

Supplement to Citizen Petition by Gluten Free Watchdog

FDA-2017-P-5118

January 14, 2018

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I. Introduction

Petitioners filed a citizen petition on August 23, 2017 (the “Petition”). We are filing this supplement to the Petition in order to inform FDA of important recent developments.

1. Additional Facially Misbranded Products Have Been Discovered: After the Petition was filed in August, consumers alerted Petitioners to 14 additional products in circulation that are “Facially Misbranded,” which is the term used by Petitioners to define products displaying a “gluten-free” claim yet also displaying gluten-containing grains (wheat, rye, barley) in the ingredients. The misbranded products appear to be from small to medium size companies offering “gluten-free” products but who do not specialize in gluten-free foods.
2. Unprecedented Support for Petition: An outpouring of support from the celiac disease community has been posted to the docket on the Petition, with over 1,200 public comments posted to-date, including comments from consumer advocacy groups.
3. Consumer Confusion: The public comments reflect considerable consumer confusion and suspicion within the celiac disease community concerning the “gluten-free” claim on labels.

In light of these recent developments, and for the reasons explained in the original Petition, we encourage FDA to implement the protocols requested in the Petition as soon as possible.

In addition, Petitioners are adding a 3rd requested action, which is for FDA to implement an educational effort targeted to small and medium size manufacturers offering “gluten-free” products, informing them of proper labeling practices under the Rule.

II. Recent Developments

A. Additional Facially Misbranded Products

Since the Petition was submitted last August, **14 more** Facially Misbranded products were discovered by consumers that were previously unknown to Petitioners. There are now 17 Facially Misbranded products that have been identified in circulation in 2017, confusing and endangering individuals with celiac disease in blatant violation of the Gluten-Free Labeling Rule found at 20 C.F.R. 101.91 (the “Rule”).¹

¹ Another 14 Facially Misbranded products were found in circulation in 2016, which brings the total number of Facially Misbranded Products discovered over the last two years to 31. 12 of those products were referenced in the Petition (barley/malt) and two were wheat-based soy sauce (not referenced in the Petition because more current examples of misbranding were available). www.glutenfreewatchdog.org/news/foods-labeled-gluten-free-yet-containing-barley-malt-ingredients/; www.glutenfreewatchdog.org/news/products-labeled-gluten-free-yet-containing-wheat-based-soy-sauce/. Because Petitioners lack resources to determine if the 14 products are still in circulation, they are not included in the list of 17 Facially Misbranded products above. FDA should investigate the 2016 products.

This is alarming. FDA should immediately (1) issue Warning Letters to each of the manufacturers within its jurisdiction on the basis of the improper labels and (2) issue a recall for all of the offending products.² While these 17 products can be found in the docket for the Petition, we provide a complete list below for quick reference, with photographs of each product compiled at the end of this document as Attachment B.

List of Facially Misbranded Products Discovered in Circulation in 2017
(photos are attached at end of this document for quick reference at Attachment B)

	Product	Date Added to Docket	Link to Citizen Petition Docket submission
1	Teriyaki Marinade	8/23/17 (with Petition)	https://www.regulations.gov/document?D=FDA-2017-P-5118-0003 https://www.regulations.gov/document?D=FDA-2017-P-5118-0004
2	Teriyaki Sauce and all Sauces containing Shoyu	8/23/17 (with Petition)	https://www.regulations.gov/document?D=FDA-2017-P-5118-0005 https://www.regulations.gov/document?D=FDA-2017-P-5118-0006
3	Yogurt and Berries Mini Rice-Cakes	8/23/17 (with Petition)	https://www.regulations.gov/document?D=FDA-2017-P-5118-0007 https://www.regulations.gov/document?D=FDA-2017-P-5118-0008
4	Aloha Sauce	8/31/17	https://www.regulations.gov/document?D=FDA-2017-P-5118-0201
5	Barbecue Sauce	9/28/17	https://www.regulations.gov/document?D=FDA-2017-P-5118-0645
6	Muffins	10/25/17	https://www.regulations.gov/document?D=FDA-2017-P-5118-1027
7	Gummie Vitamins	11/24/17	https://www.regulations.gov/document?D=FDA-2017-P-5118-1093
8	Instant Herbal Beverage	11/24/17	https://www.regulations.gov/document?D=FDA-2017-P-5118-1075
9	Instant Cereal Drink	11/24/17	https://www.regulations.gov/document?D=FDA-2017-P-5118-1075
10	Potato Chips	11/24/17	https://www.regulations.gov/document?D=FDA-2017-P-5118-1046
11	Cookies	11/24/17	https://www.regulations.gov/document?D=FDA-2017-P-5118-1045
12	Cough Drops	12/5/17	https://www.regulations.gov/document?D=FDA-2017-P-5118-1116
13	Chocolates	12/5/17	https://www.regulations.gov/document?D=FDA-2017-P-5118-1117
14	Cookies	1/2/18	https://www.regulations.gov/document?D=FDA-2017-P-5118-1172
15	Cookies	1/8/18	https://www.regulations.gov/document?D=FDA-2017-P-5118-1184
16	Jerky	10/13/17	https://www.regulations.gov/document?D=FDA-2017-P-5118-0924
17	Pot Roast	12/18/27	https://www.regulations.gov/document?D=FDA-2017-P-5118-1133

² All of Petitioner’s submissions to the Docket are redacted, and we will provide manufacturer information to FDA if requested. While items 16 and 17 are not within FDA jurisdiction, these products provide examples of how manufacturers are not complying with the rules. USDA was contacted about items 16 and 17 soon after their discovery.

The fact that these products made it into the hands of consumers conclusively demonstrates a deficit in the current system. One product discovered just twelve (12) days ago is especially concerning. Item #14 on the list above references “gluten-free “cookies given as a Christmas gift. The first item on the ingredients list is whole wheat flour. It was confirmed with the manufacturer that the product does, in fact, contain whole wheat flour and that the “gluten-free” label was due to “printer error.” FDA-2017-P-5118-1172.³ No better example than item #14 can be produced as to why Facial Misbranding is a real problem, why there needs to be an easy avenue for consumer reporting to FDA, and why FDA must promptly notify manufacturers immediately when one of these products finds their way to a consumer. This simply must end.

