Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: October 9, 2015

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: American Pure Whey - RECALL [Food]

AFFECTED PRODUCT: Whey protein products

SUMMARY: Unclassified Recall; The recall has been initiated because the product contains undeclared milk allergen and soy allergen.

The whey products were manufactured under the following brand names:

Brand	Flavor	Lot number	Exp. Date	UPC Code
American Pure Whey Protein Matrix	Chocolate	69205	9/2017	456456789004
American Pure Whey Protein Matrix	Vanilla	69205	09/2017	783521095013
American Pure Whey Protein Isolate	Chocolate	29026	09/2017	753182812809
American Pure Whey Protein Isolate	Vanilla	29026	09/2017	78333109591
Body Construct Meal Replacement	Cinnamon Roll	78124	9/2017	839893989858
Build Your Own Body Protein Powder	Chocolate	67134	9/2017	456789517480

These products are available in 2 lb. and 5 lb. containers or in factory sealed food grade mylar bags.

The products were distributed to Indiana, Illinois, Kentucky, Michigan, and Ohio and reached directly to customers through mail order.

SUGGESTED ACTION: Recommend notification of affected parties via phone, fax, or e-mail. Consumers who have purchased whey protein products are urged to return it to the place of purchase for a full refund. Own label distributors are urged to return the product to us as soon as they have received the returns. Consumers with questions may contact the company at 1-888-399-0580, 8 a.m. to 5 p.m. Eastern Time, Monday through Friday, excluding holidays. Furthermore, if any recalled products are found, notify this office at 317-233-8475.

****

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

American Pure Whey Issues Allergy Alert on Undeclared Milk and Soy in Whey Protein Products

Contact:
Consumer:
888-399-0580

FOR IMMEDIATE RELEASE – October 7, 2015 – New Bern, NC – American Pure Whey, New Bern, NC is recalling its whey protein products, because they contain undeclared milk allergen and soy allergen. People who have an allergy or severe sensitivity to specific type of milk and soy run the risk of serious or life threatening allergic reaction if they consume these products.

The products were distributed to, AE, AZ, CA, CO, CT, DC, FL, IL, IN, KY, KS, MA, MD, MI, MO, NC, NE, NV, NY, OH, OK, OR, PA, TN, UT, VT, WA, WI & WY and reached directly to customers through mail order.

The whey products were manufactured under the following brand names:

Brand	Flavor	Lot number	Exp. Date	UPC Code
American Pure Whey Protein Matrix	Chocolate	69205	9/2017	456456789004
American Pure Whey Protein Matrix	Vanilla	69205	09/2017	783521095013
American Pure Whey Protein Isolate	Chocolate	29026	09/2017	753182812809
American Pure Whey Protein Isolate	Vanilla	29026	09/2017	78333109591
Body Construct Meal Replacement	Cinnamon Roll	78124	9/2017	839893989858
Build Your Own Body Protein Powder	Chocolate	67134	9/2017	456789517480

These products are available in 2 lb. and 5 lb. containers or in factory sealed food grade mylar bags.

No illnesses have been reported to date.

