

NETZSCH

Incorporated U.S. Manufacturer of Industrial Equipment 119 Pickering Way Exton, PA 19341-1393 Phone. 610.363.8010 Fax. 610.363.0971

August 19, 2003

Docket Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear SUPAC Steering Committee,

NETZSCH Incorporated, a United States subsidiary of the globally operating group of NETZSCH companies, manufactures a complete line of wet grinding and dispersion and dry grinding and classification equipment. NETZSCH has been manufacturing size reduction machines for over 130 years and currently has more than 60 manufacturing and sales facilities located worldwide.

NETZSCH is interested in becoming a recommended manufacturer in your "Guidance for Industry – SUPAC IR/MR and SUPAC SS" reports. Enclosed in this packet are two complete sets of all necessary information requested by your committee. This includes:

1. Indicated Nature of Requested Change
2. Indication of how Equipment Name should appear
3. Supporting Brochures and Technical Documents
4. Specification of SUPAC documents and Unit Operations and proposed class and subclass
5. Appropriate information to determine basis for classifying equipment
6. Notes

If you have any questions about our intent, or our suggested equipment classifications, please do not hesitate to contact me directly at 610-280-1235. Thank you.

Very truly yours,
NETZSCH Incorporated



Christ Zoga
Vice President, Grinding and Dispensing

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encl:

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1. Indicated Nature of Requested Change

NETZSCH Incorporated would like to add multiple equipment names to the Guidance for Industry: SUPAC-IR/MR and SUPAC-SS Manufacturing Equipment Addendums. NETZSCH has never completed this application process and would like to pursue becoming a part of the FDA's classification guidance documents.

2. Indication of How Equipment Name Should Appear

The list below first notes the trade name of the NETZSCH machine. The second name is the name of the NETZSCH Product Group/Division that this machine is related to. NETZSCH-CONDUX® is the Dry Grinding division of NETZSCH; NETZSCH MASTERMIX is the Mixing division of NETZSCH; NETZSCH Grinding is the Wet Grinding division of NETZSCH; and NETZSCH Pumps is the Positive Displacement Pump division of NETZSCH. Our equipment names include:

- Universal Mill CUM – NETZSCH-CONDUX®
- Impact Mill CP – NETZSCH-CONDUX®
- High Density Bed Jet Mill Conjet – NETZSCH-CONDUX®
- Fluidized Bed Jet Mill CGS – NETZSCH-CONDUX®
- Hammer Mills CHM – NETZSCH-CONDUX®
- Cutting Granulator CS – NETZSCH-CONDUX®
- Classifier Mills CSM - NETZSCH-CONDUX®
- PMD-VC Disperser – NETZSCH Mastermix
- PML Planetary Mixer – NETZSCH Grinding
- DA Deaerator – NETZSCH Mastermix
- NEMO® Pumps – NETZSCH Pumps

3. Supporting Brochures and Technical Documents

Please find enclosed the General Catalog of the full range NETZSCH Grinding products. The pages that contain further information about the equipment noted in section #2 of this document is flagged.

In addition, enclosed is a specific brochure highlighting our grinding equipment used in pharmaceutical, food and personal care applications.

A number of miscellaneous grinding machines and new designs are not included in the General Catalog. For this reason, I am enclosing a number of other brochures and data sheets, specifically for the Cutting Granulator CS, Hammer Mill CHM, and High Density Bed Jet Mill Conjet.

A NETZSCH NEMO® Pump brochure is also enclosed.

The most current information about all of these machines can be found on our web site: www.netzschusa.com

4. Specification of SUPAC Documents and Unit Operation and proposed Class and Subclass for each machine

Universal Mill CUM

- SUPAC-IR/MR; Particle Size Reduction; Impact Mills; Pin/Disc
- SUPAC-IR/MR; Particle Size Reduction; Impact Mills; Hammer Air Swept
- SUPAC-IR/MR; Particle Size Reduction; Screening Mills; Rotating Impeller
- SUPAC-SS; Particle Size Reduction; Impact Mills; Hammer Air Swept
- SUPAC-SS; Particle Size Reduction; Impact Mills; Pin/Disc
- SUPAC-SS; Particle Size Reduction; Screening Mills; Rotating Impeller

Impact Mill CP

- SUPAC-IR/MR; Particle Size Reduction; Impact Mills; Hammer Air Swept
- SUPAC-SS; Particle Size Reduction, Impact Mills, Hammer Air Swept

Hammer Mill CHM

- SUPAC-IR/MR; Particle Size Reduction, Impact Mills, Hammer Conventional
- SUPAC-SS; Particle Size Reduction, Impact Mills, Hammer Conventional

High Density Bed Jet Mill Conjet

- SUPAC-IR/MR; Particle Size Reduction; Fluid Energy Mills; Tangential Jet
- SUPAC-SS; Particle Size Reduction; Fluid Energy Mills; Tangential Jet

Fluidized Bed Jet Mill CGS

- SUPAC-IR/MR; Particle Size Reduction; Fluid Energy Mills; Fluidized Bed
- SUPAC-IR/MR; Particle Size Reduction; Fluid Energy Mills; Opposed Jet with Dynamic Classifier
- SUPAC-SS; Particle Size Reduction; Fluid Energy Mills; Fluidized Bed
- SUPAC-SS; Particle Size Reduction; Fluid Energy Mills; Opposed Jet with Dynamic Classifier

Cutting Granulator CS

- SUPAC-IR/MR; Particle Size Reduction, Cutting Mills; None Identified
- SUPAC-IR/MR; Soft Gelatin Capsules; Deaggregators; Cutting Mills
- SUPAC-SS; Particle Size Reduction, Cutting Mills; None Identified

