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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION

CENTER FOR FOOD SAFETY, *et al.*, *Plaintiffs*, v. MARGARET A. HAMBURG, M.D., *Defendant*.	Case No.: 12-cv-04529-PJH **CONSENT DECREE**

WHEREAS on January 4, 2011, Congress enacted the Food Safety Modernization Act (FSMA) to address the ongoing epidemic of foodborne illness in our country, which strikes one

in six Americans annually;

WHEREAS Congress set deadlines for the Food and Drug Administration (FDA) to promulgate and finalize FSMA's implementing regulations, and FDA did not meet those deadlines;

WHEREAS Plaintiffs Center for Food Safety and Center for Environmental Health (Plaintiffs) filed this action on August 29, 2012, alleging that FDA had violated FSMA and the Administrative Procedure Act (APA) by unlawfully withholding the FSMA regulations beyond the required statutory deadlines, and seeking declaratory and injunctive relief requiring FDA to issue the regulations pursuant to a court-ordered timeline;

WHEREAS the Court granted Plaintiffs' Motion for Summary Judgment and denied FDA's Motion for Summary Judgment, and held that declaratory and injunctive relief were appropriate, *see Ctr. for Food Safety v. Hamburg*, No. C 12-4529 PJH, 2013 WL 1741816 (N.D. Cal. Apr. 22, 2013);

WHEREAS the Court acknowledged "FDA's showing of the complexity of the task, which involves making major modifications to procedures for food inspections and food handling, and its showing of diligence in attempting to discharge its statutory duty to promulgate regulations," *Ctr. for Food Safety v. Hamburg*, No. C 12-4529 PJH (N.D. Cal. June 21, 2013);

WHEREAS the Court nevertheless crafted a close-ended timeline for completion of the FSMA regulations, *Ctr. for Food Safety v. Hamburg*, No. C 12-4529 PJH (N.D. Cal. June 21, 2013);

WHEREAS the Court subsequently denied FDA's motions for reconsideration and a stay pending appeal, *Ctr. for Food Safety v. Hamburg*, No. C 12–4529 PJH, 2013 WL 4396563, (N.D. Cal. Aug. 13, 2013) and *Ctr. for Food Safety v. Hamburg*, No. C 12-4529, 2013 WL 5718339 (N.D. Cal. Oct. 21, 2013);

WHEREAS FDA appealed the decision;

WHEREAS the Ninth Circuit's Motions Panel denied in pertinent part FDA's emergency motion for a stay pending appeal, *Center for Food Safety v. Hamburg*, No. 13-16841, (9th Cir. Nov. 4, 2013);

WHEREAS the Parties agree that resolution of this matter without further litigation is in the best interest of the Parties and the public, and that entry of this Consent Decree is the most appropriate means of resolving this action.

NOW, THEREFORE, upon consent of the Parties, and upon consideration of the mutual promises contained herein,

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

I. GENERAL TERMS

1. This Consent Decree applies to, is binding upon, and inures to the benefit of the Parties (and their successors, assigns, and designees).

2. The Parties to this Consent Decree understand that Margaret Hamburg was sued in her official capacity as Commissioner of the United States Food and Drug Administration, and that obligations arising under this Consent Decree are to be performed by FDA and not Margaret Hamburg in her individual capacity.

II. DEFINITIONS

3. Whenever terms listed below are used in this Consent Decree, the following definitions shall apply:

a. "Complaint" means the complaint filed in this case by the Center for Food Safety and the Center for Environmental Health on August 29, 2012 to initiate the lawsuit titled above.

b. "Consent Decree" means this document.

c. "FDA" means the United States Food and Drug Administration and/or the Defendant in this action, Margaret Hamburg, Commissioner of the United States Food and Drug Administration, or her duly authorized representative.

d. "Plaintiffs" means the Center for Food Safety and the Center for Environmental Health.

e. "Party" means either Plaintiffs or FDA.

f. "Parties" shall collectively refer to Plaintiffs and FDA.

g. "FSMA rulemakings" means the seven rulemakings required by the FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011), that were the subject of the Complaint.

III. SCHEDULE FOR FDA ACTION

4. The Parties agree to the following schedule for FDA action with respect to the FSMA rulemakings. Upon entry of this Consent Decree, this schedule supersedes the schedule established by the District Court's remedy order and judgment, as modified by that Court and the U.S. Court of Appeals for the Ninth Circuit. The deadlines for issuing the final rules for each of the FSMA rulemakings are revised as set forth below. The dates provided are dates by which FDA will submit the final rule to the Federal Register for publication, rather than the dates by which the final rule will be published. The deadlines originally provided for the close of comment periods are no longer operative.

a. Preventive Controls for Human Food (FSMA Section 103(a) and 103(c))

Final rule: August 30, 2015

b. Preventive Controls for Animal Food (FSMA Section 103(a) and 103(c))

Final rule: August 30, 2015

c. Foreign Supplier Verification Program (FSMA Section 301(a))

Final rule: October 31, 2015

d. Produce Safety Standards (FSMA Section 105(a))

Final rule: October 31, 2015

e. Accreditation of Third Party Auditors (FSMA Section 307)

Final rule: October 31, 2015

f. Sanitary Transport of Food and Feed (FSMA Section 111)

Final rule: March 31, 2016

g. Intentional Contamination (FSMA Section 106(b))

Final rule: May 31, 2016

IV. SEEKING EXTENSIONS AND FAILURE TO COMPLY WITH DEADLINES

5. FDA agrees in good faith to complete the rulemakings by the above deadlines and shall make every effort to meet or precede these dates. Nothing in this Consent Decree shall be construed as precluding FDA from finalizing the FSMA rules by dates earlier than those set forth in this document.

