

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

NATURAL RESOURCES DEFENSE COUNCIL, INC.,

Plaintiff,

v.

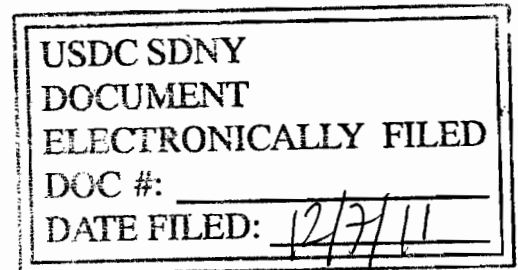
UNITED STATES DEPARTMENT OF HEALTH
AND HUMAN SERVICES; KATHLEEN SEBELIUS,
in her official capacity as Secretary, United States
Department of Health and Human Services;
UNITED STATES FOOD AND DRUG
ADMINISTRATION; MARGARET HAMBURG,
in her official capacity as Commissioner,
United States Food and Drug Administration,

Defendants.

No. 11-cv-5801 (BSJ) (AJP)

ECF Case

CONSENT JUDGMENT



CONSENT JUDGMENT

WHEREAS the Natural Resources Defense Council (Plaintiff) filed a Complaint in this action (No. 11-cv-5801) against Defendants the United States Department of Health and Human Services (HHS) and Kathleen Sebelius, in her official capacity as Secretary of HHS, and against the United States Food and Drug Administration (FDA) and Margaret A. Hamburg, M.D., in her official capacity as Commissioner of Food and Drugs, on August 18, 2011;

WHEREAS this action concerns the Petition submitted by Plaintiff on October 21, 2008 to FDA requesting that FDA promulgate a regulation prohibiting the use of bisphenol A (BPA) in food packaging;

WHEREAS the Plaintiff alleged in its Complaint that FDA had unreasonably delayed in issuing a final decision to the Petition and sought relief under the Administrative Procedure Act (APA), 5 U.S.C. § 706(1);

WHEREAS the Defendants maintain that FDA has not unreasonably delayed under § 706(1) of the APA in issuing a final decision to the Petition;

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

WHEREAS the Parties recognize, and the Court by entering this Consent Judgment finds, that this Consent Judgment has been negotiated by the Parties as a settlement of Plaintiff's claims in good faith and will avoid further litigation of the events alleged in the Complaint between the Parties, and that this Consent Judgment represents a just, fair, adequate, and equitable resolution of the claims raised in this action;

NOW, THEREFORE, with the consent of the Parties, it is hereby ORDERED as follows:

I. GENERAL TERMS

1. The Parties to this Consent Judgment understand that (a) Kathleen Sebelius was sued in her official capacity as Secretary of HHS and Margaret A. Hamburg, M.D., was sued in her official capacity as Commissioner of Food and Drugs; (b) obligations arising under this Judgment are to be performed by FDA and HHS and not Kathleen Sebelius and Margaret A. Hamburg, M.D., in their individual capacities.

2. This Consent Judgment applies to, is binding upon, and benefits the Parties (and their successors, assigns, and designees).

3. The Parties to this Consent Judgment agree that the Court has jurisdiction over any disputes pertaining to any alleged violations of this Consent Judgment.

II. DEFINITIONS

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

- a) “Commissioner” means Margaret A. Hamburg, M.D., the Commissioner of Food and Drugs, or the Commissioner’s duly authorized representative.
- b) “Complaint” means the complaint filed in this case by the Natural Resources Defense Council on August 18, 2011, to initiate the lawsuit titled above.
- c) “Consent Judgment” means this document.
- d) “Defendants” means the United States Department of Health and Human Services and Kathleen Sebelius, in her official capacity as Secretary of HHS, and the United States Food and Drug Administration and Margaret A. Hamburg, M.D., in her official capacity as Commissioner of Food and Drugs.
- e) “FDA” means the United States Food and Drug Administration.
- f) “Final decision” means a decision by the Commissioner approving or denying a petition, or approving in part and denying in part a petition, as provided for in 21 C.F.R. § 10.30(e)(2)(i), (2)(ii), & (3). “Final decision” does not mean a “tentative response” as provided for in 21 C.F.R. § 10.30(e)(2)(iii). The “final decision” constitutes final agency action on the Petition for purposes of judicial review under the APA.
- g) “HHS” means the United States Department of Health and Human Services.
- h) “Petition” means the petition the Natural Resources Defense Council submitted to FDA on October 21, 2008, requesting that FDA promulgate a regulation prohibiting the use of BPA in food packaging.
- i) “Plaintiff” means the Natural Resources Defense Council.