In addition, the Facial Misbranding problem has a wider unacceptable impact when it comes to products that are used in restaurants and cafeterias. It appears that one manufacturer on the list above distributes its products to food service entities: Schools/colleges/universities, hospitals/clinics, restaurants, caterers, value-added/prepared foods, and the military.⁴ Those entities, relying on the false “gluten-free” label, then use the product in the “gluten-free” foods they serve to their customers. Those customers rely on a good-faith representation that the food they are eating is gluten-free. But the food is not, in-fact, gluten-free if it is made with a Facially Misbranded product. The restaurant or cafeteria is an unwitting participant in distributing misbranded food to its customers who eat gluten-free.

The number of Facially Misbranded products in circulation is unacceptable. Only when FDA creates a system that allows for easy consumer reporting and swift agency response will manufacturers cease this dangerous practice.

B. Overwhelming and Universal Public Support for Petition

The Petition has received overwhelming public support, with over 1,200 favorable comments received to-date. The public comments come almost entirely from individual consumers, most of whom are celiac disease patients, and many comments contain compelling personal stories.

In addition, the Petition has been supported by important consumer organizations:⁵

- Center for Science in the Public Interest (“CSPI”)
- The National Celiac Association
- Beyond Celiac.

³ Fortunately, the recipient of the gift read the ingredients list, noticed the whole wheat flour ingredient, and did not consume the product. FDA-2017-P-5118-1172.

⁴ Petitioners will provide additional information to FDA upon request.

⁵ See CSPI’s public comment to docket in a letter dated 12/20/17 (<https://www.regulations.gov/document?D=FDA-2017-P-5118-1156>); National Celiac Association public comment to docket on 11/24/17 (<https://www.regulations.gov/document?D=FDA-2017-P-5118-1053>); Beyond Celiac public comment to docket on 8/31/17(<https://www.regulations.gov/document?D=FDA-2017-P-5118-0230>).

No other citizen petition filed with FDA in the non-rulemaking “food” category in 2017 or 2016 has received that volume of public support. Petitioners are unaware of any comments filed from industry.⁶ There have been no credible adverse comments submitted.⁷

The level of concern expressed publicly on the Petition sends a clear message to FDA that this issue is of paramount importance to the vulnerable community protected by the Gluten-Free Labeling Rule.

C. Consumer Confusion

Reading through the public comments on the Petition, a clear theme of consumer confusion and suspicion surfaces. While one could argue that “only” 17 Facially Misbranded products are in circulation, the mere existence of these products in the hands of consumers creates a significant “tip of the iceberg” problem.⁸ It has caused consumers to lose trust in the Gluten-Free Labeling Rule. Many commenters also express frustration that they have relied on the Rule when they tell their children with celiac disease and well-meaning extended family members and friends that when the words “gluten-free” are on a package, that means the product is safe to eat. Indeed, that is presumably what the consumer thought when purchasing item #14, discussed earlier on page 3. Unfortunately, too many products have surfaced in violation of the Rule, such that now the words “gluten-free” are not credible when displayed on product labels, and individuals with celiac disease have returned to the laborious task of scrutinizing labels.

It is time to restore confidence within the celiac disease community. The Gluten-Free Labeling Rule was an important and welcome regulation, statutorily mandated and necessary to ensure safety within the celiac disease community. FDA recognized the Rule was “necessary to ensure that individuals with celiac disease are not misled and are provided with truthful and accurate information with respect to foods so labeled.” 78 FR 47155 (August 5, 2013). The Gluten-Free Labeling Rule itself is not the issue here. The Rule is a good regulation promulgated under statutory mandate. It is the lack of enforcement that has caused misbranded products to surface and consumers to lose confidence in labels. When FDA increases its surveillance and follow-up with manufacturers, it will restore consumer confidence in “gluten-free” labels, consistent with the underlying objectives of the Rule.⁹

⁶ None of the comments marked as from “industry” appear to be from industry. See, e.g., <https://www.regulations.gov/document?D=FDA-2017-P-5118-0131>; <https://www.regulations.gov/document?D=FDA-2017-P-5118-0131>

⁷ A single “troll” comment should be completely disregarded because it is uninformed and inflammatory (calling celiac disease a “farcical hysteria,” “en vogue” and an “asinine and inconsequential fad.”). One hesitates to even mention it in a footnote.

⁸ Petitioners suspect that the 17 Facially Misbranded products that surfaced since the Petition was filed are not the only misbranded products in circulation.

⁹ While the Petition addresses Facial Misbranding, Petitioners encourage FDA to increase its surveillance and enforcement of products that are misbranded because they display a “gluten-free” claim but reliable testing indicates they exceed the regulatory limit of 20ppm gluten.

III. Action Requested

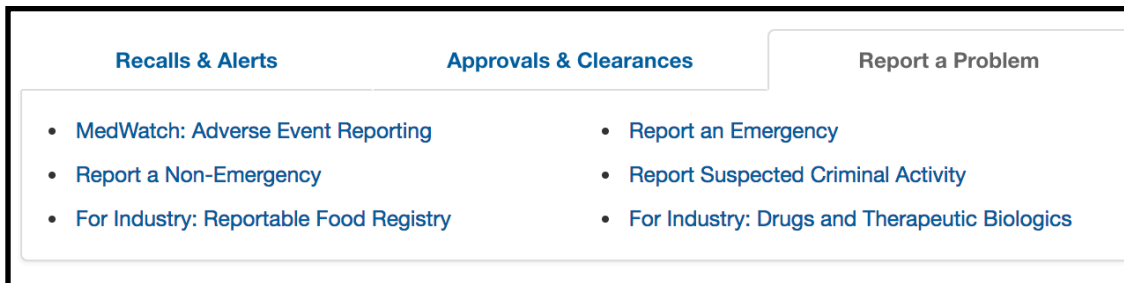
A. Electronic Consumer Reporting System for Misbranding

Given the developments on the Petition in the last few months, especially the alarming number of misbranded products that surfaced, we encourage FDA to create an electronic reporting system now so that additional unlawful products can easily be made known to FDA.

