STUART F. DELERY
Acting Assistant Attorney General
MAAME EWUSI-MENSAH FRIMPONG
Deputy Assistant Attorney General
MICHAEL S. BLUME
Director, Consumer Protection Branch
GERALD C. KELL
Senior Trial Counsel
Consumer Protection Branch
U.S. Department of Justice
P.O. Box 386
Washington, DC 20044
Tel: (202) 514-1586
Fax: (202) 514-8742
Email: gerald.kell@usdoj.gov

Attorneys for Defendant

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION

CENTER FOR FOOD SAFETY, *et al.*, Plaintiffs, v. MARGARET HAMBURG, M.D., Defendant.	No. 12-cv-04529 PJH DEFENDANT'S MOTION FOR RECONSIDERATION OR STAY Date: August 28, 2013 Time: 9:00 a.m.

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that on August 28, 2013, at 9:00 a.m., before the Honorable Phyllis J. Hamilton of the United States District Court for the Northern District of California, defendant will move the Court for reconsideration of its order of June 21, 2013, (Doc. 63) as it applies to two of the seven rulemakings at issue in this case, the sanitary transport rule and the intentional adulteration rule. In the alternative, defendant will move the Court to stay its order

with respect to those rulemakings pending a decision by the Solicitor General whether to authorize an appeal in this case.

ISSUES TO BE DECIDED

1. Whether the Court should reconsider and amend its order of June 21, 2013, with respect to the sanitary transport rule.

2. Whether the Court should reconsider and amend its order of June 21, 2013, with respect to the intentional adulteration rule.

3. Whether the Court should stay its order of June 21, 2013, with respect to the sanitary transport rule.

4. Whether the Court should stay its order of June 21, 2013, with respect to the intentional adulteration rule.

INTRODUCTION

The government respectfully moves this Court under Federal Rule of Civil Procedure 59(e) for reconsideration of its opinion and order of June 21, 2013, as it applies to two of the seven rulemakings at issue in this case. In the alternative, the government asks the Court to stay its order pending the Solicitor General's determination whether to authorize an appeal.

The Court granted summary judgment for plaintiffs and ordered the United States Food and Drug Administration (FDA) to publish proposed rules by November 30, 2013, with final rules to follow no later than June 30, 2015. Although FDA respectfully continues to disagree with the Court's reasoning, it is allocating its resources so as to be able to publish the rules at the earliest possible time. The agency has already published two of the proposed rules, *see* 78 Fed. Reg. 3504 (Jan. 16, 2013); 78 Fed. Reg. 3646 (Jan. 16, 2013), and it is currently on track to

publish three more proposed rules by November 30. Despite the agency's efforts, however, it cannot publish proposed rules governing intentional adulteration and sanitary transport by November 30 in a manner that would be consistent with Congress' substantive objectives in enacting the FDA Food Safety Modernization Act (FSMA), Pub. L. No. 111-353, 124 Stat. 3885 (2011). The declarations of Michael R. Taylor, FDA's Deputy Commissioner for Foods and Veterinary Medicine, explain the agency's efforts and the circumstances that prevent publication of these proposed rules by November 30.

STATEMENT

The Food Safety Modernization Act directed FDA to promulgate a variety of rules addressing diverse but interrelated issues of food safety, including the seven rules at issue in this litigation. The statute allocated limited time for accomplishing these disparate tasks, requiring FDA to promulgate seven proposed or final rules within 18 months of the enactment of the statute. Plaintiffs filed suit against FDA under the Administrative Procedure Act (APA), 5 U.S.C. § 706, in August 2012—less than two months after the date indicated in the statute. FDA has been working diligently toward promulgation of the FSMA rules, giving due consideration to the competing interests in proceeding expeditiously and promulgating rules carefully calculated to achieve Congress' purpose of implementing effective and efficient food safety procedures and standards.

