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 MARCH 16, 2011

Pursuant to the Court's Order of September 17, 2010, (DR¹ 29) (the "Order") defendants hereby submit their Status Report advising the Court of further proceedings defendants contend are necessary and appropriate in this case. Attached herewith is the Food and Drug Administration's ("FDA") administrative determination on the three questions referred to it by the Court in the Order. <u>See</u> Ex. A.

In its Memorandum and Opinion Order Regarding Defendants' Motion to Dismiss, (DR 27) (the "Opinion") the Court denied without prejudice defendants' challenges to subject matter jurisdiction, denied defendants' administrative exhaustion claims, and reserved ruling on whether plaintiffs' complaint failed to state a claim upon which relief can be granted. Opinion at 25. The Court stayed further proceedings pending an administrative determination by FDA. Order at 3.

¹ "DR" refers to the docket report.

Defendants suggest the most economical and expeditious way to reach a final disposition of the case would be for the parties to file supplemental motions and briefs as to defendants' Motion to Dismiss. Through such supplemental briefing, the outstanding issues from the Motion to Dismiss may be resolved. Furthermore, defendants propose to file the administrative record with respect to the adoption of 21 C.F.R. § 1240.61 and § 131.110 by April 18, 2010, which would allow defendants to move, in the alternative, for summary judgment regarding the merits of plaintiffs' pre-enforcement challenges to those regulations under the Administrative Procedure Act, 5 U.S.C. § 701 et seg., and to present any affirmative defenses.

Defendants expect to be ready to file their supplemental brief and motion by May 11, 2011, and, unless otherwise agreed to by the parties, would propose that plaintiffs submit their supplemental resistance on June 10, 2011, with defendants filing their reply on July 1, 2011.

Respectfully submitted,

STEPHANIE M. ROSE United States Attorney

Lawrence Kudej
Assistant United States Attorney
401 First St. SE, Suite 400
Cedar Rapids, IA 52401-1825
319-363-6333
319-363-1990 (fax)
Larry.Kudej@usdoj.gov

By: /s/ Roger Gural
ROGER GURAL
Trial Attorney
Office of Consumer Litigation
Department of Justice
Civil Division
P.O. Box 386
Washington, D.C. 20044
202-307-0174
202-514-8742 (fax)
roger.gural@usdoj.gov

Of Counsel:

SALLY A. HOWARD Acting General Counsel

RALPH S. TYLER Chief Counsel Food and Drug Division

ERIC M. BLUMBERG Deputy Chief Counsel, Litigation

THOMAS J. COSGROVE Associate Chief Counsel United States Department of Health and Human Services Office of the General Counsel 10903 New Hampshire Avenue Building 32, Room 4330 Silver Spring, MD 20993-0002 (301) 796-8613

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 March 16, 2011.

UNITED STATES ATTORNEY

BY: s/ Roger Gural

COPIES TO:

David G. Cox (OH Sup. Ct. No. 0042724) 4240 Kendale Road Columbus, OH 43220

Wallace L. Taylor 118 3rd Avenue, S.E. Cedar Rapids, IA 52401-1210