FDA does not need to await the close of the public comment period to act on this suggestion, and it can be done independent of FDA's determination on the Petition's second request of issuing Warning Letters in response to reports of Facial Misbranding. Not a single comment has voiced opposition to the electronic consumer reporting recommendation.

As discussed at length in the original Petition and in CSPI's public comment ([FDA-2017-P-5118-1156](#)), the current reporting mechanisms are inadequate for reporting misbranding violations. The Petition's proposed solution is simple and efficient. FDA need only create a link on its website, with photo uploading. The submissions can be automatically directed to CFSAN personnel, label enforcement personnel, and the regional office where the manufacturer is located. The link can be added to the "Report a Problem" section of the FDA website, for "Report a Mislabeled Product." See Attachment A as an example of a simple form.

Screenshot of current FDA website



Indeed, the submission of public comments on the Petition provided an excellent example of the efficient electronic consumer reporting mechanism we are requesting. Photos of misbranded products were easily uploaded to the Petition's docket. FDA expended no resources looking for these violations and now has 17 documented violations needing its follow-up. Because we know FDA has limited resources to devote to searching for misbranded products, FDA should welcome consumer reporting in the efficient manner proposed by Petitioners so it can turn its attention to following-up with the manufacturers. Consumers are the best tool for finding misbranded products.¹⁰

¹⁰ To the extent FDA wants to create an electronic consumer reporting mechanism to collect all misbranded product violations under any FDA rule, Petitioners agree with such a mechanism. However, plans for a larger program should not cause delay in implementation of the simple protocol recommended by Petitioners for Gluten-Free Labeling Rule violations, which should be used as a pilot program before FDA expands into other labeling areas.

Alternatively, as mentioned by CSPI on page 2 of its letter filed as a public comment to the Petitions' docket (FDA-2017-P-5118-1156), FDA's "Bad Ad" program might provide a model for consumer reporting, in which reports of misleading prescription drug promotion can be made via email.¹¹ While an FDA email address for consumer reporting of Facial Misbranding is an acceptable method for consumer reporting, Petitioners believe an electronic form submission would be superior and more efficient over the long-term. An electronic form ensures complete and uniform collection of information, with few resources needed by FDA to interpret, collect and forward the submissions.

B. Swift FDA Response to Electronic Consumer Reporting

The Petition requests that FDA routinely issue a Warning Letter within thirty (30) days of receiving a documented Facial Misbranding violation. This type of consistency is essential for removing misbranded products from circulation as soon as possible. Petitioners have discovered a total of 31 Facially Misbranded products in circulation at some point since 2016, some of which were identified to FDA. Yet we are unable to locate any Warning Letter issued on the basis of Facial Misbranding, where the violation is evident from the label itself. Only five companies have recalled Facially Misbranded products, but they are not among the 31 Facially Misbranded products.¹² Petitioners cannot determine if the recalls were in response to an FDA request. If FDA has engaged in additional enforcement action, Petitioners are unaware of it and it most certainly has not been visible enough to provide deterrence. If FDA's position is that it has been unaware of the extent of Facially Misbranded products in circulation, the solution for that problem is to create a uniform electronic consumer reporting mechanism.

While FDA appears to be somewhat active in searching for products that are misbranded because they are labeled "gluten-free" and contain in excess of 20ppm gluten, that is not the subject of the Petition and such actions are irrelevant to the existence of the current Facial Misbranding violations needing follow up from FDA.¹³

¹¹ <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/DrugMarketingAdvertisingandCommunications/ucm209384.htm#ContactInformation>

¹² According to the Enforcement database, five companies issued recall for Facially Misbranded products since August 2014, when the Rule became effective: Vitamins (<https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=132334> and <https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=132335>); potato chips (<https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=141348P>); yogurt with granola (<https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=141954>); yogurt with mislabeled overwrap (<https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=148851>); pre-packaged meal (<https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=150816>).

¹³ Petitioners can find only one Warning Letter issued because a product labeled "gluten-free" contained in excess of 20ppm of gluten. See FDA 6/21/16 letter to Popsalot, issued three months after inspection of the facility. <https://www.fda.gov/iceci/enforcementactions/warningletters/2016/ucm508278.htm>. The product was recalled. <https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=146406>. Petitioners are also aware of FDA's "Gluten-Free Food Product Surveillance Sampling" in 2015-16, in which 250 products were collected and sampled, and one product was found to contain gluten in excess of the 20ppm limit and was recalled for "undeclared wheat." <https://www.fda.gov/food/complianceenforcement/sampling/ucm560840.htm>; <https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=140707>; <https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=140712>.

Because Facially Misbranded products persist in circulation, it is imperative that FDA consistently and timely issue a simple and straightforward Warning Letter when it receives photographs documenting a Facial Misbranding violation.

C. Education Outreach to Small and Medium-Size Manufacturers

In reviewing the list of 31 Facially Misbranding products dating back to January of 2016, none come from large manufacturers, nor do any come from the numerous reputable companies that have long been making products that are gluten-free.

To be clear, the gluten-free community relies on responsible manufacturers of gluten-free food and greatly appreciates their efforts and commitment to provide safe and properly labeled foods. There are many such manufacturers.

However, there are too many small and medium size manufacturers — at least 17 in 2017 — who are either uninformed, indifferent or intentionally misbranding. Not only should these companies be subject to immediate enforcement when they violate the labeling laws, FDA should consider educational outreach to all the companies in this category, informing them of exactly what is required before a product can display a “gluten-free” claim.¹⁴

D. No Interim Response on the Petition

To the extent FDA is contemplating the issuance of an Interim Response on this Petition, we strongly urge FDA to reconsider. While several citizen petitions in the non-rulemaking “food” category have been met with an Interim Response from FDA indicating the agency will not make a decision due to limited resources and higher priorities, this matter should not suffer the same fate.