FDA urged that judicial intervention was unwarranted based on consideration of the factors identified in *Telecommunications Research & Action Center v. FCC (TRAC)*, 750 F.2d 70, 80 (D.C. Cir. 1984). *TRAC* directs courts to consider not only the statutory timetable but also the implications of delay for human health and welfare, the effect on other agency priorities, any

interests prejudiced by the delay, and whether the agency is acting in good faith. *Id.*; *see also Brower v. Evans,* 257 F.3d 1058, 1070 (9th Cir. 2001) (applying the *TRAC* analysis in assessing the reasonableness of agency delay); *Independence Mining Co. v. Babbitt,* 105 F.3d 502, 507-11 (9th Cir. 1997) (considering the *TRAC* factors in determining whether injunctive relief was warranted). FDA explained that these factors, on balance, support the reasonableness of the agency's action in this case and its continuing efforts to promulgate these rules.

On April 22, 2013, the Court granted plaintiffs' motion for summary judgment, holding that "because the FMSA includes specific deadlines, the failure to comply with those deadlines constitutes a failure to act under the APA" and no balancing of the *TRAC* factors is necessary or appropriate. S.J. Op. at 8-9 (Doc. 57) (internal quotation marks and citation omitted). While noting that "'a statutory violation does not always lead to the automatic issuance of an injunction,'" the court concluded based on the existence of statutory deadlines that an injunction was necessary to effectuate Congress' purpose. *Id.* at 9 (quoting *Biodiversity Legal Found. v. Badgley*, 309 F.3d 1166, 1177 (9th Cir. 2002)). The Court then ordered the parties to submit a joint statement setting forth proposed deadlines. *Id.* When the parties were unable to reach consensus, the Court ordered FDA to publish notices of proposed rulemaking (NPRMs) for all seven rules by November 30, 2013, with final rules to follow by June 30, 2015. FDA had no opportunity before the Court's order issued to respond to plaintiffs' proposed schedule and its unsupported suggestion that all seven rules should be published on the same compressed timeline.

DISCUSSION

I. Reconsideration Is Warranted Because the Court's Remedial Analysis Did Not Consider Differences Among the Rules, and the Resulting Schedule for the Sanitary Transport and Intentional Adulteration Rules Is at Odds with Congress' Purpose of Promoting Food Safety

Courts have been extremely reluctant to interfere with pending agency action, particularly where, as here, the agency has demonstrated good faith in working toward finalization of the action at issue. *See W. Coal Traffic League v. Surface Transp. Bd.*, 216 F.3d 1168, 1176 (D.C. Cir. 2000); *In re Barr Labs., Inc.*, 930 F.2d 72, 74 (D.C. Cir. 1991). This reluctance reflects the courts' recognition that agencies must exercise expert judgment in drafting and promulgating the rules for which they are responsible and that the exercise of this responsibility often requires agencies to allocate limited resources among competing priorities. Requiring FDA to act before it has the opportunity to collect and evaluate the information necessary for reasoned decision-making threatens to compromise Congress' purpose in enacting FSMA. FSMA's deadlines reflect Congress' intent that FDA act expeditiously, but nothing in the Act suggests that Congress intended expediency at the expense of substantive results.

FSMA for the first time gave FDA explicit authority to require comprehensive, science-based preventive controls across the food supply. To establish a new regulatory scheme, FDA must "build a cohesive, integrated system of regulatory controls" in which each regulation "must be coordinated with other regulations." First Decl. of Michael R. Taylor (First Decl.) (Doc. 23-1) ¶ 9. "Since the enactment of FSMA, several hundred employees have devoted all or some of their time to working on FSMA projects, from rulemakings to inspection pilot projects to development of IT systems." *Id.* ¶ 17.

Because "these rulemakings draw upon the same specialized agency resources, the agency could not staff the simultaneous development of all seven rules." Third Decl. of Michael R. Taylor (Third Decl.) (submitted herewith) ¶ 5. "FDA selected four rules that would be in the 'first wave': Preventive Controls (PC) for Human Food; Produce Safety Standards; Foreign Supplier Verification Program; and PC for Animal Food. These rules were selected to be in the first wave because they are foundational for other rules and offer the most public health benefits." First Decl. ¶ 18; *see also* Third Decl. ¶ 5.

