

KORSCH America Inc.

12 K World's Fair Drive
Somerset, NJ 08873
Tel: (732) 563-4222
Main Fax: (732) 563-9499
Service/Parts Fax: (732) 868-4478
www.korschamerica.com

KORSCH

4235 '00 MAR 14 P1:47

March 6, 2000

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

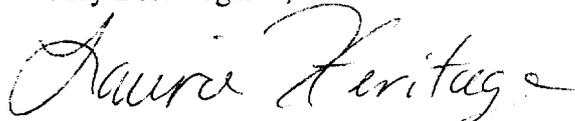
RE: Docket No. 95D-0349

To Whom It May Concern:

With regard to the Guidance for Industry web page, it was brought to my attention that KORSCH is not listed in your list of tablet press manufacturers. I have attached a printout of the section we should be listed in. Please let me know if we can be added, or what I need to do to have us added to this list.

Thank you very much.

Very Best Regards,



Laurie Heritage
Sales Administrative Assistant
KORSCH America Inc.

Enclosure

LAURIE HERITAGE
SALES ADMINISTRATIVE ASSISTANT

KORSCH America Inc.
12K World's Fair Drive
Somerset, N.J. 08873
Tel. (732) 563-4222
Fax (732) 563-9499
E-mail: laurie.heritage@korschamerica.com

KORSCH

Subsidiary of:
KORSCH PRESSEN AG
Berlin, Germany

95D-0349

C17

Guidance for Industry

SUPAC-IR/MR: Immediate Release and Modified Release Solid Oral Dosage Forms

Manufacturing Equipment Addendum

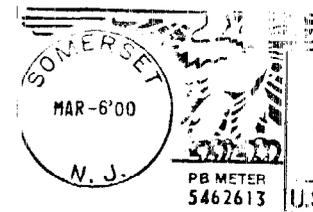
**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
January 1999**

**CMC 9
Revision 1**

Table 1 Unit Dosing

Class	Subclass	Examples
Tablet Press	Gravity	Colton (Vector) Manesty (Thomas Engineering) Stokes KORSCH
	Power Assisted	Colton (Vector) Courtroy (AC Compacting) Fette Hata (Elizabeth Carbide) Kikusui Kilian Manesty (Thomas Engineering) KORSCH
	Centrifugal	Comprima (IMA)
	Compression Coating	Manesty (Thomas Engineering) Kikusui Kilian KORSCH
Encapsulator	Auger	Capsugel Type B Elanco No. 3
	Vacuum	Perry
	Vibratory	Osaka (Sharpley-Stokes)
	Dosing Disk	H&K/ Bosch Index
	Dosator	Macofar (Romaco) MG2 Zanasi/Pharmatic/IMA
Powder Filler	Vacuum	Bosch Perry Zanasi
	Auger	All-Fill Calumatic

KORSCH America Inc.
2 K World's Fair Drive
Somerset, NJ 08873



FIRST CLASS MAIL



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