UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CENTER FOR FOOD SAFETY, *Plaintiff,* v. SYLVIA BURWELL, SECRETARY OF U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, and MARGARET A. HAMBURG, M.D., COMMISSIONER OF U.S. FOOD AND DRUG ADMINISTRATION, *Defendants.*	**Case No. 1:14-cv-267-RC** **CONSENT DECREE** **Administrative Procedure Act Case**

WHEREAS on April 17, 1997, the United States Food and Drug Administration (FDA) issued a proposed rule, *see* Substances Generally Recognized As Safe, 62 Fed. Reg. 18938 (Apr. 17, 1997) (the Proposed Rule), and thereafter reopened the comment period on the Proposed Rule, *see* 75 Fed. Reg. 81536 (Dec. 28, 2010);

WHEREAS on February 20, 2014, the Center for Food Safety (Plaintiff) filed a Complaint (D.E. 1) in the above-captioned action against FDA, the Secretary of Health and Human Services, and the Commissioner of Food and Drugs (collectively, Defendants), and thereafter filed a First Amended Complaint (D.E. 8);

WHEREAS the First Amended Complaint alleges that the Proposed Rule was not promulgated in accordance with the rulemaking requirements of the Administrative Procedure Act (APA) and asks this Court to vacate the Proposed Rule;

WHEREAS Defendants filed a Motion to Dismiss the First Amended Complaint on May 14, 2014 (D.E. 10);

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, it is hereby ORDERED 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 the Secretary of Health and Human Services and the Commissioner of Food and Drugs were sued solely in their official capacities and that obligations arising under this Consent Decree are to be performed by FDA and HHS, not Sylvia Burwell and Margaret Hamburg, M.D. in their individual capacities.

II. DEADLINE AND GOOD FAITH EXTENSIONS

3. Pursuant to this Consent Decree, FDA shall submit a final rule regarding "Substances Generally Recognized as Safe" to the Federal Register for publication no later than August 31, 2016. Nothing in this Consent Decree shall be construed as precluding FDA from issuing a final rule by a date earlier than the time frame set forth in this document.

4. FDA agrees in good faith to complete the rulemaking by August 31, 2016, and shall make every effort to submit the final rule to the Federal Register for publication on or before that date. If despite FDA's best efforts (meaning commitment of agency time, energy, and resources that FDA reasonably anticipates will result in meeting the deadline in this Consent Decree), FDA believes good cause exists to seek an extension of the deadline, the deadline for publication of the final rule 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 the deadline, FDA may seek modification of the date in accordance with the procedure specified below.

a. FDA shall file such a motion requesting modification of the deadline for publication of the final rule established by this Consent Decree at least thirty days before the deadline. In such a motion, FDA shall have the burden to show good cause and/or exceptional circumstances warranting the extension. Any such motion 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 not feasible, 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 Plaintiff of its intent to file a motion to modify the deadline established by this Consent Decree as soon as reasonably possible, and in any event no later than one week prior to the filing of its motion unless good cause and/or exceptional circumstances warrant a shortened notice period.

c. Plaintiff shall have fourteen days from the date of FDA filing such motion to file a memorandum presenting to the Court its 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.

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

5. In the event that FDA has failed to meet its deadline as set forth in paragraph 3 of this Consent Decree and has not sought to modify it pursuant to the procedures set forth in this paragraph, Plaintiff's first remedy shall be a motion to enforce the terms of this Consent Decree.

III. DISPUTE RESOLUTION AND MODIFICATIONS

6. In the event of a disagreement among the Parties concerning the interpretation or performance of any aspect of this Consent Decree, 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.

IV. CONTINUING JURISDICTION

7. 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 any claims regarding attorneys' fees and costs; and granting any further relief as the interests of justice may require.

V. EFFECTIVE DATE

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

VI. TERMINATION OF CONSENT DECREE AND DISMISSAL OF CLAMS

9. This Consent Decree shall terminate upon FDA's fulfillment of its obligations under Paragraph 3 of this Consent Decree.

VII. NOTICE AND CORRESPONDENCE

10. 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 or an overnight mail/delivery service. For any matter relating to this Consent Decree, the contact persons are:

Donna F. Solen
Center for Food Safety
303 Sacramento Street, 2d Floor
San Francisco, CA 94111
dsolen@centerforfoodsafety.org

Andrew E. Clark
U.S. Department of Justice
Consumer Protection Branch
P.O. Box 386
Washington, D.C. 20044-0386
Andrew.Clark@usdoj.gov

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

VIII. RELEASE BY PLAINTIFF AND RESERVATION OF RIGHTS

11. Plaintiff agrees that termination of this Consent Decree as set forth in paragraph 9 shall constitute full satisfaction of all its claims in *Center for Food Safety v. Burwell*, Civ. No. 1:14-cv-267-RC (D.D.C.), and shall serve as a release of all claims in that case.

12. Plaintiff further releases, discharges, and covenants 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 Defendants upon the same transactions or occurrences as those at issue in the First Amended Complaint.

13. Nothing in this Consent Decree shall limit Plaintiff's rights to assert the claim pleaded in Plaintiffs' First Amended 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 Paragraphs 4-6. Nor shall anything in this Consent Decree be construed to limit Defendants' arguments in favor of modifying the deadline.

14. Nothing in this Consent Decree shall waive or limit Plaintiff's rights to challenge, in a separate lawsuit, the merits of the final rule, including but not limited to claims relating to whether FDA's final action complies with the APA and other applicable laws.

15. This release does not encompass any claims by Plaintiff related to this action, pursuant to the Equal Access to Justice Act, for their reasonable fees and costs. This Consent Decree shall not be construed to include a finding or concession that (a) Plaintiff is a prevailing party, (b) the position of Defendants or their counsel in this litigation was not substantially justified, or (c) Defendants are liable as a matter of law for the payment of any attorneys' fees, expenses, or costs.

IX. MUTUAL DRAFTING AND CONSTRUCTION

16. 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.

X. EFFECT OF CONSENT DECREE

17. 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.

XI. SCOPE OF CONSENT DECREE

18. 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. Nothing in this Consent Decree alters or affects the standards for judicial review of any final FDA action.

XII. COUNTERPARTS

19. 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.

XIII. ENTIRE AGREEMENT

20. 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.

XIV. APPLICABLE LAW

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

XV. COMPLIANCE WITH OTHER LAWS

22. 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.

XVI. REPRESENTATIVE AUTHORITY

23. 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.

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Attorneys for Plaintiff

ENTERED AND DATED this ___ day of _____, 2014

_____
United States District Judge