Proceeding according to this plan, on January 16, 2013, FDA published NPRMs for preventive controls for human food, 78 Fed. Reg. 3646, and produce safety standards, 78 Fed. Reg. 3504. The agency expects to publish NPRMs for three of the other rules—the foreign supplier verification program, third-party accreditation, and preventive controls for animal food—by November 30, 2013. For the reasons discussed, the challenges posed by the intentional adulteration and sanitary transport rulemakings preclude issuance of proposed rules by that date.

The Sanitary Transport Rule

At the time FSMA was enacted, FDA was evaluating the data and information received in response to an earlier Advance Notice of Proposed Rulemaking (ANPRM) for the sanitary transport rule. Relying on information obtained in response to the ANPRM, the agency working group has now completed a first draft of the proposed rule and "projects that it will be able to publish this proposed rule by January 31, 2014." Third Decl. ¶ 19. The agency has explained the steps it must complete in the intervening period. First, "FDA must reach final decisions at the senior leadership level on complex policy and legal issues with respect to the approach taken

in and the scope of the proposal (e.g., what entities and activities should be covered)." *Id.* ¶16. "Second, FDA must complete a draft 'regulatory impact analysis'—the economic analysis that is required by executive order to accompany significant regulatory actions." *Id.* ¶ 17. "Third, the proposed rule and draft economic impact analysis must undergo Department of Health and Human Services (HHS) and interagency review" pursuant to Executive Order 12866, which establishes a standard 90-day period for interagency review coordinated by the Office of Information and Regulatory Affairs in the Office of Management and Budget. *Id.* ¶ 18. As the foregoing shows, FDA is continuing to proceed responsibly with a complex undertaking that predated enactment of FSMA, and there is no basis on which to truncate the agency's completion of that task.

The Intentional Adulteration Rule

Issuing regulations to protect against the intentional adulteration of food under 21 U.S.C. § 350i(b) poses even more significant challenges. FDA is tasked with identifying vulnerable points in the food supply chain and establishing science-based mitigation strategies to address a broad range of vulnerabilities. Third Decl. ¶ 6. Indeed, although FDA currently intends to address intentional adulteration in an integrated rulemaking, the statutory mandate actually encompasses several related areas, and "the multi-faceted nature of this rulemaking . . . adds to its already substantial complexity." *Id.* "The regulations are to include those foods for which the Secretary has identified clear vulnerabilities (including short shelf life or susceptibility to intentional contamination at critical control points) and that are in bulk or batch form, prior to being packaged for the consumer," and they will also address preventive controls and produce safety standards as they apply to intentional adulteration. *Id.*

The rulemaking will involve "the development of novel requirements without clear regulatory precedent or models because the prevention of intentional adulteration is an area in which FDA has not previously regulated." *Id.* ¶ 7. Among other things, it will be necessary "to develop criteria for when preventive controls are appropriate (i.e., the level of vulnerability of the points in the food supply chain that warrants action) and identify acceptable mitigation measures, which could encompass a range of activities." *Id.* To accomplish this task effectively, "FDA will need additional information to enable it to ascertain, among other things, 'the best available understanding of uncertainties, risks, costs, and benefits.' 21 U.S.C. § 420(a)(1)(B)." *Id.* As the Taylor Declaration notes, "[t]o date, preventive controls against intentional adulteration have been voluntary, so the existing risk/benefit analyses in this area have not previously been publicly evaluated or weighed, and the task will be challenging and time-consuming." *Id.*

To promulgate a fully considered rule that would survive judicial scrutiny in an APA challenge, FDA has developed a draft ANPRM, which is undergoing review within FDA at this time. *Id.* ¶ 8. The ANPRM will seek information as to "how industry currently assesses vulnerability, measures industry currently employs against intentional adulteration, and whether those measures are preventive for both intentional and unintentional adulteration." *Id.* ¶ 9. Information relevant to an accurate cost/benefit analysis "is not readily available in the public arena, in part because much of it is sensitive, proprietary and confidential." *Id.* To "issue the ANPRM, collect comments, and thoroughly review and consider the comments before developing a proposed rule," *id.* ¶ 10, will require a period well beyond the November 30 date included in this Court's order. Although the agency is committing its resources to development

of the rule, it cannot realistically expect to issue the proposed rule until the second half of 2015. *Id.*

