Worldwide Safety & Regulatory
Pfizer Inc
401 N. Middletown Road
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Worldwide Research & Development

May 23, 2013

John Farley, MD
Acting Director
Office of Antimicrobial Products
Center for Drug Evaluation and Research
Food and Drug Administration
c/o Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

Re: NDA 21-632 for ERAXIS (anidulafungin) INJECTION

Response to PREA Non-Compliance Letter dated April 12, 2013 and Deferral Extension Request

Please refer to the Technical Annex for submission format information

Dear Dr. Farley:

The purpose of this submission is to provide our response to the PREA Non-Compliance Letter dated April 12, 2013 and a deferral extension request for the deferred pediatric study as described in the letter. This information can be found in Module 1.11.3.

As requested in the PREA non-compliance letter, subsequently a paper copy of this cover letter is being sent to the CDER Pediatric and Maternal Health Staff and a cross-reference letter is being submitted to IND 54,597.

If you have any questions about this submission, please contact me at (845) 602-5614, via fax at (845) 602-4139 or via e-mail at Melodee.Diss@pfizer.com.

Sincerely,

Melodee Diss
Senior Manager, Worldwide Safety & Regulatory
as agent for Vicuron Holdings LLC, a subsidiary of Pfizer Inc.

cc: Greg DiBernardo

Annex - Electronic Submission Technical Information

Submission Sequence Number	0058
Approximate Size of Submission	1 MB
Index/Number of Media Units Per full Set	Gateway
Electronic Media Virus Checking	The submission has been scanned using McAfee VirusScan Enterprise Version 8.8 and is virus free
Technical Point of Contact	Mike Tagliaferi Email: mike.tagliaferi@pfizer.com Tel: (484) 865-5918

US Region Submissions are assembled in compliance with version 2.01 of the US Regional Module 1 Specification and ICH v3.2.2.

All sections of the submission are being filed electronically.