Applied Nutriceuticals 11/30/15

Department of Health and Human Services

Public Health Service
Food and Drug Administration
College Park, MD 20740

NOV 30, 2015
WARNING LETTER

VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

Don Orrell
Applied Nutriceuticals, Inc.
13135 Danielson Street
Poway, CA 92064

Re: 483224

Dear Mr. Orrell:

This letter concerns your product HG4UP, which is labeled and/or offered for sale as a dietary supplement. Your product labeling lists the substance Picamilon as a dietary ingredient. This ingredient is also called, among other names, pikatropin, pikamilon, nicotinyl-gamma-aminobutyric acid, and nicotinoyl-GABA (hereinafter referred to as picamilon).

Under section 201(ff)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(ff)(1)], a dietary ingredient is a vitamin; mineral; herb or other botanical; amino acid; dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of the preceding substances. Picamilon is not a vitamin, a mineral, an herb or other botanical, or an amino acid. In addition, according to our research, picamilon is not a dietary substance for use by man to supplement the diet by increasing the total dietary intake. Finally, picamilon is not a concentrate, metabolite, constituent, extract, or combination of a vitamin; mineral; herb or other botanical; amino acid; or dietary substance for use by man to supplement the diet by increasing the total dietary intake. Rather, picamilon is a unique chemical entity synthesized from the dietary ingredients niacin and gamma-aminobutyric acid. As such, it is absorbed into the body, crosses the blood-brain barrier and accumulates in the brain as a separate chemical entity. Because picamilon does not fit in any of the dietary ingredient categories under section 201(ff)(1) of the Act, it is not a dietary ingredient as defined in the Act. Declaring picamilon in your product labeling as a dietary ingredient causes your products marketed as dietary supplements to be misbranded under section 403(a)(1) of the Act [21 U.S.C. § 343(a)(1)] in that the labeling is false or misleading in any particular.

We request that you take prompt action to correct the violation cited above, as well as any other violations associated with your HG4UP product or other products marketed by your firm that list picamilon as a dietary ingredient in the labeling. It is your responsibility to ensure that your firm complies with all requirements of federal law and FDA regulations. Failure to immediately cease distribution of your HG4UP product, and any other products you market that list picamilon as a dietary ingredient in the labeling, could result in enforcement action by FDA without further notice. Sections 302 and 304 of the Act provide for seizure of violative products and injunction against the manufacturers and distributors of violative products [21 U.S.C. §§ 332 and 334].

Additionally, picamilon is not approved as a food additive or prior sanctioned for use in dietary supplements. Further, FDA's review of this substance does not identify a basis to conclude the substance is GRAS for use in food. If you contend that this substance is GRAS for use in food, please provide your basis for concluding that picamilon is GRAS for use in dietary supplements, including supporting data or other documentation.

We request that you advise us in writing, within 15 days of receipt of this letter, as to the specific steps that have been or will be taken to correct these violations, including any steps taken with respect to product currently in the marketplace. Your response should also include an explanation of each step taken to ensure that similar violations do not recur, as well as documentation to support your response. Your written reply should be directed to Aaron Dotson, United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835. If you have any questions, please contact Aaron Dotson at **aaron.dotson@fda.hss.gov (mailto:aaron.dotson@fda.hss.gov)**.

Sincerely,
/S/
William A. Correll
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

Cc:
8112 Statesville Road, Suite G
Charlotte, NC 28269

More in 2015 (/ICECI/EnforcementActions/WarningLetters/2015/default.htm)

Better Body Sports, LLC 4/22/15

Department of Health and Human Services

Public Health Service
Food and Drug Administration
College Park, MD 20740

WARNING LETTER
APR 22, 2015

VIA ELECTRONIC MAIL
VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

Jason Vaught
Better Body Sports, LLC
326 Burl Ave
Ventura, CA 93003

Re: 456726

Dear Mr. Vaught:

This letter concerns your product Phoenix Extreme, which is labeled and/or offered for sale as a dietary supplement. Your product labeling lists the substance R-beta-methylphenethylamine as a dietary ingredient in your "Phoenix Extreme Blend." This ingredient is also called, among other names, Beta-methylphenethylamine, βMePEA, or BMPEA (hereinafter referred to as BMPEA).