"If the agency were required to comply with the November 30, 2013 deadline for issuing a proposed rule on intentional contamination, it would need to immediately develop a proposed rule without the input of information and ideas that the agency has determined it needs." *Id.* ¶ 11. Given the current dearth of information and the limited amount of time provided by the Court for developing a proposal, there is a real risk that FDA would issue a proposed rule that does not properly assess vulnerabilities and potential health risks, fails to consider available mitigation strategies, or inadequately considers the costs and benefits of those strategies. *Id.* If these shortcomings result, FDA might be required to issue a subsequent, revised proposal for the rule, with a second public comment period, thereby extending the time needed for promulgating a final rule. Full consideration of the relevant information and available approaches is necessary to achieving a good result. A process calculated to achieve sound results furthers the public's interest in food safety and avoids an inefficient use of FDA's limited rulemaking resources.

FDA "is in a unique—and authoritative—position to view its projects as a whole, estimate the prospects for each, and allocate its resources in the optimal way." *In re Barr Labs.*, 930 F.2d at 76. Exercising its expert judgment, FDA has explained that additional time is needed to promulgate NPRMs for the intentional adulteration and sanitary transport rules. "Where, as in this case, there is no evidence (or indeed, allegation) of bad faith on the part of the agency, and the agency has demonstrated a reasonable need for delay, [the court] ha[s] no reason to think that judicial intervention would advance either fairness or Congress's policy objectives." *Western Coal*, 216 F.3d at 1176 (internal quotation marks omitted).

II. In the Alternative, the Court Should Stay Its Order Pending the Solicitor General's Determination Whether To Authorize an Appeal

In the alternative, the government respectfully asks this Court to stay its order and judgment requiring FDA to publish proposed intentional adulteration and sanitary transport rules by November 30 pending the Solicitor General's determination whether to authorize an appeal,[1] and, in the event an appeal is authorized, during the pendency of the appeal. The agency has described its commitment of resources to issuing these two rules and has explained why it cannot responsibly issue the proposed rules on the same schedule as the other five rules that are the subject of this suit.

It would not further Congress' purpose or the public interest to compel issuance of regulations on a schedule that is not viable. Requiring FDA to set aside other priorities to promulgate an underdeveloped proposal also represents a misuse of limited agency resources. Because plaintiffs share the public's interest in promoting food safety and protecting the public health—interests that will be best served by responsible agency action—a stay of the deadlines for the intentional adulteration and sanitary transport rules pending appeal would be consistent with, rather than detrimental to, their interests.

CONCLUSION

For the foregoing reasons, the Court should grant the government's motion for reconsideration or, in the alternative, grant the government a stay pending appeal.

[1] The Solicitor General is charged with determining "whether, and to what extent, appeals will be taken by the Government to all appellate courts." 28 C.F.R. § 0.20.

Respectfully submitted,

STUART F. DELERY
Acting Assistant Attorney General

MAAME EWUSI-MENSAH FRIMPONG
Deputy Assistant Attorney General

MICHAEL S. BLUME
Director
Consumer Protection Branch

/s/ Gerald C. Kell
GERALD C. KELL
Senior Trial Counsel
Consumer Protection Branch
U.S. Department of Justice
P.O. Box 386
Washington, DC 20044
Tel: (202) 514-1586
Fax: (202) 514-8742
Email: gerald.kell@usdoj.gov

Attorneys for Defendant

Of Counsel:

WILLIAM B. SCHULTZ
Acting General Counsel

ELIZABETH H. DICKINSON
Associate General Counsel
Food and Drug Division

ANNAMARIE KEMPIC
Deputy Chief Counsel, Litigation

KAREN SCHIFTER
Senior Counsel
U.S. Dept. of Health & Human Services
Office of the General Counsel
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002