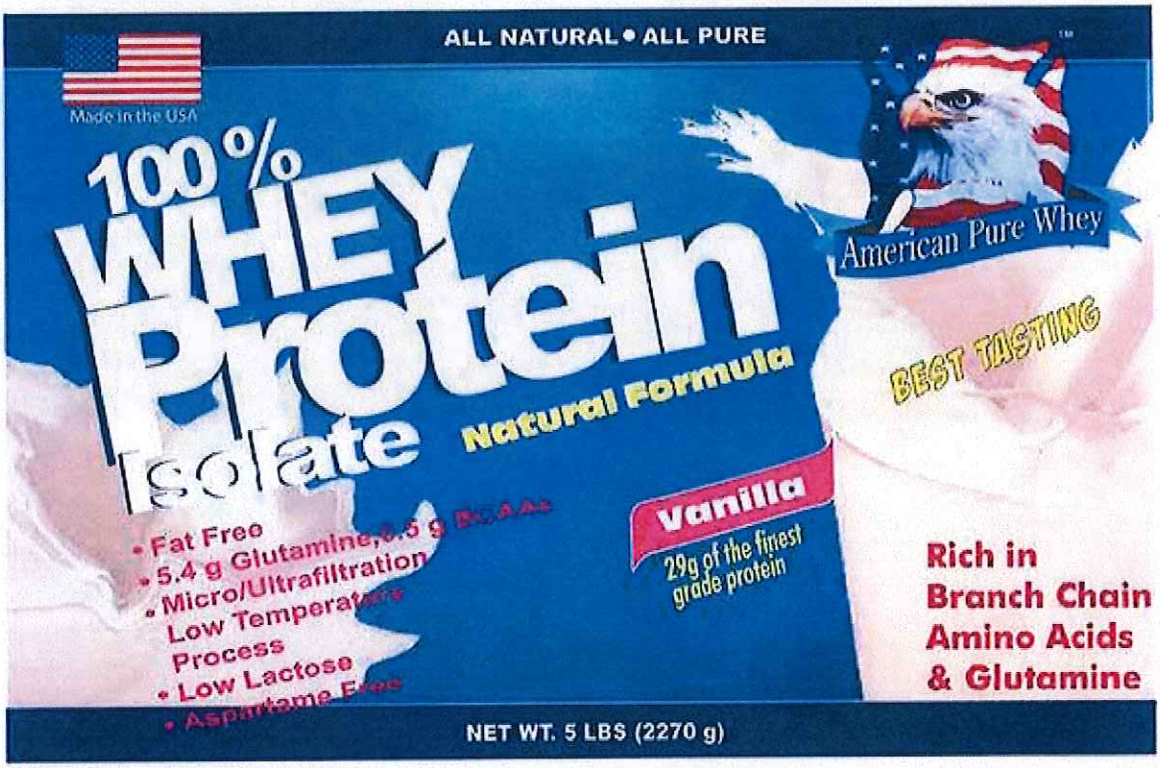
The recall was initiated after it was discovered that product containing whey (from milk) and soy lecithin (from soy) was distributed in packaging that did not reveal the presence of the allergens on the label. Subsequent investigation indicates, the problem was caused by a temporary breakdown in the company's production and packaging processes.

Consumers who have purchased whey protein products are urged to return it to the place of purchase for a full refund. Own label distributors are urged to return the product to us as soon as they have received the returns. Consumers with questions may contact the company at 1-888-399-0580, 8 a.m. to 5 p.m. Eastern Time, Monday through Friday, excluding holidays.

The U.S. Food and Drug Administration have been notified of this voluntary recall.

###

American Pure Whey Issues Allergy Alert on Undeclared Milk and Soy in Whey Protein Products
Photo



DIRECTIONS FOR USE

As a dietary supplement, mix 1 level scoop of 100% Whey Protein Isolate with 5-6 ounces of water or milk. Try with juice for a different flavor combination. Stir, shake, or blend until dissolved. Enjoy right away! Add 100% Whey Protein Isolate to your oatmeal, pudding, or favorite recipes for a protein kick!

AMINO ACID PROFILE

	Whey Protein Isolate 33 g protein per serving mg/serving
Alanine	1.470
Arginine	0.656
Aspartic acid	4.002
Cysteine / Cystine	0.87
Glutamic acid	5.452
Glycine	0.551
Histidine*	0.551
Isoleucine*	1.827
Leucine*	3.045
Lysine*	2.552
Methionine*	0.754
Phenylalanine*	1.015
Proline	1.705
Taurine	0
Serine	1.470
Threonine*	2.088
Tryptophan*	0.696
Tyrosine	0.899
Valine*	1.711
*essential amino acids (BCAAs)	

American Pure Whey

www.AmericanPureWhey.com
MANUFACTURED BY AMERICAN PURE WHEY
3918 HWY US 70E
NEW BERN, NC 28560

Nutrition Facts
Vanilla

Serving Size: 1 oz. = 1 scoop (33 g)
Servings : 69

	Amount Per Serving	% Daily Value*
Calories	121	
Calories from Fat	1.92	
Total Fat	0 g	0%
Saturated Fat	0 g	0%
Trans Fat	0 g	0%
Cholesterol	4.64 mg	1%
Total Carbohydrate	1.55 g	0%
Dietary Fiber	0 g	1%
Sugars	1 g	0%
Calcium	139 mg	14%
Phosphorus	68.4 mg	7%
Sodium	49 mg	2%
Potassium	99 mg	3%
Protein	29 g	58%
BCAA	500 mg	0%
Creatine Monohydrate	437.5 mg	0%
Magnesium Creatine Chelate	437.5 mg	0%
Ribose	600 mg	0%