Under section 201(ff)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(ff)(1)], a dietary ingredient is a vitamin; mineral; herb or other botanical; amino acid; dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of the preceding substances. BMPEA is not a vitamin, a mineral, an herb or other botanical, or an amino acid. In addition, BMPEA is not a dietary substance for use by man to supplement the diet by increasing the total dietary intake. Finally, BMPEA is not a concentrate, metabolite, constituent, extract, or combination of a vitamin; mineral; herb or other botanical; amino acid; or dietary substance for use by man to supplement the diet by increasing the total dietary intake. Accordingly, BMPEA is not a dietary ingredient within the definition set forth in section 201(ff)(1) of the Act [21 U.S.C. § 321(ff)(1)]. Declaring BMPEA in your product labeling as a dietary ingredient causes your product marketed as a dietary supplement to be misbranded under section 403(a)(1) of the Act [21 U.S.C. § 343(a)(1)] in that the labeling is false or misleading in any particular.

We request that you take prompt action to correct the violation cited above, as well as any other violations associated with your Phoenix Extreme product or other products marketed by your firm that contain BMPEA. It is your

responsibility to ensure that your firm complies with all requirements of federal law and FDA regulations.

Failure to immediately cease distribution of your Phoenix Extreme product, and any other products you market that contain BMPEA, could result in enforcement action by FDA without further notice. Sections 302 and 304 of the Act provide for seizure of violative products and injunction against the manufacturers and distributors of violative products [21 U.S.C. §§ 332 and 334].

Additionally, BMPEA is not approved as a food additive or prior sanctioned for use in dietary supplements. Further, FDA's review of this substance does not identify a basis to conclude the substance is GRAS for use in food. If you contend that this substance is GRAS for use in food, please provide your basis for concluding that BMPEA is GRAS for use in dietary supplements, including supporting data or other documentation.

We request that you advise us in writing, within 15 days of receipt of this letter, as to the specific steps that have been or will be taken to correct these violations, including any steps taken with respect to product currently in the marketplace. Your response should also include an explanation of each step taken to ensure that similar violations do not recur, as well as documentation to support your response. Your written reply should be directed to Mabel Lee, United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835. If you have any questions, please contact Ms. Lee at **BMPEATaskforce-CFSAN@fda.hhs.gov (mailto:BMPEATaskforce-CFSAN@fda.hhs.gov)**.

Sincerely,
/S/
William A. Correll
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

More in 2015 (/ICECI/EnforcementActions/WarningLetters/2015/default.htm)

DBM Nutrition 11/30/15

Department of Health and Human Services

Public Health Service
Food and Drug Administration
College Park, MD 20740

NOV 30, 2015
WARNING LETTER

VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

Darin Booton
DBM Nutrition
203 South Somonauk Road
Cortland, IL 60112

Re: 483226

Dear Mr. Booton:

This letter concerns your product DBM Endurance World Championship Countess, which is labeled and/or offered for sale as a dietary supplement. Your product labeling lists the substance Picamilon as a dietary ingredient. This ingredient is also called, among other names, pikatropin, pikamilon, nicotinyl-gamma-aminobutyric acid, and nicotinoyl-GABA (hereinafter referred to as picamilon).

Under section 201(ff)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(ff)(1)], a dietary ingredient is a vitamin; mineral; herb or other botanical; amino acid; dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of the preceding substances. Picamilon is not a vitamin, a mineral, an herb or other botanical, or an amino acid. In addition, according to our research, picamilon is not a dietary substance for use by man to supplement the diet by increasing the total dietary intake. Finally, picamilon is not a concentrate, metabolite, constituent, extract, or combination of a vitamin; mineral; herb or other botanical; amino acid; or dietary substance for use by man to supplement the diet by increasing the total dietary intake. Rather, picamilon is a unique chemical entity synthesized from the dietary ingredients niacin and gamma-aminobutyric acid. As such, it is absorbed into the body, crosses the blood-brain barrier and accumulates in the brain as a separate chemical entity. Because picamilon does not fit in any of the dietary ingredient cateogries under section 201(ff)(1) of the Act, it is not a dietary ingredient as defined in the Act. Declaring picamilon in your product labeling as a dietary ingredient causes your products marketed as dietary supplements to be misbranded under section 403(a)(1) of the Act [21 U.S.C. § 343(a)(1)] in that the labeling is false or misleading in any particular.

