



GLUTEN FREE WATCHDOG

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Dear Dr. Balentine and Food Labeling and Standards Staff,

Please investigate labeled gluten-free foods containing wheat-based soy sauce and **enforce your own rule**.

- FDA, you state the following in the online document, “Questions and Answers: Gluten-Free Food Labeling Final Rule” available at <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm362880.htm#Compliance>:
 - **Compliance**
 - **How will FDA check that food manufacturers labeling their foods gluten-free comply with the requirements of the final rule?**

The agency will use the full range of its routine post-market monitoring activities to enforce the final rule on gluten-free food labeling. These activities include sampling, periodic inspections of food manufacturing facilities; food label reviews; follow-up on consumer and industry complaints reported to the agency; and when needed, gluten analyses of food samples.
- FDA, please review the food labels of the following labeled gluten-free products that appear to contain wheat-based soy sauce as an ingredient:
 - **Chef Myron’s Teriyaki Sauce and all Myron’s sauces containing shoyu (i.e., soy sauce):** Information on their website reads, “Our Chef Myron’s Aged Shoyu (all purpose soy sauce) is one of the base ingredients of many of our sauces. The soy sauce contains soy beans, wheat, water, and salt. Therefore, the products that contain the Aged Shoyu also contain wheat. However, they are still certified as gluten free. Here is why:” For the rest of their statement

see http://www.chefmyrons.com/images/stories/pdfs/gluten_free_statement.pdf

- Product purchased by Gluten Free Watchdog on July 6, 2017 from Amazon (Best By 08/25/18):
 - A gluten-free claim is included on the front label.
 - Ingredients: Naturally aged shoyu (water, soybeans, wheat, salt), Evaporated cane juice, Sake (rice, koji rice, water), Water, Fresh garlic, Rice starch, Rice vinegar and Spices
 - Label also states, “About gluten and wheat: all gluten from the wheat in this product is converted to amino acids during the fermentation process. More information and certifications are on our website.”
 - Label also states, “Contains wheat and soy.”
- **Salamida State Fair Big Hawaii Teriyaki Marinade:**
 - Product purchased by Gluten Free Watchdog on July 6, 2017 from Wal-Mart (Best By 12/14/18):
 - A gluten-free claim is made on the neck tag; the back label includes the claim, “No Gluten.”
 - Ingredients: Pineapple juice (water, pineapple juice concentrate), Soy sauce (water, soybeans, wheat, salt), Water, Vinegar (distilled, cider, water), Brown sugar, Sugar, Salt, Dehydrated garlic, Raisin juice concentrate, Spices, Orange peel, Caramel color, Natural flavor, Dehydrated onion, Vegetable gums (for consistency), Potassium sorbate & Sodium benzoate (preservatives).
- FDA, this is what you state in the online document, “Proposed Rule for Gluten-Free Labeling of Fermented or Hydrolyzed Foods” available at <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm472735.htm>:
 - **What additional requirements does FDA propose to verify a “gluten-free” claim on hydrolyzed or fermented foods?**
 - Because the current gluten tests do not adequately detect and quantify gluten in fermented and hydrolyzed foods or ingredients, FDA proposes that, in order to make a “gluten-free” claim, manufacturers of these foods would have to make and keep records to show all of the following:
 - The food meets the definition for “gluten-free” in 21 CFR 101.91(a)(3), including that the food had less than 20 ppm gluten, before fermentation or hydrolysis.
 - **What is an example of a hydrolyzed or fermented food product that would still not be permitted to bear the “gluten-free” claim in its labeling under this proposed rule?**

- Fermented or hydrolyzed soy sauce made from gluten-containing grains would not be permitted to bear a “gluten-free” claim, unless the grains were processed to remove gluten and the use of the ingredient resulted in the presence of less than 20 ppm gluten in the food. If, however, the soy sauce was made using a roasted grain that does not contain gluten, then it would be permitted to bear the “gluten-free” claim if it meets the other requirements of the gluten-free labeling rule.
- FDA, have you changed your policy on the use of wheat-based soy sauce in labeled gluten-free foods?
- 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, Gluten Free Watchdog is more than happy to send you the products we have in our possession for label verification.
- FDA, protect the health of people with celiac disease and **enforce your own rule.**

Sincerely,

Gluten Free Watchdog community member

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