* Percent Daily Values are based on 2000 calories. Your daily values may be higher or lower depending on your calorie needs

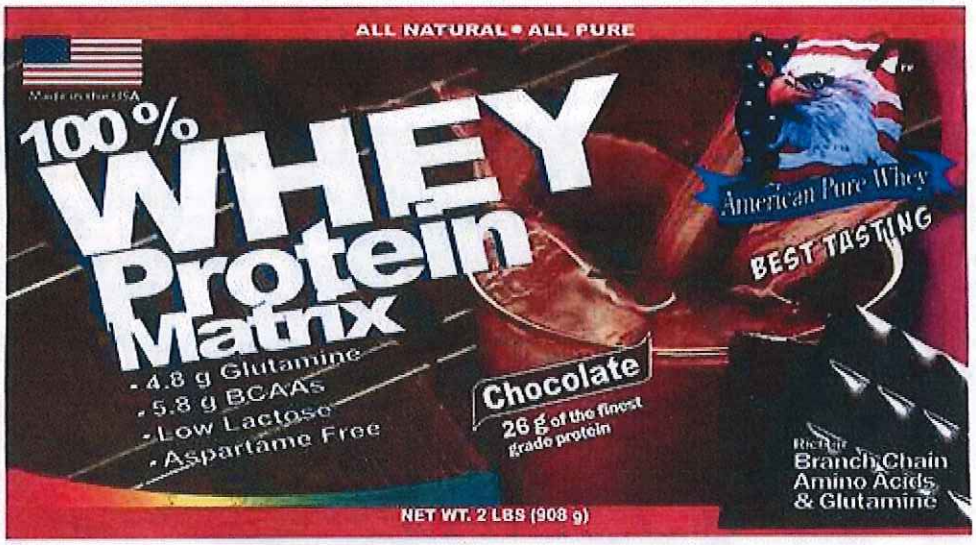
	Calories	2000	2500
Total Fat	Less Than	65 g	80 g
Saturated Fat	Less Than	20 g	25 g
Cholesterol	Less Than	300 g	300 g
Sodium	Less Than	2400 mg	2400 mg
Potassium		3500 mg	3500 mg
Total Carbohydrate		300 g	375 g
Dietary Fiber		25 g	30 g
Protein		50 g	65 g

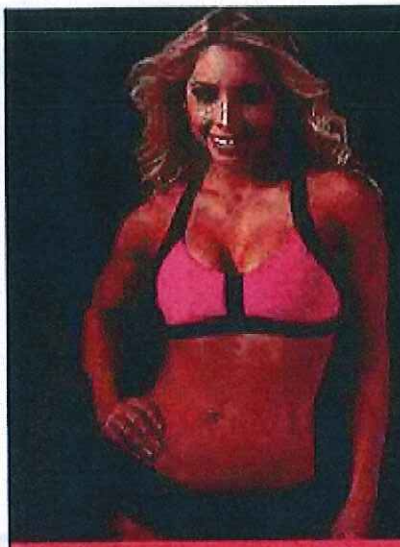
Calories per gram: Fat = 9, Protein = 4, Carbohydrate = 4
INGREDIENTS: Pure Whey Protein Isolate, Natural Flavor, Xanthan Gum, Stevia

Contains Milk and Soy

48597 85875 7

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.


ALL NATURAL • ALL PURE
Made in the USA
100% WHEY Protein Matrix
• 4.8 g Glutamine
• 5.8 g BCAAs
• Low Lactose
• Aspartame Free
American Pure Whey
BEST TASTING
Chocolate
26 g of the finest grade protein
Rich in Branch Chain Amino Acids & Glutamine
NET WT. 2 LBS (908 g)



BODY CONSTRUCT™

LORI-ANN MARCHESE

Meal Replacement

- ✔ 25 g of Protein per Scoop
- ✔ Low Carbs, Low Sodium, Low Calorie
- ✔ Aspartame Free, Sweetened with Stevia
- ✔ All Natural
- ✔ Zero sugar
- ✔ Gluten free

Cinnamon Roll

Net Wt. 2lb. (32 oz.) (907 g)

Sold by Weight, not by volume. Contents may settle after packaging.

