

July 16, 2007

RE: Request for Correction of Information Regarding Thresholds for Major Food Allergens and for Gluten in Food

Dear

This letter is an interim response to your January 15, 2007, request for reconsideration pursuant to Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001, Pub.L. No.106-554, 114 Stat. 2763A-153 (2000) (the Federal Data Quality Act). Your original complaint requested that corrections be made to two documents:

- 1) Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food (March 2006) (referred to herein as the "Threshold Report")
- 2) FDA's Responses to Public Comments on the Draft Threshold Report

FDA's data quality guidance, which is part of the Department of Health and Human Services Guidelines for Ensuring the Quality of Information Disseminated to the Public, states that FDA will respond to a data quality complaint within 60 days, either by issuing a decision or by providing you with an estimated decision date.

We have not yet completed our response to your request for reconsideration. We anticipate providing you with a response within 60 days from the date of this letter.

Sincerely,

Laurie Lenkel  
FDA Office of the Ombudsman