We request that you take prompt action to correct the violation cited above, as well as any other violations associated with your DBM Endurance World Championship Countess product or other products marketed by your firm that list picamilon as a dietary ingredient in the labeling. It is your responsibility to ensure that your firm complies with all requirements of federal law and FDA regulations.

Failure to immediately cease distribution of your DBM Endurance World Championship Countess product, and any other products you market that list picamilon as a dietary ingredient in the labeling, could result in enforcement action by FDA without further notice. Sections 302 and 304 of the Act provide for seizure of violative products and injunction against the manufacturers and distributors of violative products [21 U.S.C. §§ 332 and 334].

Additionally, picamilon is not approved as a food additive or prior sanctioned for use in dietary supplements. Further, FDA's review of this substance does not identify a basis to conclude the substance is GRAS for use in food. If you contend that this substance is GRAS for use in food, please provide your basis for concluding that picamilon is GRAS for use in dietary supplements, including supporting data or other documentation.

We request that you advise us in writing, within 15 days of receipt of this letter, as to the specific steps that have been or will be taken to correct these violations, including any steps taken with respect to product currently in the marketplace. Your response should also include an explanation of each step taken to ensure that similar violations do not recur, as well as documentation to support your response. Your written reply should be directed to Aaron Dotson, United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835. If you have any questions, please contact Aaron Dotson at **aaron.dotson@fda.hss.gov (mailto:aaron.dotson@fda.hss.gov)**.

Sincerely,
/S/
William A. Correll
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

Cc:
P.O. Box 1177
St. Charles, IL 60174

More in 2015 (/ICECI/EnforcementActions/WarningLetters/2015/default.htm)

Hi-Tech Pharmaceuticals, Inc. 4/22/15

Department of Health and Human Services

Public Health Service
Food and Drug Administration
College Park, MD 20740

WARNING LETTER
APR 22, 2015

VIA ELECTRONIC MAIL
VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

Jared Wheat, CEO
Hi-Tech Pharmaceuticals, Inc.
6015-B Unity Drive
Norcross, GA 30071

Re: 456722

Dear Mr. Wheat:

This letter concerns your products Fastin®-XR, Fastin® Rapid Release, and Lipodrene® Extended Release, which are labeled and/or offered for sale as dietary supplements. Your product labeling lists the substance R-beta-methylphenethylamine as a dietary ingredient in the form of an extract of *Acacia rigidula* (leaves). This ingredient is also called, among other names, Beta-methylphenethylamine, βMePEA, or BMPEA (hereinafter referred to as BMPEA).

Under section 201(ff)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(ff)(1)], a dietary ingredient is a vitamin; mineral; herb or other botanical; amino acid; dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of the preceding substances. BMPEA is not a vitamin, a mineral, an herb or other botanical, or an amino acid. In addition, BMPEA is not a dietary substance for use by man to supplement the diet by increasing the total dietary intake. Finally, BMPEA is not a concentrate, metabolite, constituent, extract, or combination of a vitamin; mineral; herb or other botanical; amino acid; or dietary substance for use by man to supplement the diet by increasing the total dietary intake. Although your product labeling asserts that BMPEA is an extract of the botanical *Acacia rigidula*, we are aware of no evidence to support an assertion that BMPEA is, in fact, a constituent of this botanical. Accordingly, BMPEA is not a dietary ingredient within the definition set forth in section 201(ff)(1) of the Act [21 U.S.C. § 321(ff)(1)]. Declaring BMPEA in your product labeling as a dietary ingredient causes your products marketed as dietary supplements to be

misbranded under section 403(a)(1) of the Act [21 U.S.C. § 343(a)(1)] in that the labeling is false or misleading in any particular.**[1]**

We request that you take prompt action to correct the violation cited above, as well as any other violations associated with your Fastin®-XR, Fastin® Rapid Release, and Lipodrene® Extended Release products or other products marketed by your firm that contain BMPEA. It is your responsibility to ensure that your firm complies with all requirements of federal law and FDA regulations.

Failure to immediately cease distribution of your Fastin®-XR, Fastin® Rapid Release, and Lipodrene® Extended Release products, and any other products you market that contain BMPEA, could result in enforcement action by FDA without further notice. Sections 302 and 304 of the Act provide for seizure of violative products and injunction against the manufacturers and distributors of violative products [21 U.S.C. §§ 332 and 334].

