Hellerstein, A.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

NATURAL RESOURCES DEFENSE COUNCIL, INC.,

Plaintiff,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION; KATHLEEN SEBELIUS, in her official capacity as Secretary, United States Department of Health and Human Services; and MARGARET HAMBURG, in her official capacity as Commissioner, United States Food and Drug Administration;

Defendants.

10 Civ. 5690 (AKH)

CONSENT DECREE

WHEREAS, the Natural Resources Defense Council ("NRDC") filed a complaint in this action (10 Civ. 5690) on July 27, 2010, against the United States Food and Drug Administration ("FDA"); Kathleen Sebelius, in her official capacity as Secretary, United States Department of Health and Human Services; and Margaret Hamburg, in her official capacity as Commissioner, United States Food and Drug Administration ("Defendants") (the signatories to this Consent Decree are collectively referred to as "the Parties");

WHEREAS, NRDC alleges that FDA violated the Administrative Procedure Act ("APA"), 5 U.S.C. § 555(b), and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355, by unreasonably delaying the issuance of monographs establishing conditions for use of certain products containing triclosan as the active ingredient;

WHEREAS, pursuant to the Court's Order of July 23, 2013, FDA provided NRDC with an estimated timeline for completing the monographs for Consumer Antiseptic Hand Wash

Products, Healthcare Antiseptic Products, and Consumer Antiseptic Hand Rub Products, and this timeline was submitted to the Court on September 11, 2013, as part of a joint status report;

WHEREAS, FDA, without admitting or denying any of the allegations in NRDC's Complaint, and NRDC have agreed to the timeline for FDA's completion of the monographs for Consumer Antiseptic Hand Wash Products, Healthcare Antiseptic Products, and Consumer Antiseptic Hand Rub Products with respect to the active ingredient triclosan reflected below and to the other terms of this Consent Decree;

WHEREAS by entering into this Consent Decree, the Parties do not waive or limit any claims or defenses on any grounds related to any claims that are not resolved by this Consent Decree;

WHEREAS it is in the interests of the public, the Parties, and judicial economy to resolve the issues in this action without protracted litigation;

WHEREAS the Court finds and determines that this Consent Decree represents a just, fair, adequate, and equitable resolution of the claims raised in this action;

NOW THEREFORE, it is hereby ORDERED, ADJUDGED, AND DECREED as follows:

I. GENERAL TERMS

1. The Parties to this Consent Decree understand that (a) Kathleen Sebelius and Margaret Hamburg were sued in their official capacities as Secretary of the United States Department of Health and Human Services and Commissioner of the United States Food and Drug Administration, respectively; and (b) obligations arising under this Consent Decree are to

be performed by FDA and not Kathleen Sebelius or Margaret Hamburg in their individual capacities.

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

3. For the purposes of entry and enforcement of this Consent Decree only, the Parties to this Consent Decree agree that the Court has jurisdiction over any disputes pertaining to any alleged violations of this Consent Decree.

II. DEFINITIONS

4. For the purposes of this Consent Decree, the following terms shall have the meanings provided below:

a. "Complaint" means the complaint filed in this case by the Natural Resources Defense Council on July 27, 2010, to initiate the lawsuit titled above, and the First Amended Complaint filed on June 17, 2013.

b. "Consent Decree" means this document.

c. "FDA" means Kathleen Sebelius, Secretary of the United States Department of Health and Human Services and Margaret Hamburg, Commissioner of the United States Food and Drug Administration, or their duly authorized representative, and the United States Food and Drug Administration.

d. "Plaintiff" or "NRDC" means the Natural Resources Defense Council.

e. "Tentative Final Monograph" has the meaning provided in 21 C.F.R. § 330.10(a)(7).

f. "Final Monograph" has the meaning provided in 21 C.F.R. § 330.10(a)(9).