We have demonstrated current misbranding violations, and over 1,200 people have gone on record in support of the Petition. To defer a decision here by issuing an Interim Response would cause a severe blow to the vulnerable community who relies on FDA and the Rule to protect them and would send a message to manufacturers that FDA is not enforcing its Rule. The public comments make clear that the celiac disease community is concerned, confused and feels it is not being protected. FDA should grant the petition and create the simple and efficient system recommended.

¹⁴ Petitioners suspect that there are far more misbranded products in circulation than the products we have identified.

IV. Conclusion

As FDA is well-aware, it was a long journey over several years to finalize the Gluten-Free Labeling Rule. The Rule is a good regulation, reflecting considerable input from doctors, scientists, dietitians, consumers and industry. The Rule has increased the availability of safe foods for those with celiac disease. Many responsible gluten-free food manufacturers have taken the time and resources to ensure their labeling practices comply with the Rule, and Petitioners once again acknowledge and appreciate those manufacturers for their efforts.

But the journey is not complete. Too many misbranded products remain in circulation. We only ask that FDA promptly turn its attention to the manufacturers who blatantly are not in compliance. These manufacturers should not continue to profit off their unlawful practices at the expense of the health and welfare of the celiac disease community. Further, the playing field should be leveled for the benefit of the large number of conscientious manufacturers who take the time to understand and comply with the Rule.

Petitioners' proposed system of consumer reporting and FDA follow-up is neither complicated nor resource intensive. Just the existence of such a system will provide deterrence. Specific manufacturers who are either uninformed, indifferent or intentionally misbranding will promptly change their practices when they hear from FDA on one of their products. This, in turn, will reduce the number of misbranded products in circulation, thereby meeting the objectives of the Gluten-Free Labeling Rule and restoring consumer confidence in the terms "gluten-free" when they appear on a product.

Petitioners sincerely appreciate FDA's consideration of the Citizen Petition and this Supplement.

Respectfully submitted,

Petitioners:

Tricia Thompson, MS, RD
Founder, Gluten Free Watchdog, LLC, a consumer advocacy group
www.glutenfreewatchdog.org

and

Kaki Schmidt
Individual Consumer and member of Gluten Free Watchdog, LLC.

V. ATTACHMENTS

ATTACHMENT A: SAMPLE FORM FOR ELECTRONIC CONSUMER REPORTING OF MISBRANDED PRODUCTS UNDER GLUTEN- FREE LABELING RULE

This sample form is “live” online and can be sampled here: <https://goo.gl/forms/EgDe0UVbvHMobz5F3>

-
- This form is for consumers to report mislabeled products.
 - Your submission requires that you upload photographs of the entire product label(s) and that the product is in-hand and photographed by you personally.
 - Your photos should capture the ENTIRE PRODUCT LABEL and words/symbols must be in focus and legible.
 - Photographs from websites will not be considered.
 - Incomplete submissions will not be considered.
 - If you were made ill by consuming this product, please also do the following:
 1. Complete a MedWatch Voluntary Report form: <https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=consumer.reporting1>
- AND
2. Call your state's Consumer Complaint Coordinator (<https://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators/>)
-

1. Email address

[Your email](#)

2. UPLOAD PHOTOGRAPHS SHOWING ALL LABELS ON THE PRODUCT. You must have the product in-hand and photograph it yourself. Photographs from websites will not be considered.

[ADD FILE](#)

3. Name of Product

[Your answer](#)

4. Check all words or symbols below that appear on this product's label claiming that the product is gluten-free. If there is no indication on the product that leads you to believe the product is "gluten-free," STOP and do not proceed further.

"Gluten-Free"

"Certified Gluten-Free"

"No gluten"

"Free of gluten"

"Without gluten"

Other: Your answer_____

5. Check all gluten-containing ingredients that appear on the product label.

"Wheat"

"Rye"

"Barley"

"Malt"

Other: Your answer_____

6. Is this product a soy sauce or a product that lists soy sauce as an ingredient?

Yes

No

7. Does this product list "wheat" as a sub-ingredient in parenthesis for a soy sauce ingredient? Example: "Soy sauce (Water, Soy Beans, Wheat, Salt)."

Yes

No

8. Does the product have a "CONTAINS: WHEAT" statement near the ingredients list? A "MAY CONTAIN" statement does not qualify for a "yes" on this question.

Yes

No

9. If the product lists "wheat" as an ingredient or in a CONTAINS statement, is there an asterisk (*) next to the word "wheat" on the label with reference to another asterisk containing the language quoted below?

"*The wheat has been processed to allow this food to meet the Food and Drug Administration (FDA) requirements for gluten-free foods."

Yes

No

10. Manufacturer of Product

Your answer

11. State of Manufacture

Your answer

12. "Use by" or "Best By" Date

Your answer

13. Lot Number

Your answer

14. Indicate the name of the store or online vendor where this product is for sale.

Your answer

15. Other comments.

Your answer

16. Name and contact information for consumer submitting the form.

Your answer

ATTACHMENT B: PHOTOS OF FACIALLY MISBRANDED PRODUCTS IN CIRCULATION IN 2017

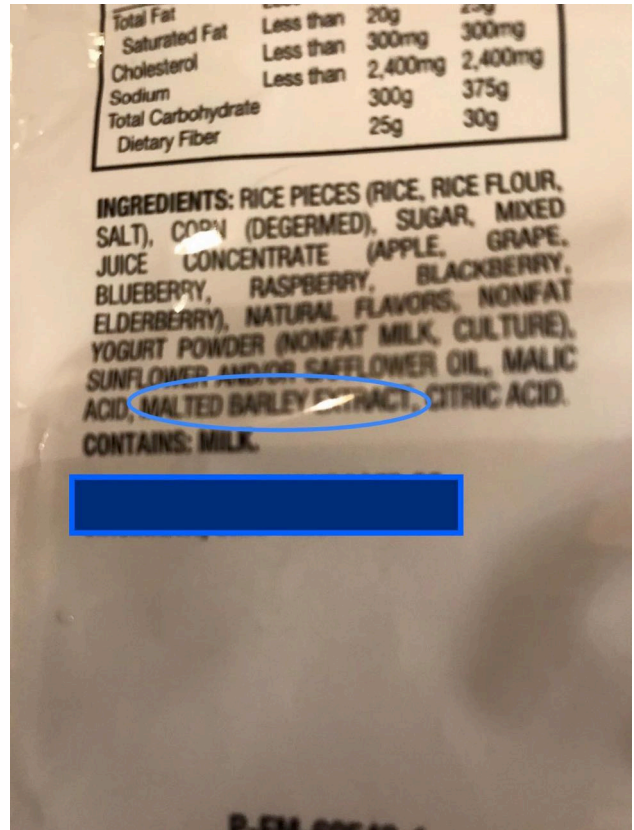
1. Teriyaki Marinade (FDA-2017-P-5118-0003 and 0004) / Posted with Petition 8/23/17



