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January 3, 2014

**By Hand Delivery**

Division of Dockets Management  
United States Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Lane, Room 1061 (HFA-305)  
Rockville, MD 20852

**Re: Docket No. FDA-2013-P-0283  
CSL Behring's Comments in Opposition to Hyman Phelps' Citizen Petition,  
Supplement No. 1 (containing confidential Exhibit to Comments)**

On behalf of CSL Behring LLC ("CSL Behring"), we respectfully submit this supplement to comments submitted by us on behalf of CSL Behring on November 25, 2013 in opposition to a citizen petition submitted by the law firm Hyman, Phelps & McNamara, P.C. and assigned Docket No. FDA-2013-P-0283.

Pursuant to 21 CFR 20.61(d) and prior notice to the Food and Drug Administration's ("FDA's") Division of Dockets Management, we are submitting under cover of this supplement the enclosed internal CSL Behring TEE Analysis Report (referenced in the comments as Tab 2), and are requesting that this report and its attached appendices be treated confidentially and remain exempt from disclosure.

Because this report and its attached appendices contain trade secrets and confidential commercial information, as defined by 21 CFR 20.61, that are protected from public disclosure under the Freedom of Information Act ("FOIA") and the Trade Secrets Act, CSL Behring considers them exempt from disclosure in their entirety under exemption 4 of the FOIA.

This report and its attached appendices are not for public dissemination either by posting on [www.regulations.gov](http://www.regulations.gov), through the Division of Dockets Management, or in any other manner. They are enclosed for the agency's internal and confidential use only.

Pursuant to 21 CFR 61(e), if FDA receives a request for the enclosed report or any of its attached appendices and determines that disclosure may be required, CSL Behring requests to be notified, and be permitted five (5) business days from receipt of such notice, to object to any disclosure.

January 3, 2014

Respectfully submitted,

A handwritten signature in cursive script, reading "Michael Druckman / M.D.", written in dark ink.

Michael N. Druckman  
Hogan Lovells LLP  
555 Thirteenth St., N.W.  
Washington, D.C. 20004  
(202) 637-6000

Attorneys for CSL Behring, LLC

Attachments