CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20582/S001

CHEMISTRY REVIEW(S)

	1.ORGANIZATION	2. NDA NUMBER		
CHEMIST'S REVIEW	DMEDP, HFD-510	20-582		
3. NAME AND ADDRESS OF AP	PLICANT	4. SUPPLEMENT NUMBER, DATE		
Organon Inc.		S-001		
375 Mt. Pleasant Avenue	e	5/18/98		
West Orange, New Jerse	y 07052	, , , , , ,		
5. NAME OF THE DRUG	6.NONPROPRIETARY NAME	USER FEE DATE: 11/19/98		
Foliistism	Follitropin beta for	7		
	injection			
		8.AMENDMENTS/REPORT, DATE		
7. SUPPLEMENT PROVIDES FOR	Amendment 11/4/98			
changing the diluent from	0.45% sodium chloride to			
sterile water for injection				
9. PHARMACOLOGICAL CATEGOR		11.RELATED IND/NDA/DMF		
Hormone , follicle stir	mulating hormone Rx	DMF		
12. DOSAGE FORM	13. POTENCY	7		
Lyophilized Powder	75 IU or 150 IU/vial	7		
for injection				
14. CHEMICAL NAME AND STRU	JCTURE.			
See Chemistry Review #	1	· I · · · · · · · · · · · · · · · · · ·		

15. COMMENTS

The amendment dated 11/4/98 contains additional information requested over the phone by the reviewer and a request for wavier of bioequivalence study made by the applicant, regarding the use of a new diluent. During the telephone inquiry on 10/22/98, Organon was asked to revise the tonicity limit for the reconstituted solution and provide the test and stability results for the new diluent. Firm indicated in this amendment that the tonicity limit will be revised, however, the value was not provided. Also, the firm also referred to the DMF for the tests and specifications and the stability data for the new diluent. Although the chemistry information for the new diluent provided in DMF has been reviewed and found adequate, Organon still needs to provide acceptance tests to be performed on the diluent received from the suppliers. In a second telephone inquiry made on 11/16/98, Mr. Mayo of the Organon indicated that Organon performs acceptance tests for all materials received from outside suppliers. Also the revised tonicity has been set as - $0.25\ \text{to}\ -0.35^{\circ}\text{C}$ (freezing point depression). The information was provided in a fax on the same day and according to Mr. Mayo, a formal submission will follow(see attached). In addition, Dr. Jarugula, the Biopharm reviewer colocated with HFD-580, also indicated that the request for wavier of bioequivalence study included in this amendment is acceptable, based on the previous data provide in the original NDA. At this point, there is no more outstanding issue concerning the approval of this supplement. This chemistry review now supersedes the previous review dated 10/23/98, in which an approvable letter with information requests was recommended.

16. CONCLUSION AND RECOMMENDATION

Adequate information has been provided. The supplement can now be approved. Issue an approval letter.

17. NAME		REVIEWE	R S	IGNATUR	Œ	DATE	COMPLETED	
Duu-Gong Wu,			73	7	···			
Team Leader,				-		11	/16/98	
DISTRIBUTION:	ORIGINAL	JACKET	<u> </u>	cso	REVIEWER		DIVISION FILE	

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