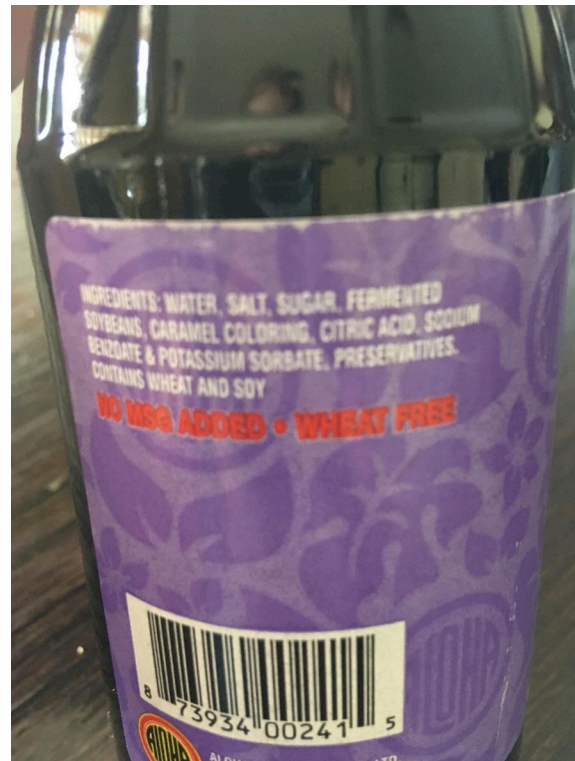
2. Teriyaki Sauce and all Sauces containing Shoyu (FDA-2017-P-5118-0005 and 0006) / Posted with Petition 8/23/17



3. Yogurt and Berries Mini Rice Cakes (FDA-2017-P-5118-0007 and 0008) / Posted with petition 8/23/17



4. Aloha Sauce (FDA-2017-P-5118-0201) / Posted to docket 8/31/17



5. **Barbecue Sauce** (FDA-2017-P-5118-0645) / Posted to docket 9/28/17



6. Muffins (FDA-2017-P-5118-1027) / Posted to docket 10/25/17

Meet your next favorite flavor!

BANANA CHOCOLATE CHIP *made for PROTEIN LOVERS*

CHOCOLATE CHIP *made GLUTEN FREE*

PEANUT BUTTER *made for PROTEIN LOVERS*

CRAN BRAN *made with SUPERFOODS*
Cranberries, Dates, Chia Seeds & Flaxseed

WILD BLUEBERRY *74% ORGANIC*

INGREDIENTS: WHOLE WHEAT FLOUR, ORGANIC SUGAR, CHOCOLY ROOT EXTRACT (BINUANG), ORGANIC OAT FIBER, ORGANIC CHOCOLATE CHIPS (ORGANIC CANE SUGAR, ORGANIC UNSWEETENED CHOCOLATE, ORGANIC COCOA BUTTER, ORGANIC DEXTROSE, ORGANIC SOY LECITHIN [AN EMULSIFIER]), ORGANIC COCOA POWDER, NONORGANIC CHOCOLATE CHIPS (SUGAR, CHOCOLATE LIQUOR, COCOA BUTTER, SOY LECITHIN [AN EMULSIFIER]), EGG WHITE, LEAVENING (SODIUM ACID PYROPHOSPHATE, SODIUM BICARBONATE), NATURAL FLAVOR, NON FAT DRY MILK, SALT, XANTHAN GUM, GUAR GUM, NUTRIENTS FROM WHOLE FRUIT AND VEGETABLE CONCENTRATES, STEVIA EXTRACT

CONTAINS: EGG, MILK, SOY, WHEAT

KEEP FROZEN UNTIL READY FOR USE

Manufactured for Classic Cooking
Jamaica, NY, 11434
vitalicious.com
877-VITA-877

Certified Organic by NOFA-NY

We'd love to talk to you!
Facebook.com/vitatops
telius@vitalicious.com

Product of USA

OUR PROMISE

We believe in having your cake and eating it too. You don't have to make sacrifices because our baked goods give you the best of taste, calories, and nutrients.