Classifier Mill CSM

- SUPAC-IR/MR; Particle Size Reduction; Impact Mills; Hammer Air Swept
- SUPAC-SS; Particle Size Reduction; Impact Mills; Hammer Air Swept

PMD-VC Disperser

- SUPAC-IR/MR; Soft Gelatin Capsules; Mixers and Mixing Vessels, High Energy
- SUPAC-IR/MR; Soft Gelatin Capsules; Mixers and Mixing Vessels, Jacketed with and without Vacuum

- SUPAC-SS; Mixing; Convection Mixers, High Shear; Dispersator
- SUPAC-SS; Emulsification; High Shear Emulsifiers; Dispersator
- SUPAC-SS; Deaeration; Deaerators; Vacuum Vessel

PML Planetary Mixer

- SUPAC-IR/MR; Soft Gelatin Capsules; Mixers and Mixing Vessels, Planetary
- SUPAC-SS; Mixing; Convection Mixers; Low Shear; Planetary

DA Deaerator

- SUPAC-IR/MR; Soft Gelatin Capsules; Deaerators, Vacuum Vessel
- SUPAC-SS; Deaeration; Deaerators; Off Line/In Line

NETZSCH NEMO® Pumps

- SUPAC-IR/MR; Soft Gelatin Capsules; Encapsulators; Positive Displacement Pump
- SUPAC-SS; Transfer; Low Shear; Screw or Helical Screw

5. Appropriate Information for Determining Basis for Classifying Equipment

For more detailed descriptions; please refer to the enclosed literature samples

Universal Mill CUM – The Universal Mill CUM is used to grind material to $d_{97}=44 \mu\text{m}$ to $d_{97}=500 \mu\text{m}$. Four different grinding tools offer the ability to grind a broad range of feed material. Interchangeability is a key feature of this mill.

Impact Mill CP – The Impact Mill CP is a unique single drive version of the classifier mill used to grind material to $d_{97}=30 \mu\text{m}$ to $150 \mu\text{m}$. Outlet particle size is controlled with a variable area classifier wheel.

High Density Bed Jet Mill Conjet – The Conjet High Density Bed Jet Mill combines a spiral jet mill design, with a patented dynamic air classifier wheel. With this combination, the NETZSCH-CONDUX® Conjet achieves high degrees of fineness independent of product loading, thereby resulting in higher throughput rates.

Fluidized Bed Jet Mill CGS – The Fluidized Bed Jet Mill CGS uses high pressure air or nitrogen to reduce friable particles of any hardness to a size of $2 \mu\text{m}$ to $70 \mu\text{m}$. Jet Mills are used primarily for hard, abrasive materials and/or temperature-sensitive materials and to achieve high fineness when steep particle size distributions are required.

Cutting Granulator CS – NETZSCH-CONDUX® Cutting Granulator CS is used to cut a wide variety of brittle and non brittle materials to less than 1000

micron. The shape and execution of the rotor body can be adapted to meet specific demands.

Classifier Mills CSM - The Classifier Mill CSM is used to grind materials up to a Mohs' hardness of 3.5. De-agglomeration is possible on products up to a Mohs' hardness of 5. Particle sizes of 8 μm to 180 μm can be achieved and tightly controlled by the built-in classifier. High volume air flows allow the processing of temperature-sensitive materials

PMD-VC Dispenser – The patented NETZSCH Mastermix PMD-VC is a totally enclosed automated dispersion processing system for batch sizes ranging from 50 - 10,000 liters and larger, for low to high viscosity dispersion and for high shear dispersion/low speed agitation. The PMD-VC furnishes high quality product, provides a cleaner and safer working environment, a lower atmospheric emission (VOC) and complete automatic control. Its optimal use is for large volume, frequent and similar product batches.

PML Planetary Mixers – NETZSCH Planetary Mixers process high viscosity pastes in the range of 1 Pascal/second to 2,000 Pascal/second. These mixers process materials that increase in viscosity during the dispersion phase without any loss in dispersion efficiency. This is due to the ability to adjust the mixing and dispersing speeds. Dispersion of extremely high viscosity products like window glue or carbon blacks is easily accomplished with the mixer's high shear energy. Dispersing very light or agglomerated powders in any liquid results in optimal degrees of fineness and distribution. The PML model is a low speed mixer with axial flow agitators that performs kneading or low energy dispersion. It is ideal for applications where the viscosity is constant, only low shear forces are necessary or materials are temperature-sensitive. The PML offers excellent results on products up to 6,000 poise or less.

DA Deaerator – The NETZSCH Mastermix De-Aerator is a versatile continuous machine used to remove air from various slurries over a wide range of viscosities. This is especially important for products requiring defoaming and when specific density requirements must be achieved. NETZSCH De-Aerators can de-gas quantities as low as 25 liters and can be fitted in-line from a bulk storage vessel.

NEMO® Pumps – NEMO® Progressing Cavity Pumps are positive displacement pumps used to convey many types of fluids and slurries while maintaining a non-pulsating, accurate metered flow. These pumps range in size from the industry's smallest metering pumps to high volume pumps designed for the most difficult pumping situations.

6. Notes

NETZSCH would like to suggest that the following additional proposed classes be added under two Unit Operations already outlined in the Equipment Classifications Addendums. These include:

- i. Fluid Energy Mills/New: Tangential Jet with Dynamic Classifier (NETZSCH-CONDUX[®] Conjet)
- ii. Impact Mills/New: Blast Mill (NETZSCH-CONDUX[®] CUM Mill with Blast Rotor)