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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

CENTER FOR FOOD SAFETY and CENTER FOR ENVIRONMENTAL HEALTH, *Plaintiffs*, v. ALEX M. AZAR II, SECRETARY OF U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; NORMAN E. SHARPLESS, M.D., ACTING COMMISSIONER OF FOOD AND DRUGS;[1] and U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *Defendants*.	Case No.: 4:18-cv-06299-YGR **CONSENT DECREE**

[1] Norman E. Sharpless, M.D. became Acting Commissioner of Food and Drugs on April 5, 2019. By operation of Fed. R. Civ. P. 25(d), Dr. Sharpless is automatically substituted as a

WHEREAS, this case comes before the Court upon the Joint Stipulation for Entry of Consent Decree ("Stipulation") of Plaintiffs Center for Food Safety and Center for Environmental Health and Defendants Alex M. Azar II, Secretary of U.S. Department of Health and Human Services; Norman E. Sharpless, M.D., Acting Commissioner of Food and Drugs; and U.S. Department of Health and Human Services. Plaintiffs and Defendants are collectively referred to as the "Parties."

WHEREAS on January 4, 2011, Congress enacted the Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011) (FSMA). This statute set deadlines for the Food and Drug Administration (FDA) to (1) designate high-risk foods for which additional recordkeeping requirements are appropriate and necessary to protect the public health (Section 204(d)(2)(A) of FSMA), and (2) publish a notice of proposed rulemaking to establish recordkeeping requirements for facilities that manufacture, process, pack, or hold such foods (Section 204(d)(1) of FSMA). This statute also required FDA to publish the list of the foods designated as high-risk on the FDA's website at the time the agency promulgates the final rule establishing recordkeeping requirements for facilities that manufacture, process, pack, or hold high-risk foods (Section 204(d)(2)(B) of FSMA). Plaintiffs filed this action on October 15, 2018, alleging that FDA violated FSMA and the Administrative Procedure Act (APA) by failing to meet the statutory deadlines and to complete the other actions identified in the previous two sentences, and seeking declaratory and injunctive relief requiring FDA to take the actions described in the statute pursuant to a court-ordered timeline;

WHEREAS Defendants neither admit nor deny the allegations in the Complaint;

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 Alex M. Azar II and Norman E. Sharpless, M.D., were sued in their official capacities as Secretary of the United States Department of Health and Human Services (HHS), and Acting Commissioner of Food and Drugs, respectively, and that obligations arising under this Consent Decree are to be performed by HHS and FDA, and not Alex M. Azar II or Norman E. Sharpless, M.D. in their individual capacities.

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 October 15, 2018, to initiate this case.

b. "Consent Decree" means this document.

c. "FDA" means the United States Food and Drug Administration and/or Defendant in this action, Norman E. Sharpless, M.D., Acting Commissioner of Food and Drugs, or his duly authorized representative.

d. "HHS" means Defendant in this action, the United States Department of Health and Human Services and/or Defendant in this action, Alex M. Azar II, Secretary of the United States Department of Health and Human Services, or his duly authorized representative.

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

f. "Party" means either Plaintiffs or Defendants.

g. "Parties" shall collectively refer to Plaintiffs and Defendants.

III. SCHEDULE FOR FDA ACTION

4. The Parties agree to the following schedule for FDA action. Except as otherwise specified below, the dates provided are dates by which FDA will submit documents to the Office

of the Federal Register for publication, rather than the dates by which the documents will be published.

a. Designation of the list of high-risk foods required by FSMA Section 204(d)(2)(A)

September 8, 2020

b. Recordkeeping requirements for the designated high-risk foods as required by FSMA Section 204(d)(1)

Proposed rule: September 8, 2020

Final rule: November 7, 2022

c. Publication on the FDA website of the list of high-risk foods required by FSMA Section 204(d)(2)(B)

Upon publication of the Final rule in the Federal Register

IV. SEEKING EXTENSIONS AND FAILURE TO COMPLY WITH SCHEDULE

5. FDA agrees in good faith to complete the actions in the above schedule and shall make every effort to meet or precede these dates. Nothing in this Consent Decree shall be construed as precluding FDA from satisfying the above schedule 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 schedule in this Consent Decree), FDA believes good cause exists to seek an extension of the schedule, any date in the schedule set forth above may be extended by written agreement of the Parties and notice to the Court. The Parties agree to negotiate in good faith to reach a mutually agreeable outcome with respect to any such extension of the schedule, as the circumstances may warrant.

7. In the unlikely event that FDA believes an extension of the schedule set forth in this Consent Decree is necessary and the Parties are unable to agree to the terms of the extension, as a measure of last resort FDA may seek modification of the schedule in accordance with the procedure specified below.

a. FDA shall file a motion requesting modification of any date established by this Consent Decree at least thirty days before the date at issue. 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. FDA bears the burden of demonstrating that modification of the schedule is warranted.

8. In the event that FDA has failed to meet the schedule established in this Consent Decree, Plaintiffs' first remedy shall be a motion to enforce the terms of this Consent Decree. FDA retains all rights to defend against such a motion.

V. DISPUTE RESOLUTION AND MODIFICATIONS

9. In the event of a disagreement among the Parties concerning the interpretation or performance of any aspect of this Consent Decree including compliance with the schedule as explained above, the dissatisfied Party shall provide the other Party or Parties with written notice of the dispute and a request for negotiations. The Parties shall confer within twenty-one days of the written notice, or such time thereafter as is mutually agreed, in order to attempt to resolve the dispute. In the event that the Parties are unable to resolve the dispute, 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

10. 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

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