Additionally, BMPEA is not approved as a food additive or prior sanctioned for use in dietary supplements. Further, FDA's review of this substance does not identify a basis to conclude the substance is GRAS for use in food. If you contend that this substance is GRAS for use in food, please provide your basis for concluding that BMPEA is GRAS for use in dietary supplements, including supporting data or other documentation.

We request that you advise us in writing, within 15 days of receipt of this letter, as to the specific steps that have been or will be taken to correct these violations, including any steps taken with respect to product currently in the marketplace. Your response should also include an explanation of each step taken to ensure that similar violations do not recur, as well as documentation to support your response. Your written reply should be directed to Mabel Lee, United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835. If you have any questions, please contact Ms. Lee at **BMPEATaskforce-CFSAN@fda.hhs.gov (mailto:BMPEATaskforce-CFSAN@fda.hhs.gov)**.

Sincerely,
/S/
William A. Correll
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

cc:
Via Electronic Mail
Via Overnight Delivery
Return Receipt Requested
E.Vaughn Dunnigan, P.C.
2897 N. Druid Hills Rd., Ste. 142
Atlanta, GA 30329

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[1] To the extent that any of these products also contain 1,3-Dimethylamylamine HCl (DMAA) or its chemical equivalent, they are also adulterated as alleged in the seizure action, *United States v. Undetermined quantities of all articles of finished and in-process foods, etc.,* C.A. No. 1:13-cv-3675 (N.D. Ga.).

More in 2015 (/ICECI/EnforcementActions/WarningLetters/2015/default.htm)

Human Evolution Supplements, Inc. 4/22/15

Department of Health and Human Services

Public Health Service
Food and Drug Administration
College Park, MD 20740

WARNING LETTER
APR 22, 2015

VIA ELECTRONIC MAIL
VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

Heinz Senior, President
Human Evolution Supplements, Inc.
3440 Hollywood Blvd., Suite 415
Hollywood, FL 33021

cc:
20533 Biscayne Blvd., Suite 514
Miami, FL 33180

Re: 456727

Dear Mr. Senior:

This letter concerns your product Core™ Burner Watermelon powder, which is labeled and/or offered for sale as a dietary supplement. Your product labeling lists the substance R-beta-methylphenethylamine HCl as a dietary ingredient in your "CORE BURNER™ PROPRIETARY BLEND." This ingredient is also called, among other names, Beta-methylphenethylamine, βMePEA, or BMPEA (hereinafter referred as BMPEA).

Under section 201(ff)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(ff)(1)], a dietary ingredient is a vitamin; mineral; herb or other botanical; amino acid; dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of the preceding substances. BMPEA is not a vitamin, a mineral, an herb or other botanical, or an amino acid. In addition, BMPEA is not a dietary substance for use by man to supplement the diet by increasing the total dietary intake. Finally, BMPEA is not a concentrate, metabolite, constituent, extract, or combination of a vitamin; mineral; herb or other botanical; amino acid; or dietary substance for use by man to supplement the diet by increasing the total dietary intake. Accordingly, BMPEA is not a dietary ingredient within the definition set forth in section 201(ff)(1) of the Act [21

U.S.C. § 321(ff)(1)]. Declaring BMPEA in your product labeling as a dietary ingredient causes your product marketed as a dietary supplements to be misbranded under section 403(a)(1) of the Act [21 U.S.C. § 343(a)(1)] in that the labeling is false or misleading in any particular.

We request that you take prompt action to correct the violation cited above, as well as any other violations associated with your Core™ Burner Watermelon powder product or other products marketed by your firm that contain BMPEA. It is your responsibility to ensure that your firm complies with all requirements of federal law and FDA regulations.

Failure to immediately cease distribution of your Core™ Burner Watermelon powder product, and any other products you market that contain BMPEA, could result in enforcement action by FDA without further notice. Sections 302 and 304 of the Act provide for seizure of violative products and injunction against the manufacturers and distributors of violative products [21 U.S.C. §§ 332 and 334].

Additionally, BMPEA is not approved as a food additive or prior sanctioned for use in dietary supplements. Further, FDA's review of this substance does not identify a basis to conclude the substance is GRAS for use in food. If you contend that this substance is GRAS for use in food, please provide your basis for concluding that BMPEA is GRAS for use in dietary supplements, including supporting data or other documentation.