III. TERMS OF AGREEMENT

5. FDA will complete the tasks described below for the monographs for Consumer Antiseptic Hand Wash Products, Healthcare Antiseptic Products, and Consumer Antiseptic Hand Rub Products for the active ingredient triclosan, no later than the corresponding dates set forth in the timeline below:

a. Consumer Antiseptic Hand Wash Products Monograph

i. Publication of tentative final monograph. **December 16, 2013**

ii. Comment period for tentative final monograph. **June 16, 2014**

iii. End of period to submit new data and information for tentative final monograph. **December 16, 2014**

iv. Rebuttal comment period for tentative final monograph. **February 17, 2015**

v. FDA review of comments, data, and information; drafting of the final monograph; and final review and approval by FDA, Department of Health and Human Services, and Office of Management and Budget. **August 31, 2016**

vi. Publication of Final Monograph. **September 15, 2016**

b. Healthcare Antiseptic Products Monograph

i. Publication of tentative final monograph. **April 30, 2015**

ii. Comment period for tentative final monograph. **October 31, 2015**

iii. End of period to submit new data and information for tentative final monograph. **April 30, 2016**

iv. Rebuttal comment period for tentative final monograph. **June 30, 2016**

v. FDA review of comments, data, and information; drafting of the final monograph; and final review and approval by FDA, Department of Health

and Human Services, and Office of Management and Budget. **December 31, 2017**

vi. Publication of Final Monograph. **January 15, 2018**

c. Consumer Antiseptic Hand Rub Products Monograph

i. Publication of tentative final monograph. **June 30, 2016**

ii. Comment period for tentative final monograph. **December 31, 2016**

iii. End of period to submit new data and information for tentative final monograph. **June 30, 2017**

iv. Rebuttal comment period for tentative final monograph. **August 31, 2017**

v. FDA review of comments, data, and information; drafting of the final monograph; and final review and approval by FDA, Department of Health and Human Services, and Office of Management and Budget. **March 31, 2019**

vi. Publication of Final Monograph. **April 15, 2019**

6. FDA will submit status reports to the Court and the Plaintiff, at six month intervals, beginning six months after the date of entry of this Consent Decree and continuing until each monograph is completed. Each report shall be in writing, shall be provided within fifteen (15) days after the conclusion of the six-month period to which it relates, and shall include a description of the actions taken by FDA with respect to its obligations under the Consent Decree during the preceding six-month period and a description of the actions FDA intends to take with respect to its responsibilities under the Consent Decree during the following six months.

IV. EFFECTIVE DATE

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

V. REMEDY, SCOPE OF JUDICIAL REVIEW

8. 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, expect for the purposes of determining FDA's compliance with this Consent Decree.

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

VI. RELEASE BY PLAINTIFF

10. Upon entry of this Consent Decree by the Court, this Consent Decree shall constitute a complete and final settlement of all claims that were asserted, or that could have been asserted, by Plaintiff against Defendants related to the allegations in the Complaint.

11. Plaintiff hereby 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 related to the Complaint. Plaintiff expressly reserves the right to challenge in any forum on any ground the lawfulness of FDA's monographs for Consumer Antiseptic Hand Wash Products, Healthcare Antiseptic Products, and Consumer Antiseptic Hand Rub Products. Defendants reserve all defenses to any such challenge.

VII. TERMINATION OF CONSENT DECREE AND DISMISSAL OF CLAMS

12. This Consent Decree shall terminate upon publication of the last of the Final Monographs for the active ingredient triclosan to be published under Paragraph 5. Upon termination of this Consent Decree, this case shall be dismissed with prejudice.

VIII. FORCE MAJEURE

13. The Parties recognize that the performance of this Consent Decree is subject to the fiscal and procurement laws and regulations of the United States. The possibility exists that circumstances outside the reasonable control of FDA could delay compliance with the obligations in this Consent Decree including, but not limited to, a government shutdown. Should a delay occur due to such circumstances, any resulting failure to fulfill any obligations set forth herein shall not constitute a failure to comply with the terms of this Consent Decree, and any deadline so affected shall be extended for one day for each day of the delay, or to an alternative date jointly agreed upon by the Parties. FDA will provide Plaintiff with reasonable notice in the event that FDA invokes this Paragraph. Any dispute regarding such invocation shall be resolved in accordance with the dispute resolution provision of the Paragraph 14 below.

