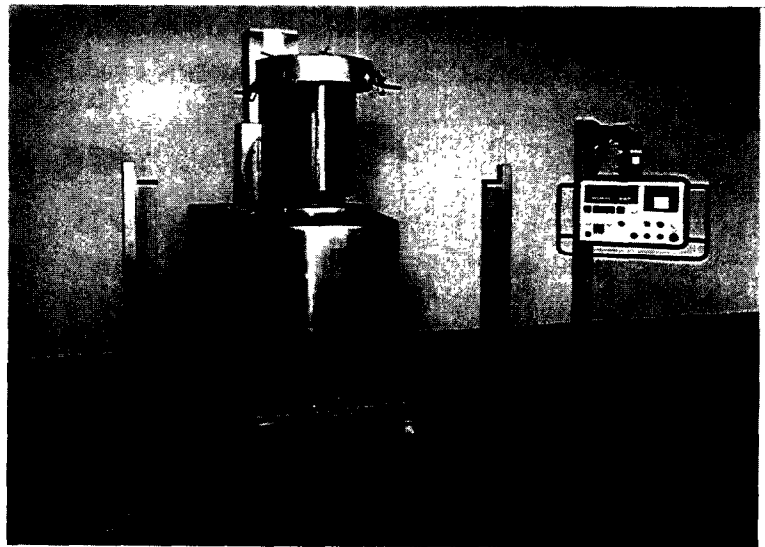
BOHLE

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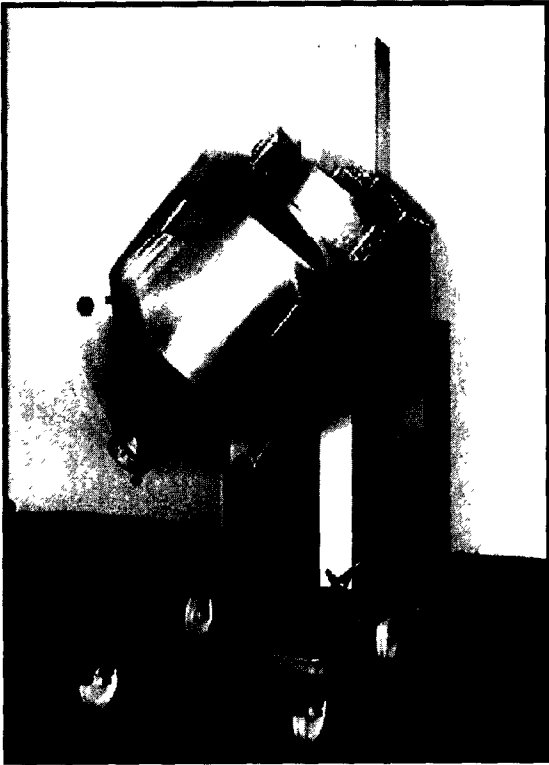


Actual Lid with Chopper Agitator

Blending: The Heart of the Bohle Blending system is the blending baffles located under the lid of each container. (Patented World Wide) The system includes a special Intensifier attached to the load arm of the Blender. This Intensifier is located between the baffles to help dissolving large granules or "chunks" of material.



When the bin is rotated for blending, the material flows between these baffles and creates a cross-current effect. (See Figure 3.) This effect allows a working volume in each bin of 20-85%. The product is blended gently at low speeds (4-6 RPMs). The bin is not tumbled, but simply rotated in a single plane, thus the dynamic forces of the blender are greatly reduced as compared to that of other bin blending technology. This allows for a much smaller footprint of the blender. It also allows the blender to act as a post hoist for lifting, swiveling and docking the bins to various other equipment after blending, i.e. tablet press, capsule filler, etc.



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 single 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.

