DEPARTMENT OF HEALTH & HUMAN SERVICES

June 4, 2013

Jim Turner
Board Chair of Citizens for Health
1400 16th Street NW
Suite 101
Washington, DC 20036

Re: Docket No. FDA-2013-P-0291/CP1

Dear Mr. Turner,

This is a tentative response to the Citizen Petition (FDA-2013-P-0291/CP1) filed with the Food and Drug Administration (FDA or Agency) on March 12, 2013.

The petition requests: The Commissioner of Food and Drugs should promulgate these regulations: (1) prohibit the sale or distribution of any food, dietary supplements, and drugs which are contaminated with more than 5Bq/kg of Cesium 134/137 (either radioisotope individually or any combination of the two), (2) require testing for Cesium 134 and 137 contamination in two levels in any and all food, dietary supplements, and drugs meant for commercial sale, (3) assign a tracking number to every food, dietary supplement, and drug containing Cesium 134/137 contamination which is then catalogued in a national database, (4) ensure that the national database described in Item (3) directly above is publicly accessible for any and all consumers via the internet, (5) prohibit a listing of "below limit" in the national database for Cesium 134/137 contamination in a food, dietary supplement, or drug; there must always be a number, (6) ensure that any established testing process for radioactivity has safeguards against co-mingling or dilution, (7) begin systematic testing of soil, trees, and waterways across the U.S. and especially on the west coast to determine our ecosystem's contamination and vulnerability. File all readings in the national database described in Item (3) above, and (8) label all food, dietary supplements, and drugs that are commercially available and contaminated with Cesium 134/137 with the amount of Cesium 134/137 contamination found.

Pursuant to the administrative regulations at 21 CFR 10.30, FDA is required to respond to your petition within 180 days. FDA is currently considering the issues raised by your citizen petition. However, the agency will require additional time to issue a final response because of the complexity and number of issues raised by your petition and because of the limited availability of resources and other agency priorities.

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FDA will issue a final response to your citizen petition after completing the analyses of all of the legal and policy issues raised in the petition.

Sincerely,

William Jones, Ph.D.

Acting Deputy Director, Office of Food Safety Center for Food Safety and Applied Nutrition

Cc:

HFA-301 (Docket No. FDA-2013-P-0291/CP1)

HFS-024 (Berry)

HFS-317 (Kim, South)

HFS-315 (Sheehan)

HFS-300 (Beru, Jones)

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