

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF IOWA  
WESTERN DIVISION

FARM-TO-CONSUMER LEGAL	)	
DEFENSE FUND, et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	No. CV-10-4018-MWB
	)	
KATHLEEN SEBELIUS, Secretary,	)	
United States Department of Health	)	
and Human Services, et al.,	)	
	)	
Defendants.	)	

**DEFENDANTS' STATUS REPORT OF OCTOBER 18, 2010**

Pursuant to the Court's Order of September 17, 2010, (Dkt. No. 29) (the "Order") defendants hereby submit their Status Report. In the Order, the Court exercised its discretion to refer questions regarding the application of 21 C.F.R. § 1240.61 to certain conduct to the United States Food and Drug Administration ("FDA") for an initial administrative determination under the doctrine of primary jurisdiction and the procedures contemplated by 21 C.F.R. §§ 10.25(c) and 10.60. As the first step in making such a determination, FDA has begun compiling the administrative record that forms the basis for promulgation of 21 C.F.R. § 1240.61. The documents comprising this record predate the issuance of the regulation in 1987 and are estimated to total approximately 40,000 pages. Since the issuance of the Order, FDA has dedicated considerable resources, including approximately 430 staff hours, to identifying, collecting, and assembling the documents that comprise the administrative record. It is estimated that an additional 300 hours will be needed to complete the task of

assembling the documents. FDA remains on schedule to furnish an initial administrative determination in accordance with the time frame set forth in the Order.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that I electronically served a copy of the foregoing document to which this certificate is attached to the parties or attorneys of record, shown below, on October 18, 2010.

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BY: s/ Roger Gural

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