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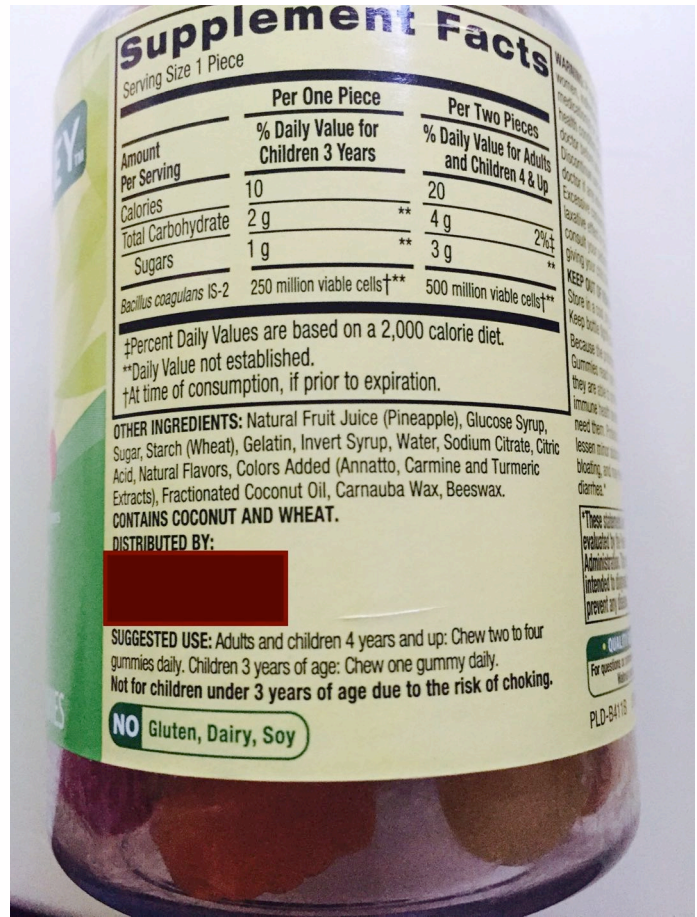
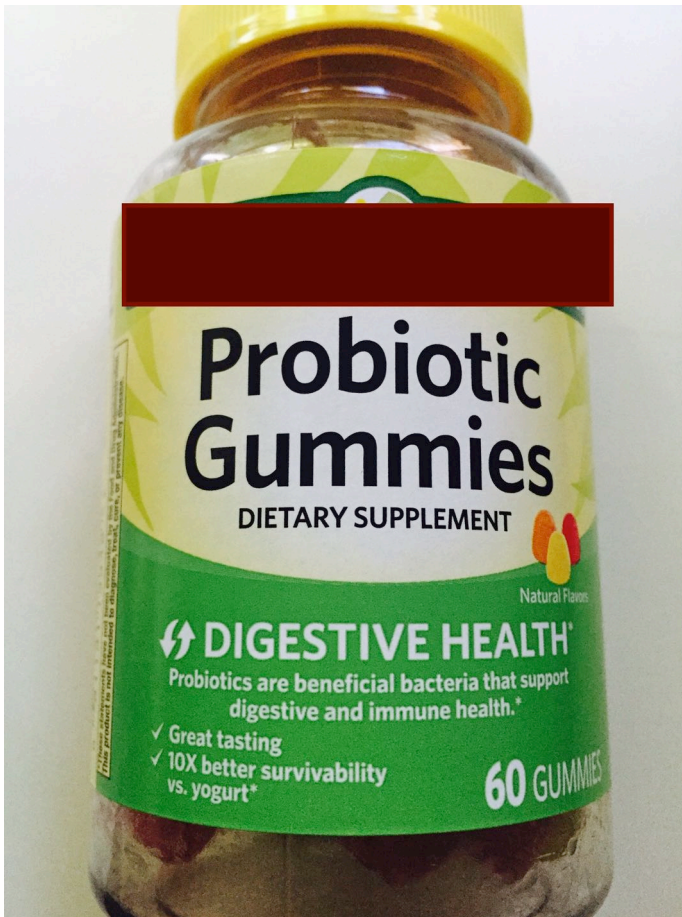
Weight Watchers® SmartPoints™ Value 4*

*The SmartPoints™ value for this product was calculated by Vitalicious, Inc., and is provided for informational purposes only. This is not an endorsement, sponsorship or approval of this product or its manufacturer by Weight Watchers International, Inc., the owner of the Weight Watchers® and SmartPoints™ registered trademarks.

Nutrition Facts
Serving Size 1 VitaTop 57g (2 oz.)
Servings Per Container 4

Amount Per Serving		% Daily Value*
Calories 100		
Total Fat 2g		3%
Saturated Fat 1g		5%
Trans Fat 0g		
Cholesterol 0mg		0%
Sodium 230mg		10%
Total Carbohydrate 27g		9%
Dietary Fiber 10g		40%
Insoluble Fiber 4g		
Sugars 11g		
Protein 3g		
Vitamin A 10%	Vitamin C 10%	
Calcium 2%	Iron 10%	
Vitamin D 10%	Vitamin E 10%	
Vitamin K 10%	Thiamin 15%	
Riboflavin 10%	Niacin 10%	
Vitamin B6 10%	Folate 10%	
Biotin 10%	Pantothenic Acid 10%	
<small>*Percent Daily Values (DV) are based on a 2000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.</small>		
	Calories	2,000 2,500
Total Fat	Less than 65g	80g
Saturated Fat	Less than 20g	25g
Cholesterol	Less than 300mg	300mg
Sodium	Less than 2,400mg	2,400mg
Total Carbohydrate	300g	375g
Dietary Fiber	25g	30g
<small>Calories per gram:</small>		
Fat	9	Carbohydrates 4 • Protein 4

7. **Gummie Vitamins (FDA-2017-P-5118-1093) /**
 Posted to docket 11/24/17



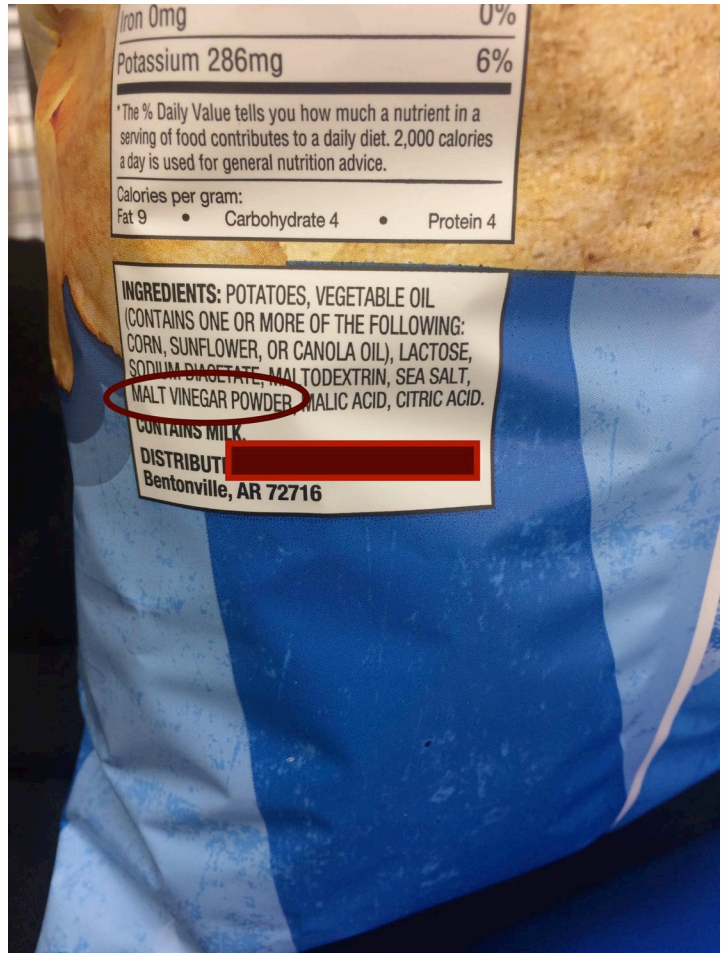
8. Instant Herbal Beverage (FDA-2017-P-5118-1075) / Posted to docket 11/24/17



