

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. C 10-4018-MWB
)	
KATHLEEN SEBELIUS, Secretary,)	
United States Department of Health)	
and Human Services, et al.,)	
)	
Defendants.)	

DEFENDANTS' MOTION TO EXCEED PAGE LIMITATIONS

COME NOW defendants Kathleen Sebelius, in her official capacity as Secretary of the United States Department of Health and Human Services, the United States Department of Health and Human Services ("HHS"), and Margaret Hamburg, Commissioner of Food and Drugs, United States Food and Drug Administration ("FDA"), who respectfully request that this Court permit them to exceed the twenty page limitation set forth in Local Rule 7(h) with respect to the accompanying Brief in Support of Defendants' Renewed Motion to Dismiss Plaintiffs' Amended Complaint, and, in the Alternative, for Summary Judgment; and Brief on the Merits in Support of FDA's Promulgation of Challenged Regulations ("Brief") for the following reasons:

1. This case challenges regulations promulgated by FDA under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399a ("FDCA"), and the Public Health Service Act ("PHSA"), 42 U.S.C. §§ 201-300ii, and makes several claims under the Administrative Procedure Act ("APA"). On April 18, 2011, defendants filed an

administrative record in connection with the challenged regulations totaling 25,085 pages. The Brief contains a detailed discussion of this voluminous record and the associated legal issues, which takes up approximately twenty-four pages in the Brief.

2. The Brief contains a discussion of defendants' affirmative defense based on the statute of limitations. This issue is legally complex, as its resolution turns in part on whether plaintiffs' claims are to be construed as "facial" or "as applied" challenges to FDA's regulations. This discussion takes up approximately twelve pages.

3. Pursuant to the Court's Order Lifting Stay and Setting Supplemental Briefing Schedule (DR 45), dated April 1, 2011, the Brief contains supplemental briefing on defendants' pending Motion to Dismiss. This discussion takes up only eleven pages.

4. Defendants believe that it is most efficient and convenient to present the foregoing issues and arguments in a single brief. Although defendants might have filed three separate briefs (constituting a freestanding motion for summary judgment, a brief on the merits with respect to plaintiffs' APA claims, and a supplemental memorandum on defendants' Motion to Dismiss), each subject to separate page limits, defendants concluded that such an approach would be inefficient and unnecessarily burdensome for this Court.

In conclusion, given the numerous complex issues to be addressed, each of which warrants a detailed explanation, defendants respectfully submit that an additional thirty-five pages (totaling fifty-five pages) are necessary and will assist this Court in evaluating the merits of the case.

WHEREFORE, defendants respectfully request that the Court grant its Motion to Exceed Page Limitations with respect to the accompanying Brief.

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 May 11, 2011.

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