III. TERMS OF AGREEMENT

5. Pursuant to this Consent Judgment, the Commissioner shall:

- a) Issue a final decision on the Petition pursuant to 21 C.F.R. § 10.30(e) on or before March 31, 2012.
- b) Concurrently with the decision on the Petition, and pursuant to 21 C.F.R. § 10.30(e)(4), notify Plaintiff in writing of the decision and place the decision in the public docket file in the FDA's Division of Dockets Management.
- c) If warranted under 21 C.F.R. § 10.30(e)(2)(i) or (e)(3), concurrently with the decision on the Petition, publish a notice in the Federal Register regarding the decision.

IV. EFFECTIVE DATE

6. This Consent Judgment shall become effective upon the date of its entry by the Court.

V. RETENTION OF JURISDICTION, SCOPE OF JUDICIAL REVIEW

7. The Court shall retain exclusive jurisdiction over this case until the termination of this Consent Judgment, for the purpose of resolving disputes arising under this Judgment, or effectuating or enforcing compliance with the terms of this Judgment.

8. Nothing in this Consent Judgment 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 Judgment, except for the purpose of determining FDA's compliance with this Consent Judgment.

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

VI. EFFECT OF CONSENT JUDGMENT / RESERVATION OF RIGHTS

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

11. By entering into this Consent Judgment, the Parties do not waive or limit any claims or defense on any grounds related to any claims that are not resolved by this Consent Judgment.

12. Plaintiff expressly reserves the right to challenge in any forum and on any ground the lawfulness of the final decision ultimately adopted by FDA. Defendants reserve all defenses to any such challenge.

VII. TERMINATION OF CONSENT JUDGMENT AND DISMISSAL OF CLAIMS

13. This Consent Judgment shall terminate after fulfillment of Defendants' obligations under this Judgment. Upon termination of this Consent Judgment, this case shall be dismissed with prejudice.

VIII. ATTORNEY'S FEES AND COSTS

14. Plaintiff believes it is entitled to attorney's fees and costs under the Equal Access to Justice Act, 28 U.S.C. § 2412(d). Defendants believe Plaintiff is not entitled to attorney's fees and costs. Plaintiff will make a subsequent motion to seek attorney's fees and costs if it desires.

IX. REPRESENTATIVE AUTHORITY

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

X. MUTUAL DRAFTING

16. This Consent Judgment was jointly drafted by the Parties. Accordingly, 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 Judgment.

XI. INTEGRATION

17. This Consent Judgment constitutes the final, complete, and exclusive agreement and understanding among the Parties with respect to the settlement embodied in the Judgment and supersedes all prior agreements and understandings, whether oral or written. No other document, nor any representation, inducement, agreement, understanding, or promise constitutes any part of the Judgment or the settlement it represents, nor shall it be used in construing the terms of this Judgment.

XII. FINAL JUDGMENT

18. Upon approval and entry of this Consent Judgment by the Court, this Consent Judgment shall constitute a final judgment between Plaintiff and Defendants.

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

FOR THE DEFENDANTS:

Dated: Dec. 1, 2011

By:

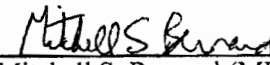


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FOR THE PLAINTIFF, Natural Resources Defense Council:

Dated: Dec. 1, 2011

By:



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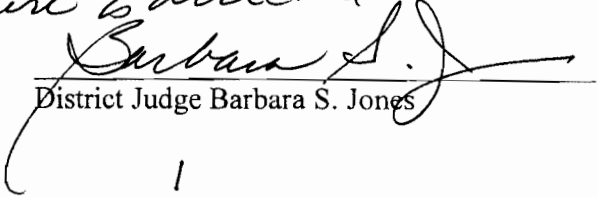
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ORDER

UPON CONSIDERATION OF THE FOREGOING, this Consent Judgment is hereby
APPROVED AND ENTERED.

SIGNED and ENTERED this 6 day of December, 2011.

The Clerk of the Court is directed to close this case.


District Judge Barbara S. Jones