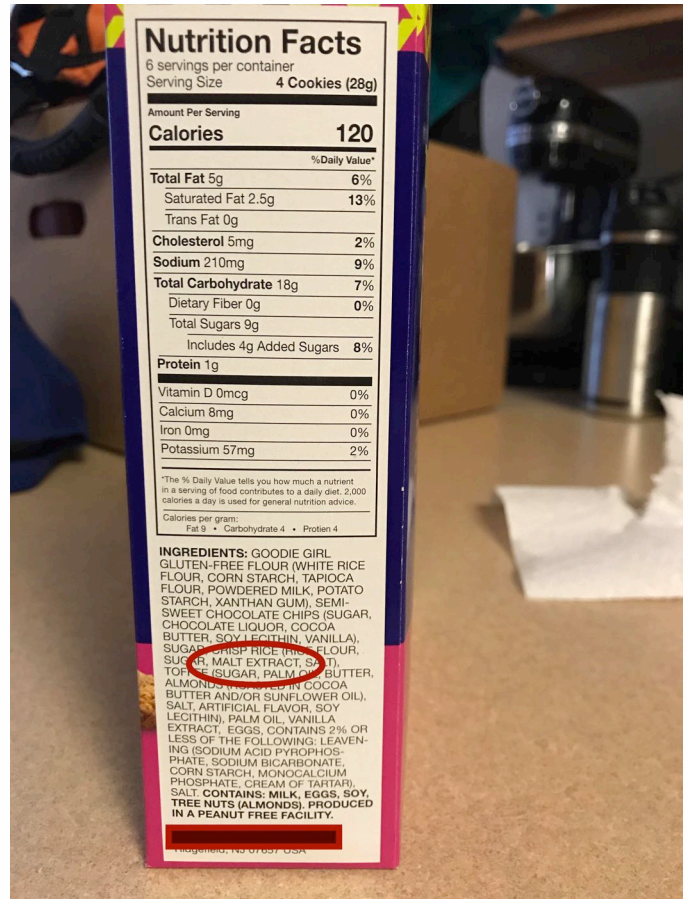
9. **Instant Cereal Drink (FDA-2017-P-5118-1075)** /
Posted to docket 11/24/17



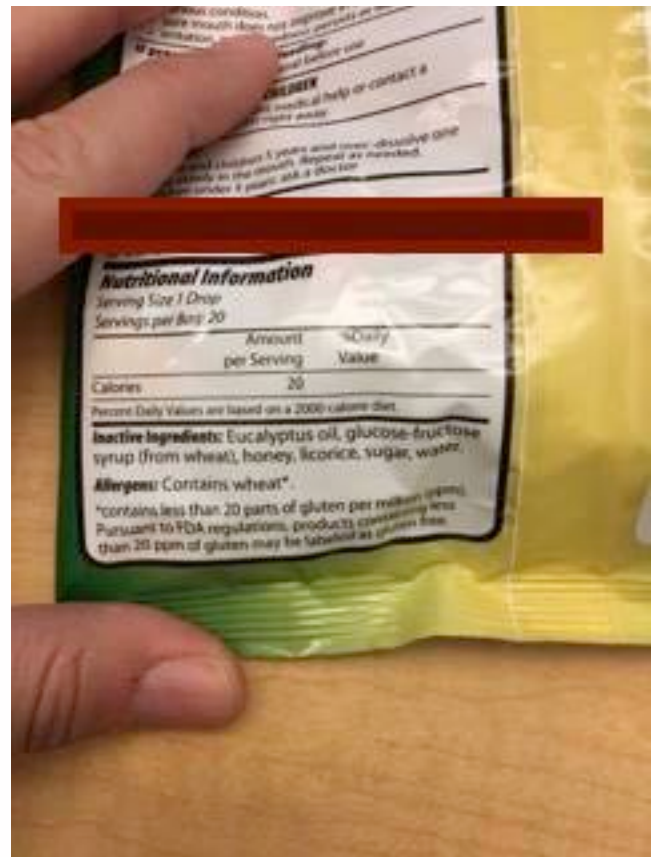
10. **Potato Chips (FDA-2017-P-5118-1046)** / Posted to docket 11/24/17



11. Cookies (FDA-2017-P-5118-1045) / Posted to docket 11/24/17




12. Cough Drops (FDA-2017-P-5118-1116) / Posted to docket 12/5/17



13. Chocolates (FDA-2017-P-5118-1117) / Posted to docket 12/5/17



 (Cane sugar, cinnamon, cocoa, coffee and vanilla): traded in compliance with Fairtrade Standards, total 60%. Fairtrade means fairer trading conditions and opportunities for producers in developing countries to invest in their businesses and communities for a sustainable future. Visit www.info.fairtrade.net