6. If despite FDA's best efforts (meaning commitment of agency time, money, energy, and resources that FDA reasonably anticipates will result in meeting the deadlines in this Consent Decree), FDA believes good cause exists to seek an extension of the deadlines, any date in the schedule set forth above may be extended by written agreement of the Parties and notice to the Court. If the Parties are unable to agree to an extension of any date set forth in this Consent Decree, FDA may seek modification of the date in accordance with the procedure specified below.

a. FDA shall file such a motion requesting modification of any date established by this Consent Decree at least thirty days before the specific deadline. In such a motion, FDA shall have the burden to show good cause and/or exceptional circumstances warranting the delay, and address the effect of the delay on the public health and safety, among other relevant considerations. Any motion to modify the schedule established in this Consent Decree shall be accompanied by a motion for expedited consideration. In the event that circumstances arise less than thirty days before the specific deadline that make compliance with that deadline unfeasible, FDA may move to shorten the time required by this paragraph and shall have the burden to show good cause and/or exceptional circumstances warranting the shortened time.

b. FDA shall provide notice to Plaintiffs of its intent to file a motion to modify any date established by this Consent Decree as soon as reasonably possible, and in any event no later than a week prior to the filing of its motion unless good cause and/or exceptional circumstances warrant a shortened notice period.

c. Plaintiffs shall have fourteen days to file a memorandum presenting to the Court their position on the FDA extension request, as well as any additional information with respect to whether FDA has met its burden to show good cause and/or exceptional circumstances, as well as the effect of the requested extension on the public health and safety, or other relevant considerations.

d. The Court will determine whether FDA has met its burden warranting the extension.

7. In the event that FDA has failed to meet a deadline and has not sought to modify it pursuant to the procedures set forth in this paragraph, Plaintiffs' first remedy shall be a motion to enforce the terms of this Consent Decree.

V. DISPUTE RESOLUTION AND MODIFICATIONS

8. In the event of a disagreement among the Parties concerning the interpretation or performance of any aspect of this Consent Decree in addition to compliance with the rulemaking deadlines as explained above, the dissatisfied Party shall provide the other Party with written notice of the dispute and a request for negotiations. The Parties shall confer in order to attempt to resolve the dispute within twenty-one days of the written notice, or such time thereafter as is mutually agreed. In the event that the Parties are unable to resolve a dispute regarding the Parties' rights or obligations pursuant to this Agreement or regarding a proposed modification within twenty-one days of such conversation, a Party may file with the Court a motion to enforce the Agreement and/or to compel performance, or a motion to modify this Agreement in accordance with Federal Rule of Civil Procedure 60(b). Any modification shall be effective upon the filing and entry of an order granting such a motion with the Court.

VI. CONTINUING JURISDICTION

9. The Court shall retain jurisdiction for the purposes of overseeing compliance with the terms of this Consent Decree; resolving any disputes arising under this Consent Decree; resolving any motions to modify the terms of this Consent Decree; issuing such further orders or directions as may be necessary or appropriate to construe, implement, modify, or enforce the terms of this Consent Decree; resolving all claims regarding attorneys' fees and costs as they relate to the Consent Decree; and granting any further relief as the interests of justice may require. *See Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375 (1994).

VII. EFFECTIVE DATE

10. This Consent Decree shall be effective upon the date of its entry by the Court. If for any reason the Court does not enter this Consent Decree, the obligations set forth herein are null and void.

VIII. TERMINATION OF CONSENT DECREE AND DISMISSAL OF CLAIMS

11. This Consent Decree shall terminate upon FDA's fulfillment of its obligations under Paragraph 4 of this Consent Decree, culminating in the publication of the last of the final rules at issue in this litigation.

IX. NOTICE AND CORRESPONDENCE

12. Any notice required or made with respect to this Consent Decree shall be in writing and shall be effective on the date that notice is delivered by electronic mail. For any matter relating to this Consent Decree, the contact persons are:

George A. Kimbrell
Center for Food Safety
917 SW Oak Street, Suite 300
Portland, OR 97205
gkimbrell@centerforfoodsafety.org
(971) 271-7372

Lindsey Powell
U.S. Department of Justice
950 Pennsylvania Ave., NW
Washington, DC 20530
lindsey.e.powell@usdoj.gov
(202) 616-5372

Karen E. Schifter
Office of the General Counsel, Food & Drug Division
United States Department of Health & Human Services
10903 New Hampshire Avenue, WO31-4408
Silver Spring, MD 20993
karen.schifter@fda.hhs.gov
(301) 796-8590

Upon written notice to the other Party, any Party may designate a successor contact person for any matter relating to this Consent Decree.