DIRECTIONS FOR USE

As a dietary supplement, mix 1 level scoop of Meal Replacement with 5-6 ounces of water or milk. Try with juice for a different flavor combination. Stir, shake, or blend until dissolved. Enjoy right away! Add Meal Replacement to your oatmeal, pastries, or favorite recipes for a protein kick!

AMINO ACID PROFILE

	Meal Replacement 25 g protein per serving mg/serving
Alanine	1,304
Arginine	0.613
Aspartic acid	2.527
Cysteine / Cystine	0.767
Glutamic acid	2.605
Glycine	0.686
Histidine*	0.686
Isoleucine*/	1.610
Leucine*/	2.184
Lysine*	2.249
Methionine*	0.585
Phenylalanine*	0.695
Proline	1.559
Taurine	0
Serine	1.904
Threonine*	1.740
Tryptophan*	0.613
Tyrosine	0.602
Valine*/	1.508

*essential amino acids
/BCAAs

Nutrition Facts

Cinnamon Roll

Serving Size: 30g
Servings per container: 63

	Amount Per Serving	% Daily Value*
Calories	133	
Calories from Fat	4	
Total Fat	< 0.5 g	3%
Saturated Fat	< 1 g	0%
Trans Fat	0 g	0%
Cholesterol	20 mg	7%
Total Carbohydrate	7 g	1%
Dietary Fiber	0 g	0%
Calcium	100 mg	20%
Phosphorus	62 mg	9%
Sodium	30 mg	1%
Potassium	60 mg	2%
Protein	25 g	52%

* Percent Daily Values are based on 2000 calories. Your daily values may be higher or lower depending on your calorie needs

		Calories 2000	2500
Total Fat	Less Than	65 g	80 g
Saturated Fat	Less Than	20 g	25 g
Cholesterol	Less Than	300 g	300 g
Sodium	Less Than	2400 mg	2400 mg
Potassium		3500 mg	3500 mg
Total Carbohydrate		300 g	375 g
Dietary Fiber		25 g	30 g
Protein		50 g	65 g

Calories per gram: Fat = 9; Protein = 4; Carbohydrate = 4

INGREDIENTS: Pure Whey Protein Concentrate, Pure Whey Protein Isolate, Cocoa Powder, Natural and Artificial Flavor, Xanthan Gum, Stevia, Vitamin Blend, Vegetable Fiber

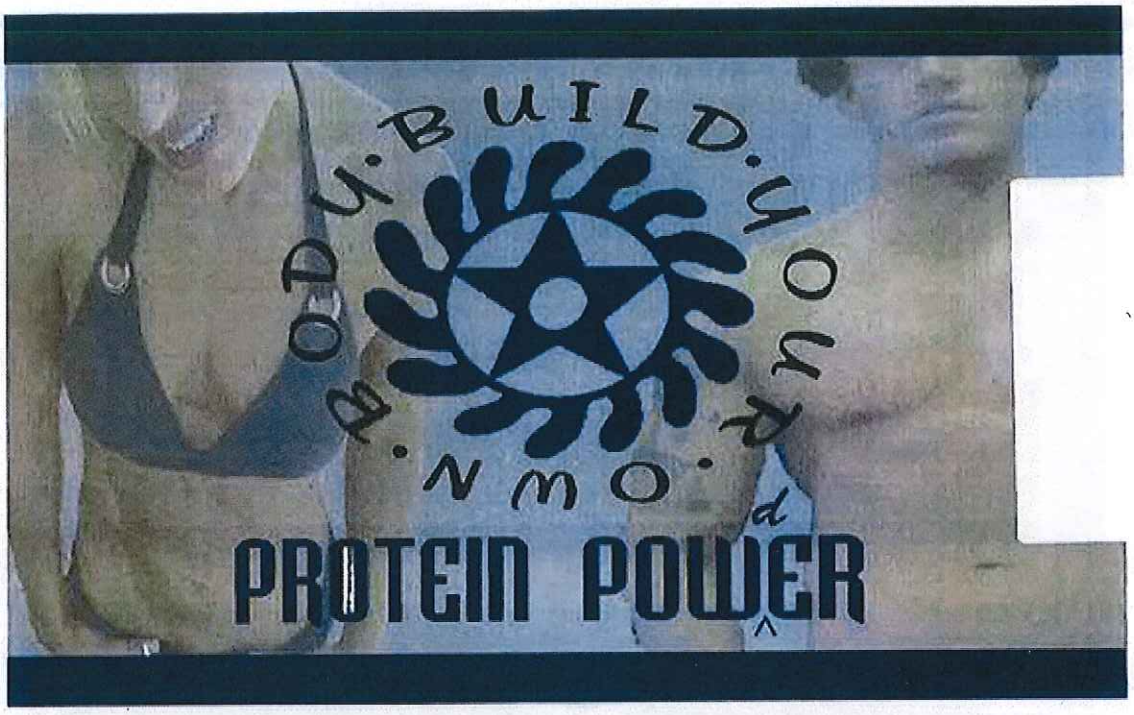
Distributed by
BODY CONSTRUCT™
www.bodyconstruct.com

