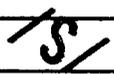


CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

**APPLICATION NUMBER
20-718/S-010**

Chemistry Review(s)

CHEMIST'S REVIEW		1. ORGANIZATION HFD-810/110	2. NDA Number 20-718
3. Name and Address of Applicant (City & State) COR Therapeutics, Inc. 256 East Grand Avenue, South San Francisco, California 94080		4. Supplement(s) Number(s) Date(s) SE2-010 June 29, 2000	
5. Drug Name Integrilin Injection	6. Nonproprietary Name eptifibatide	7. Amendments & Other (reports, etc) - Dates Amendment August 4., 2000	
8. Supplement Provides For: Request for revisions to the current product labeling because of the addition of double bolus dosing regimen based on the results of the ESPRIT clinical study.			
9. Pharmacological Category anti-thrombotic agent	10. How Dispensed Rx <input type="checkbox"/> OTC	11. Related IND(s)/ NDA(s)/DMF(s)	
12. Dosage Form(s) injection Bolus vial (2 mg/mL, 10 mL) Infusion vial (0.75 mg/mL, 100 mL	13. Potency(ies) See previous		
14. Chemical Name and Structure Cyclo (S-S)-mercaptopropyl-(L) homoarginyl-glycyl-(L) aspartyl- (L) tryptophenyl -(L) propyl -(L) cysteinamide Mol. Formula : C ₃₅ H ₄₉ N ₁₁ O ₉ S ₂ Mol. Weight: 832		15. Records/Reports Current Yes <input type="checkbox"/> No Reviewed Yes <input type="checkbox"/> No	
16. Comments: This is an efficacy supplement. There are no CMC issues involved. On our request, firm has filed a claim of categorical exclusion relating to environment assessment for this submission NDA 20-718/S-010. Mr. Michael R. Marsman, Director of Regulatory Affairs of the company, has signed the statement of compliance for this proposed action of EA exclusion criteria.			
17. Conclusions and Recommendations EA, claim for categorical exclusion for this clinical study is satisfactory.			
18. REVIEWER			
Name JV Advani	Signature 	Date Completed 4/27/01	
JVA File Name: Firm has c:\mp-rev\0718\010 R/D Init: K. Srinivasachar			



August 4, 2000

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Cardio-Renal Drug Products, HFD-110
Attention: Document Control Room
1451 Rockville Pike
Rockville, MD 20851



RE: NDA 20-718/S-010, INTEGRILIN® (eptifibatide) Injection

1. Request for Full Waiver of Pediatric Assessment Requirements

In accordance with 21 CFR, Section 314.55, COR Therapeutics Inc. (COR) hereby requests a full waiver from the requirements of 21 CFR 314.55(a) for NDA 20-718, INTEGRILIN® (eptifibatide) Injection, Supplement No. S-010. This request is based on Section 314.55(c)(2)(ii), that necessary studies are impossible or highly impractical because the number of pediatric patients undergoing the indication under review, percutaneous coronary intervention, is so small.

2. Environmental Assessment, Claim for Categorical Exclusion

In accordance with 21 CFR, Section 25.15(d), COR Therapeutics Inc. hereby files a claim of categorical exclusion relating to an environmental assessment for NDA 20-718/S-010, INTEGRILIN® (eptifibatide) Injection. The claim is based on Section 25.31(b) that the active moiety, the eptifibatide peptide, will have a concentration at the point of entry into the aquatic environment of less than 1 part per billion. A Statement of Compliance with the categorical exclusion criteria is attached.

Please contact me at 650-244-6929 if you have any questions or require additional information.

Sincerely,

Michael R. Marsman, Pharm.D.
Director, Regulatory Affairs

Desk Copy: Colleen Locicero, Project Manager

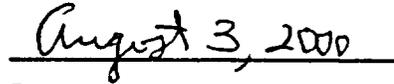
Attachment 1

**Statement of Compliance with the
Categorical Exclusion Criteria Relating to Environmental Assessment
21 CFR 25.31(b)**

The undersigned official certifies compliance with the categorical exclusion criteria 21 CFR 25.31(b) for the proposed action, filing of Supplement No. S-010 for NDA 20-718, INTEGRILIN® (eptifibatide) Injection. To the best knowledge of COR Therapeutics Inc., no extraordinary circumstances exist and the proposed action will not significantly affect the quality of the human environment.



Michael R. Marsman, Pharm.D.
Director, Regulatory Affairs



Date