

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20939

CHEMISTRY REVIEW(S)

Table DMF List

#	Subject	Holder	Status	Review Date	Letter date
	Drug Substance		Adequate (COMIS)	Jan, 27, 1998 Norm Gregory	
	Drug Substance		Adequate (COMIS)	July 7, 1999 S. Basaran	
	Microcrystalline Cellulose		*		
	Providone K30		*		
	Hydroxypropyl-methyl cellulose		*		
	Simethicone		*		
	Eudragrit NE30D		*		
	Gelatin Capsules		*		
	Printing Inks		*		
	Bottle		*		
	Bottle Resin		*		
	Bottle Resin		*		
	Cap		*		
	Liner		*		
	Adhesive		*		
	Desiccant		*		

* Satisfactory based on ANDA 75-116 review and/or sufficient information in the application.

RELATED DOCUMENTS (if applicable):

ANDA 75-116: Review # 1 (12-24-97), Review # 2 (10-22-98), Review # 3 (7-26-99) and Review # 4 (9-7-99). ANDA 75-116 has been recommended for approval.

CONSULTS:

EER Status Acceptable

REMARKS/COMMENTS:

Biopharmaceutics has recommended following dissolution methodology and specifications:

Method USP Apparatus 1 (basket), 100 rpm, 900 mL water at 37°C.

Q spec-

ANDA 75-116 (review # 4), recently approved following dissolution specifications:

Using basket at 100 rpm, 900 mL of water at 37°C.

The applicant has agreed to Biopharmaceutics recommended dissolution specifications. Based on the recommended dissolution specifications, the applicant is required to delete USP Drug Release test number in the Description section of the package insert.

There are minor deficiencies in labeling areas. These deficiencies are described in the draft deficiencies and are incorporated in the Agency's letter to the applicant. These deficiencies are easily resolvable and should not hold approval.

Method Validation by Agency will be initiated after approval of the NDA.

CONCLUSIONS & RECOMMENDATIONS:

- Satisfactory except for labeling changes and recommended for approval. The applicant requested an expiration date of 24 months and based on the stability data a 24 months expiry date is acceptable.

CC:

HFD-110/Division File

HFD-110/Ram Mittal

HFD-110/DRoeder

HFD-810/JSimmons

R/D Init by: KSrinivasachar/

/S/

Ramsharan D. Mittal Ph.D., Review Chemist
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12-3-99