

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20582/S002

CHEMISTRY REVIEW(S)

MAR 16 1999

CHEMIST'S REVIEW	1. ORGANIZATION	2. NDA NUMBER
	DMEDP, HFD-510	20-582
3. NAME AND ADDRESS OF APPLICANT		4. SUPPLEMENT NUMBER, DATE
Organon Inc. 375 Mt. Pleasant Avenue West Orange, New Jersey 07052		S-002 11/20/98
5. NAME OF THE DRUG	6. NONPROPRIETARY NAME	USER FEE DATE: 3/27/99
Follistim	Follitropin beta for injection	
7. SUPPLEMENT PROVIDES FOR:		8. AMENDMENTS/REPORT, DATE
An alternate piece of equipment to wash, sciliconize, sterlize and dry stopper		
9. PHARMACOLOGICAL CATEGORY	10. HOW DISPENSED	11. RELATED IND/NDA/DMF
Hormone, follicle stimulating hormone	Rx	
12. DOSAGE FORM	13. POTENCY	
Lyophilized Powder	75 IU or 150 IU/vial for injection	
14. CHEMICAL NAME AND STRUCTURE.		
See Chemistry Review #1		
15. COMMENTS		
<p>This is a consult review for HFD-580. The supplement, submitted as Changes Being Effected and as one of the bundled submissions, provides for an alternate piece of equipment to wash, sciliconize, sterlize and dry stopper used for the manufacture of drug product. The bundled supplements also include: NDA 16-750 (HFD-510), NDA 13-132 (HFD-580), NDA 20-328 (HFD-580), NDA 18-776 (HFD-170), NDA 17-692 (HFD-580), NDA 17-398 (HFD-170), 20-214 (HFD-170) and two OGD ANDAs. The changes has been reviewed by the lead reviewer, Dr. M. Theodorakis of HFD-170, and was found satisfactory. As part of the chemsytry review, both the Microbiology Consult Review and Establiment Inspection Report also recommended approval of these bundled supplements (see Chemistry Review #2 dated 2/19/99 for NDA 18-776/S-024, Microbiology Consult Review dated 1/11/99, and an acceptable EER dated 12/29/98).</p>		
16. CONCLUSION AND RECOMMENDATION		
Adequate information has been provided. The supplement can be approved. Issue an approval letter.		
17. NAME	REVIEWER SIGNATURE	DATE COMPLETED
Duu-Gong Wu, Ph.D. Team Leader, DNDCII	/S/	3/16/99
DISTRIBUTION:	ORIGINAL JACKET	CSO REVIEWER DIVISION FILE

R/D INITIATED BY:

FILE NAME: 20582.s02

CC: HFD-580/MJ Rhee
HFD-510/DG Wu

Chemistry Review #2		1. Division HFD-170	2. NDA 18-776
3. Name and Address of Applicant Akzo Nobel / Organon Inc. 375 Mt. Pleasant Avenue West Orange, New Jersey 07052 Attn: Albert P. Mayor tel. 973-325-4833		4. Supplement Number Date SCM-024 11/20/98	
5. Name of Drug Norcuron for Injection	6. Nonproprietary Name Vecuronium bromide for Injection		
7. Supplement Provides for: an automated process for washing, siliconizing, sterilizing and drying elastomeric closures		8. Amendment(s)	
9. Pharmacological Category	10. How Dispensed Rx	11. Related Documents	
12. Dosage Form Injection	13. Potency 10 mg/vial, 20 mg/vial		
14. Chemical Name and Structure see USANUSP			
15. Comments On 2/12/99, Compliance provided an acceptable recommendation for the facility. See also, Chemistry Review #1 of this supplement dated 2/1/99, and Microbiology Review #1 of NDA 17-398/SCM-012, dated 1/11/99. This review pertains to the following 8 bundled supplements 13-132/ 16-750/SCM-016; 17-398/SCM-012; 17-692/SCM-013; 18-776/SCM-024 20-214/SCM-009; 20-328/SCM-003 20-582/SCM-002			
16. Conclusions and Recommendations It is recommended that approval be granted to this supplemental application. CC: NDA 18-776S-024 HFD-170M Theodorakis HFD-170ADSa <i>2/22/99</i> HFD-170SSamanta DOC.D:\WORD\REVIEWS\AKZO\18776-24.SU2			
17. Name Michael C. Theodorakis, Ph.D. Senior Review Chemist		Signature <i>/s/</i>	Date 2/19/99

Chemistry Review # 1		1. Division HFD-170	2. NDA 18-776
3. Name and Address of Applicant Akzo Nobel / Organon Inc. 375 Mt. Pleasant Avenue West Orange, New Jersey 07052 Attn: Albert P. Mayor, tel. 973-325-4833		4. Supplement Number Date SCM-024 11/20/98	
5. Name of Drug Norcuron for Injection	6. Nonproprietary Name Vecuronium bromide for Injection		
7. Supplement Provides for: an automated process for washing, siliconizing, sterilizing and drying elastomeric closures.		8. Amendment(s) BC 1/8/99	
9. Pharmacological Category	10. How Dispensed Rx	11. Related Documents	
12. Dosage Form Injection	13. Potency 10 mg/vial, 20 mg/vial		
14. Chemical Name and Structure see USAN/USP			
15. Comments This review pertains to the following 8 bundled supplements 13-132; ; 16-750/SCM-016; 17-398/SCM-012; 17-692/SCM-013; 18-776/SCM-024 20-214/SCM-009; 20-328/SCM-003 20-582/SCM-002			
16. Conclusions and Recommendations This supplemental application is not approvable. Compliance has recommended withholding approval of this application. CC: NDA 18-776S-024 HFD-170/MTheodorakis HFD-170/ADSa <i>Dec 2 at 7/2/99</i> HFD-170/SSamanta DOC. D:\WORD\REVIEWS\AKZO\18776-24.SUP			
17. Name Michael C. Theodorakis, Ph.D. Senior Review Chemist		Signature <i>jsl</i>	Date 2/1/99