X. RELEASE BY PLAINTIFFS AND RESERVATION OF RIGHTS

13. Upon entry by the Court, Plaintiffs agree that this Consent Decree shall constitute full satisfaction of all its claims in *Center for Food Safety v. Hamburg*, and when it becomes effective this Consent Decree shall serve as a release of all claims in that case.

14. Plaintiffs further release, discharge, and covenant not to assert any and all claims, causes of action, suits, or demands of any kind in law or in equity that they may have had, or may now have, against Defendant upon the same transactions or occurrences as those at issue in the Complaint.

15. Nothing in this Consent Decree shall limit Plaintiffs' rights to assert the claim pleaded in Plaintiffs' Complaint and make any legal or factual assertions necessary to support a claim, in the event that the Parties are before the Court pursuant to Paragraph 5–7 ("Extensions") or Paragraph 8 ("Dispute Resolution and Modifications"). Nor shall anything in this Consent Decree be construed to limit Defendant's arguments in favor of modifying a deadline.

16. Nothing in this Consent Decree shall waive or limit Plaintiffs' rights to challenge, in a separate lawsuit, the merits of any final agency action taken by FDA pursuant to this Consent Decree (or any final agency action taken by FDA implementing FSMA), including but not limited to claims relating to whether FDA's final action complies with FSMA, the Administrative Procedure Act, the National Environmental Policy Act, and other applicable laws.

17. This release does not encompass any claims by Plaintiffs related to this action, pursuant to the Equal Access to Justice Act, for their reasonable fees and costs as prevailing Parties in this matter, which shall be resolved pursuant to a separate, concurrent agreement entered by this Court.

XI. MUTUAL DRAFTING AND CONSTRUCTION

18. It is expressly understood and agreed that this Consent Decree was jointly drafted by the Parties. Accordingly, the Parties hereby agree that any and all rules of construction to the effect that ambiguity is construed against the drafting party shall be inapplicable in any dispute concerning the terms, meaning, or interpretation of this Consent Decree.

XII. EFFECT OF CONSENT DECREE

19. This Consent Decree shall not constitute an admission or evidence of any issue of fact or law, wrongdoing, misconduct, or liability on the part of any Party. The Parties agree that this Consent Decree was negotiated in good faith and that this Agreement constitutes a settlement of claims that were denied and disputed by the Parties.

XIII. SCOPE OF CONSENT DECREE

20. Except as expressly provided in this Consent Decree, none of the Parties waives or relinquishes any legal rights, claims, or defenses it may have. Nothing in this Consent Decree shall be construed to confer upon the Court jurisdiction to review any decision, either procedural or substantive, to be made by FDA pursuant to this Consent Decree, except for the purposes of determining FDA's compliance with this Consent Decree. Nothing in this Consent Decree shall be construed to make any other person or entity not executing this Consent Decree a third-party beneficiary to this Consent Decree.

XIV. COUNTERPARTS

21. This Consent Decree may be executed in any number of counterpart originals, each of which will be deemed to constitute an original agreement, and all of which shall constitute one agreement. The execution of one counterpart by any Party shall have the same force and effect as if that Party had signed all other counterparts.

XV. ENTIRE AGREEMENT

22. This Consent Decree is the entire agreement between the Parties in this case. All prior conversations, meetings, discussions, drafts, and writings of any kind are specifically superseded by this Consent Decree.

XVI. APPLICABLE LAW

23. This Consent Decree shall be governed by and construed under the laws of the United States.

XVII. SEVERABILITY

24. Subsequent to entry of this Consent Decree by the Court, if any term, condition, or provision of this Consent Decree, or the application thereof to any person or circumstance, shall to any extent be held by a court of competent jurisdiction, or rendered by the adoption of a statute by the United States, invalid, void, or unenforceable, the remainder of the terms, covenants, conditions or provisions of this Consent Decree, or the application thereof to any person or circumstance, shall remain in full force and effect and shall in no way be affected, impaired, or invalidated thereby.

XVIII. COMPLIANCE WITH OTHER LAWS

25. This Consent Decree requires FDA to take actions by dates certain, as described above. No provision of this Consent Decree shall constitute or be interpreted as an exclusion permitting or requiring FDA to take any action in contravention of any law or regulation, either substantive or procedural.

XIX. REPRESENTATIVE AUTHORITY

26. Each undersigned representative of the Parties to this Consent Decree certifies that he or she is fully authorized by such Party to enter into and execute the terms and conditions of this Consent Decree and to legally bind such Party to this Consent Decree. By signature below, the

Parties consent to entry of this Consent Decree. Signature on a counterpart or authorization of an electronic signature shall constitute a valid signature.

For Plaintiffs:

Date: February 20, 2014

For FDA:

/s/ Gerald C. Kell

Date: February 20, 2014

ENTERED AND DATED this _____ day of _____, 2014.

_____
United States District Court Judge