



19 September 2006

Dr. Laura Tarantino
Director
Office of Food Additives
Food and Drug Administration
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5100 Paint Branch Parkway
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Dr. Robert E. Brackett
Director
Center for Food Safety and Applied Nutrition
Food and Drug Administration
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Re: Food additive petition on irradiated ground beef (Docket # 2003P-0544).

Dear Dr. Tarantino and Dr. Brackett:

Several weeks ago, Dr. Tarantino contacted both Food & Water Watch and the Center for Food Safety (CFS) concerning the status of our petition on irradiated ground beef (Docket No. 2003P-0544). During each of the calls, Dr. Tarantino suggested that the petition was not currently active before the agency because it had been withdrawn via a December 9, 2003 letter from Peter Jenkins. Dr. Tarantino's phone calls were follow-up to an August 22, 2006 letter from Dr. Robert Brackett indicating that the Office of Food Additive Safety had never received our food additive petition. After reviewing this matter, both of our organizations believe that Dr. Tarantino's interpretation of Mr. Jenkins's letter is incorrect, and subsequent actions taken by the agency with regard to petition make it clear that petition has been, and still is, properly pending before the agency as a citizen's petition.

On December 1, 2003, the CFS and Public Citizen (now Food & Water Watch) filed the petition as a food additive petition concerning the existing food additive regulation with respect to the irradiation of ground beef. The petition closely tracked the requirements for filing as a food additive petition to modify an existing food additive approval and was addressed to the Petitions Control Branch as prescribed by 21 C.F.R. § 171.1(c). Regrettably, because the petition was sent to the Division of Dockets Management, the agency apparently processed it as a citizen's petition and assigned it Docket No. 2003P-0544. Upon learning of this procedural transgression, Mr. Jenkins

immediately submitted a letter to the agency on December 9, 2003 to Mr. Lyle Jaffe, then with Dockets Management, requesting that the petition be withdrawn as a citizen's petition and correctly filed with the Office of Food Additive Safety. The letter specifically stated that if Mr. Jaffe could not do this that he inform us and we would withdraw our petition and re-file it. Mr. Jaffe never responded to this correspondence. The letter sought to clarify how the petition was to be treated by the agency and did not indicate that the petitioners wished to withdraw the petition from any further agency consideration.

Indeed, several days after the December 9, 2003 letter, Mr. Jenkins had a phone conversation with FDA Consumer Safety Officer Lane A. Highbarger concerning the status of the petition. During this phone conversation, Mr. Highbarger indicated that he was aware of the petition and that we had asked that it be considered as a food additive petition. Mr. Highbarger told Mr. Jenkins that agency had discretion on how it could treat the petition and that the agency had decided to treat it as a citizen's petition. Ever since this conversation, the FDA, CFS and Food & Water Watch have acted in a manner consistent with the agency's treatment of the petition as a citizen's petition. In no manner has either CFS or Food & Water Watch acted to withdraw the petition from consideration by the agency. To the contrary, our organizations relied upon Mr. Highbarger's determination and, over the last several years, have continued to place supplemental materials and comments into the petition's docket. And the agency has acted in a consistent manner by readily adding this material to the docket.

During Dr. Tarantino's calls she suggested that the agency recommends that we resubmit our petition as either a citizen's petition or a food additive petition. Taking such action would be redundant and serve to delay resolution of the substantive matters we have already properly placed before the agency. The petition more than met the requirements of 21 C.F.R. § 10.30(b) and was accepted by the agency for filing as a citizen's petition. A docket has been created for the petition and the agency has acted in a manner consistent with treatment as a citizen's petition.

FDA now has had more than ample time to consider the petition. While the agency may have mismanaged its internal communications and procedures, we neither believe that as a matter of law our organizations are responsible for the agency's delay in the answering the petition nor that the petition requires re-filing.

Accordingly, we again urge the agency to provide a substantive response to the petition without further unreasonable delay as required in 21 C.F.R. § 10.30(e)(2). Absent a substantive response, both organizations will be compelled to consider further legal action.

Should you wish to further discuss this matter or take action to cease the agency's process of responding to the petition please contact either Zach Corrigan (Food & Water Watch) at 202-797-6549 or Joe Mendelson (CFS) at 202-547-9359.

Sincerely,

Zach Corrigan
Staff Attorney
Food & Water Watch

Joseph Mendelson
Legal Director
Center for Food Safety

cc:

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