



# GLUTEN FREE WATCHDOG

August 2017

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Director, Office of Nutrition and Food Labeling  
Center for Food and Safety and Applied Nutrition  
Food and Drug Administration  
FDA College Park Campus CPK 1 Building Room 4C-095  
5100 Paint Branch Pkwy.  
College Park, MD 20740

Dear Dr. Balentine and Food Labeling and Standards Staff,

Please investigate labeled gluten-free foods testing at or above 20 parts per million when tested by an accredited lab using the R5 ELISA Mendez Method (i.e., one of the assays FDA uses to assess compliance to the gluten-free labeling rule).

- FDA, on January 25, 2017 you were emailed results of testing done on **Tenera Grains brown teff flour**. Testing was done at an accredited lab that is familiar to FDA using the scientifically validated R5 ELISA Mendez Method. The extractions tested at 48 and 25 parts per million of gluten.
  - FDA, you also were provided with a statement from the manufacturer to the Gluten Free Watchdog community that included the results of the manufacturer's own testing. These results were above 20 parts per million of gluten.
  - FDA, keep in mind that the gluten-free claim was NOT removed from the product label because according to the statement provided to us by the manufacturer, "...we created the labels for the flour after testing the grain but before the teff was milled and bagged."
  - FDA, we ordered a second bag of Tenera Grains brown teff flour on July 6, 2017. Six months after the original testing, the same lot date (August 4, 2017) is still being sold and the product is labeled gluten-free\*.
  - FDA, test results and the statement from the manufacturer are publicly available on Gluten Free Watchdog at <https://www.glutenfreewatchdog.org/product/tenera-grains-brown-teff-flour/559>
  - FDA, we are happy to send you this unopened bag for testing.
- FDA, on July 5, 2017 you were emailed results of testing done on **Pure Goodness pumpkin seed protein (natural chocolate flavor)** (Lot#

0593J5-RP, EXP 04/18). Testing was done at an accredited lab that is familiar to the FDA using the scientifically validated R5 ELISA Mendez Method. The extractions tested at > 84 ppm, > 84 ppm, and 376 ppm gluten.

- FDA, the lab is retaining the sample in case you would like to test it.
  - FDA, test results and information from the manufacturer are publicly available at <https://www.glutenfreewatchdog.org/product/pure-goodness-pumpkin-seed-protein-chocolate/607>
  - FDA, you have not responded to either email.
  - FDA, you state the following in the online document, “Guidance for Industry: Gluten-Free Labeling of Foods; Small Entity Compliance Guide” available at <https://www.fda.gov/RegulatoryInformation/Guidances/ucm402549.htm>
- 12. What happens if I label my food as “gluten-free” and the food is not in compliance with the “gluten-free” regulation, such as it has a gluten level above 20 ppm?**

If you label your food as “gluten-free,” but it is not in compliance with the “gluten-free” regulation, such as its gluten content level is above 20 ppm, then it would be “misbranded” under the Federal Food, Drug, and Cosmetic Act, and FDA could take regulatory action.

- FDA, have you changed your policy on the maximum level of gluten allowed in foods labeled gluten-free?
- FDA, If you have not changed your policy, please reach out to the manufacturers listed above and assess whether they are in compliance with the gluten-free labeling rule.
- FDA, protect the health of people with celiac disease and **enforce your own rule.**

Sincerely,

Gluten Free Watchdog community member

For more information please contact:

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\*After ordering the second bag of Tenera brand teff, Gluten Free Watchdog was contacted by the manufacturer letting us know that they are removing the gluten-free claim from product packaging and removing all of their inventory from Amazon at the end of the week (by July 15<sup>th</sup>). This is 6 months too late.