Assorted filled chocolates, coated with dark, milk and white chocolate

Nutrition Facts	
about 14 servings per container	
Serv size 1 oz (28g/about 2 pieces)	
Amount Per Serving	% Daily Value*
Calories 160	
Total Fat 11g	14%
Saturated Fat 7g	36%
Trans Fat 0g	
Cholesterol 10mg	3%
Sodium 10mg	0%
Total Carbohydrate 14g	5%
Dietary Fiber <1g	3%
Total Sugars 12g	
Includes 10g Added Sugars	20%
Protein 1g	
Vitamin D 0mcg	0%
Calcium 5mg	
Iron 0.1mg	0%
Potassium 120mg	2%

*The % Daily Value (DV) tells you how much a nutrient in a serving contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Ingredients: Milk Chocolate (sugar, milk, cocoa butter, unsweetened chocolate, soy lecithin as an emulsifier), Dark Chocolate (unsweetened chocolate, sugar, cocoa butter, vanilla flavor, soy lecithin as an emulsifier), Anhydrous Butterfat, White Chocolate (sugar, cocoa butter, milk, whey, soy lecithin as an emulsifier), Fresh Cream (cream, stabilizer: carrageenan), Glucose Syrup. Less than 2% of the following: Invert Sugar, Palmfat, Coconut, Coconut Butter, Hazelnuts, Water, Cocoa Nibs, Almonds, Sugar, Condensed Milk, Glycerol as a stabilizer, Soy Lecithin, Mono and Di-glycerides as emulsifiers, Pistachios, Buckwheat Flour, Butter, Sea Salt, Potato Starch, Flavor, Eggs, Milk, Spices, Leavening (baking soda, ammonium bicarbonate), Milk Protein, Nonfat Milk, Coffee, Added Color (carotenes), Citric Acid, Ethyl Alcohol.

Contains Milk, Coconut, Hazelnuts, Almonds, Pistachios, Wheat, Eggs, Soy (lecithin).

Made in Belgium by
 Chemin du Fundus /
 7822 Ghislenghien
 Belgium

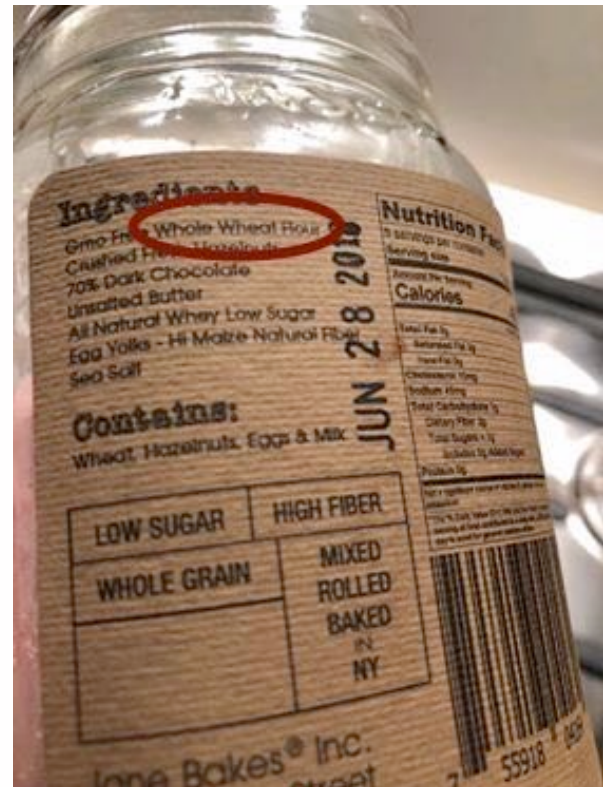
Distributed by IBC,
 a division of Advantage
 Sales & Marketing LLC,
 Marlton, NJ 08053

Modified atmosphere packaging.
 Net Wt 14.1 oz (400 g)

ITEM # 1128062

Keep in a cool and dry place

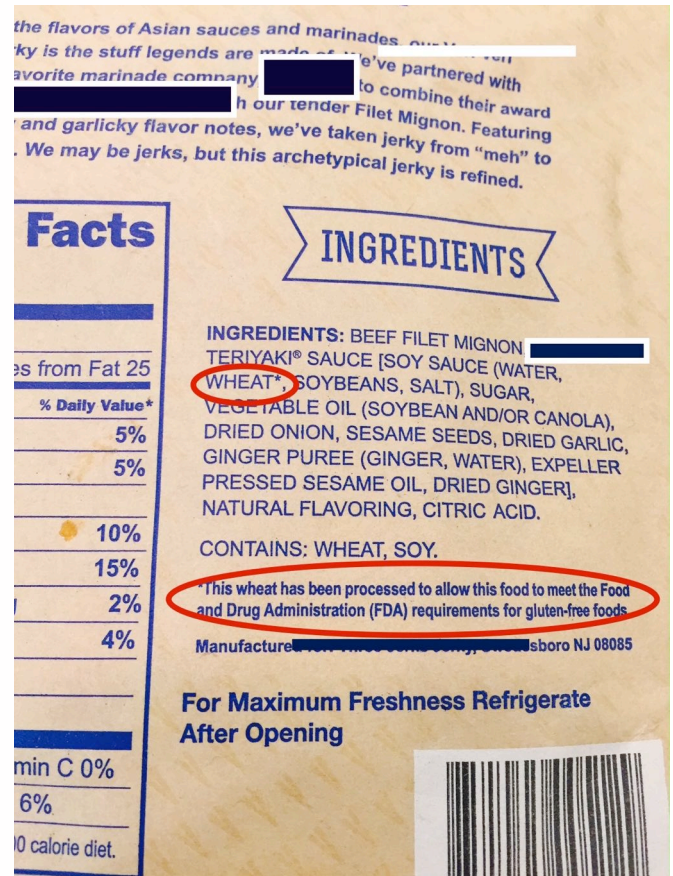
14. **Cookies (FDA-2017-P-5118-1172) / Posted to docket 1/2/18.**



15. **Cookies** (FDA-2017-P-5118-1184) / Posted to docket 1/8/18.



16. Jerky (FDA-2017-P-5118-0924) / Posted to docket 10/13/17.



17. **Pot Roast (FDA-2017-P-5118-1133)** / Posted to docket 12/18/27