VITAMIN PROFILE

Vitamin A	10%
Vitamin C	10%
Calcium	8%
Iron	6%
Vitamin D	6%
Vitamin E	6%
Vitamin K	6%
Thiamin	6%
Riboflavin	6%
Niacin	1%
Vitamin B6	3%
Vitamin B12	2%
Biotin	4%
Pantothenic Acid	2%
Phosphorus	5%
Iodine	6%
Chromium	6%
Zinc	6%
Folic Acid	4%
Copper	4%
Molybdenum	6%

6 39898 98985 8

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.



DIRECTIONS FOR USE

As a dietary supplement, mix 1 level scoop of 100% Whey Protein Isolate with 5-6 oz of water or milk. Try with juice for a different flavor combination. Stir, shake, or blend until dissolved. Enjoy right away! Add 100% Whey Protein Isolate to your oatmeal, pudding, or favorite recipes for a protein kick!

AMINO ACID PROFILE

	Whey Protein Isolate 25g protein per serving mg/serving
Alanine	1,479
Arginine	0,689
Aspartic acid	4,002
Cystine / Cystine	0,87
Glutamic acid	5,452
Glycine	0,551
Histidine*	0,551
Isoleucine*/	1,627
Leucine*/	3,045
Lysine*	2,552
Methionine*	0,754
Phenylalanine*	1,015
Proline	1,769
Taurine	0
Serine	1,475
Threonine*	2,088
Tryptophan*	0,696
Tyrosine	0,839
Valine*/	1,741
*essential amino acids /BCAAs	

www.buildyourownbody.com
Manufactured for Build your own Body
Flagstaff, Arizona

Protein Powder
Chocolate

Serving Size: 1 oz. = 1 scoop (33 g)
Servings : 26

	Amount Per Serving	% Daily Value *
Calories	121	
Calories from Fat	1,32	
Total Fat	0 g	0%
Saturated Fat	0 g	0%
Trans Fat	0 g	0%
Cholesterol	4,54 mg	1%
Total Carbohydrate	1,58 g	0%
Dietary Fiber	0 g	1%
Sugars	1 g	0%
Calcium	139 mg	14%
Phosphorus	69,4 mg	7%
Sodium	49 mg	2%
Potassium	98 mg	3%
Protein	29 g	58%

* Percent Daily Values are based on 2000 calories. Your daily values may be higher or lower depending on your calorie needs:

		Calories	2000	2500
Total Fat	Less Than		65 g	80 g
Saturated Fat	Less Than		20 g	25 g
Cholesterol	Less Than		300 g	300 g
Sodium	Less Than		2400 mg	2400 mg
Potassium			3500 mg	3500 mg
Total Carbohydrate			300 g	375 g
Dietary Fiber			25 g	30 g
Protein			50 g	65 g

Calories per gram: Fat = 9, Protein = 4, Carbohydrate = 4.
INGREDIENTS: Pure Whey Protein Isolate, Natural and Artificial Flavor, Xanthan Gum, Stevia

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.