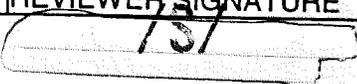


CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER for: 020182, S006

CHEMISTRY REVIEW(S)

		1. ORGANIZATION	2. NDA NUMBER
CHEMIST'S REVIEW		DMEDP, HFD-510	20-182
3. NAME AND ADDRESS OF APPLICANT		4. SUPPLEMENT NUMBER, DATE	
Sigma-Tau Pharmaceuticals, Inc. 800 S. Frederick Avenue Gaithersburg, MD 20877		SEI-006, dated 5-6-99	
5. NAME OF THE DRUG	6. NONPROPRIETARY NAME		8. AMENDMENTS/REPORT, DATE
Carnitor® Injection	levocarnitine		
7. SUPPLEMENT PROVIDES FOR:			
A revised indication to include the treatment of manifestations of carnitine deficiency in patients with End Stage Renal Disease, who are on hemodialysis.			
9. PHARMACOLOGICAL CATEGORY	10. HOW DISPENSED	11. RELATED IND/NDA/DMF	
	Rx only		
12. DOSAGE FORM	13. POTENCY		
Sterile solution for IV injection			
14. CHEMICAL NAME AND STRUCTURE.			
Levocarnitine; (3-carboxy-2-hydroxypropyl)trimethylammonium hydroxide, inner salt; C ₇ H ₁₅ NO ₃ ; 161.20 g/mol			
15. COMMENTS			
<p>This review covers the amendment dated 5-06-99, in which the firm claims a categorical exclusion for Environmental Assessment (EA), as provided for in 21 CFR § 25.31(c). This claim was filed in response to a telephone request by Ms. Maureen Hess (CSO, HFD-510), dated 5-05-99, in which Sigma-Tau was informed that, since NDA 20-182/S-006 will expand the use of the drug product (new indication), a revised EA would be required. 21 CFR § 25.31(c) states that a categorical exclusion on an NDA action will be granted ... for substances that occur naturally in the environment, when the action does not alter significantly the concentration or distribution of the substance ... According to the Merck Index (12th Edition, 1996, p. 302), carnitine is a constituent of striated muscle and liver, and is isolated from meat extract. In addition, the use in the new patient population is an Orphan designation, which, by definition, implies that the potential additional market population is quite small, and would not be expected to "significantly alter the concentration or distribution of the substance". This application meets all of the requirements of 21 CFR § 25.31(c), and the claim of categorical exclusion from Environmental Assessment is warranted.</p>			
16. CONCLUSION AND RECOMMENDATION			
Adequate information has been provided. The application is approvable, from the standpoint of chemistry, manufacture, and controls.			
17. NAME	REVIEWER SIGNATURE	DATE COMPLETED	
David B. Lewis, Ph.D.		May 20 th , 1999	
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