IX. DISPUTE RESOLUTION

14. 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 Parties with written notice of the dispute and a request for negotiations. The Parties shall meet and confer in order to attempt to resolve the dispute within 21 days of the written notice, or such time thereafter as is mutually agreed. If the Parties are unable to resolve the dispute within 21 days of such meeting, then any Party may petition the Court to resolve the dispute.

X. MODIFICATIONS AND EXTENSION

15. Any dates in the timeline set forth in Paragraph 5 may be extended by written agreement of the Parties and notice to the Court. To the extent the Parties are not able to agree to an extension of any date set forth in this Consent Degree, FDA may seek modification of the date in accordance with the procedures specified below.

a. FDA may file a motion requesting modification of any date or dates established by this Consent Decree before or within forty-five (45) days after the date occurs. Such motion shall address whether the performance of a designated task by the requested date would constitute unreasonable delay under the standard set forth in *Natural Resources Defense Council, Inc. v. FDA*, 710 F.3d 71, 84 (2d Cir. 2013) (citing *Telecomms. Research & Action Ctr. v. FCC*, 750 F.2d 70, 80 (D.C. Cir. 1984)). FDA shall provide notice to Plaintiff as soon as reasonably possible of its intent to file a motion to modify any date or dates established by this Consent Decree, and no later than the date or dates sought to be modified.

b. If the Court denies a motion by FDA to modify a date established by this Consent Decree, then the date for performance for which modification has been requested shall be such date as the Court may specify.

c. Any motion to modify the timeline established in this Consent Decree shall be accompanied by a motion for expedited consideration.

XI. CONTINUING JURISDICTION

16. The Court retains jurisdiction for the purposes of resolving any disputes arising under this Consent Decree, and issuing such further orders or directions as may be necessary or

appropriate to construe, implement, modify, or enforce the terms of this Consent Decree, and for granting any further relief as the interests of justice may require.

XII. NOTICE AND CORRESPONDENCE

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

For Plaintiff, Natural Resources Defense Council:

Dimple Chaudhary
Natural Resources Defense Council
1152 15th Street, NW, Suite 300
Washington, DC 20005
(202) 289-6868
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For Defendants:

Assistant United States Attorney John Clopper
United States Attorney's Office
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and

ANN M. OXENHAM
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United States Department of Health and Human Services
Office of the General Counsel
Food and Drug Administration
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White Oak 32, Room 4379
Silver Spring, MD 20993-0002
(301) 796-8710
ann.oxenham@fda.hhs.gov

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

XIII. REPRESENTATIVE DRAFTING

18. 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.

XIV. MUTUAL DRAFTING

19. 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.

XV. COUNTERPARTS

20. 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.

XVI. EFFECT OF CONSENT DECREE

21. The Consent Decree shall not constitute an admission or evidence of any fact, wrongdoing, misconduct, or liability on the part of the United States, its officers, or any person affiliated with it. Nothing in this Consent Decree shall constitute, or be used as evidence of, a

determination that FDA unreasonably delayed the issuance of monographs establishing conditions for use of certain products containing triclosan as the active ingredient.

XVII. COMPLIANCE WITH OTHER LAWS

22. No provision of this Consent Decree shall be interpreted as or constitute a commitment or requirement that FDA take any action in contravention of any law or regulation, either substantive or procedural.

XVIII. APPLICABLE LAW

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

XIX. THIRD-PARTY BENEFICIARIES

24. 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.

[*Remainder of page intentionally left blank.*]

The Parties consent to the form, substance, and entry of the foregoing Consent Decree.

Dated: Washington, DC
November 19, 2013

Natural Resources Defense Council

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Counsel for Plaintiff

Dated: New York, New York
November 19, 2013

PREET BHARARA
United States Attorney

By:

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Counsel for Defendants

ORDER

UPON CONSIDERATION OF THE FOREGOING, this Consent Decree is hereby APPROVED and ENTERED.

SIGNED and ENTERED this 21 day of November, 2013.

HONORABLE ALVIN K. HELLERSTEIN
UNITED STATES DISTRICT JUDGE