We request that you advise us in writing, within 15 days of receipt of this letter, as to the specific steps that have been or will be taken to correct these violations, including any steps taken with respect to product currently in the marketplace. Your response should also include an explanation of each step taken to ensure that similar violations do not recur, as well as documentation to support your response. Your written reply should be directed to Mabel Lee, United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835. If you have any questions, please contact Ms. Lee at **BMPEATaskforce-CFSAN@fda.hhs.gov (mailto:BMPEATaskforce-CFSAN@fda.hhs.gov)**.

Sincerely,
/S/
William A. Correll
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

More in 2015 (/ICECI/EnforcementActions/WarningLetters/2015/default.htm)

ICF International, LLC 11/30/15

Department of Health and Human Services

Public Health Service
Food and Drug Administration
College Park, MD 20740

NOV 30, 2015
WARNING LETTER

VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

Brandon Sojka
ICF International, LLC
840 Glynn Street South, Suite 338
Fayetteville, GA 30214

Re: 483228

Dear Mr. Sojka:

This letter concerns your product Myokem Nitramine, which is labeled and/or offered for sale as a dietary supplement. Your product labeling lists the substance Picamilon as a dietary ingredient. This ingredient is also called, among other names, pikatropin, pikamilon, nicotinyl-gamma-aminobutyric acid, and nicotinoyl-GABA (hereinafter referred to as picamilon).

Under section 201(ff)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(ff)(1)], a dietary ingredient is a vitamin; mineral; herb or other botanical; amino acid; dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of the preceding substances. Picamilon is not a vitamin, a mineral, an herb or other botanical, or an amino acid. In addition, according to our research, picamilon is not a dietary substance for use by man to supplement the diet by increasing the total dietary intake. Finally, picamilon is not a concentrate, metabolite, constituent, extract, or combination of a vitamin; mineral; herb or other botanical; amino acid; or dietary substance for use by man to supplement the diet by increasing the total dietary intake. Rather, picamilon is a unique chemical entity synthesized from the dietary ingredients niacin and gamma-aminobutyric acid. As such, it is absorbed into the body, crosses the blood-brain barrier and accumulates in the brain as a separate chemical entity. Because picamilon does not fit any of the dietary ingredient categories under section 201(ff)(1) of the Act, it is not a dietary ingredient as defined in the Act. Declaring picamilon in your product labeling as a dietary ingredient causes your products marketed as dietary supplements to be misbranded under section 403(a)(1) of the Act [21 U.S.C. § 343(a)(1)] in that the labeling is false or misleading in any particular.

We request that you take prompt action to correct the violation cited above, as well as any other violations associated with your Myokem Nitramine product or other products marketed by your firm that list picamilon as a dietary ingredient in the labeling. It is your responsibility to ensure that your firm complies with all requirements of federal law and FDA regulations.

Failure to immediately cease distribution of your Myokem Nitramine product, and any other products you market that list picamilon as a dietary ingredient in the labeling, could result in enforcement action by FDA without further notice. Sections 302 and 304 of the Act provide for seizure of violative products and injunction against the manufacturers and distributors of violative products [21 U.S.C. §§ 332 and 334].

Additionally, picamilon is not approved as a food additive or prior sanctioned for use in dietary supplements. Further, FDA's review of this substance does not identify a basis to conclude the substance is GRAS for use in food. If you contend that this substance is GRAS for use in food, please provide your basis for concluding that picamilon is GRAS for use in dietary supplements, including supporting data or other documentation.

We request that you advise us in writing, within 15 days of receipt of this letter, as to the specific steps that have been or will be taken to correct these violations, including any steps taken with respect to product currently in the marketplace. Your response should also include an explanation of each step taken to ensure that similar violations do not recur, as well as documentation to support your response. Your written reply should be directed to Aaron Dotson, United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835. If you have any questions, please contact Aaron Dotson at **aaron.dotson@fda.hss.gov (mailto:aaron.dotson@fda.hss.gov)**.

Sincerely,
/S/
William A. Correll
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

More in 2015 (/ICECI/EnforcementActions/WarningLetters/2015/default.htm)

SDC Nutrition Inc 11/30/15

Department of Health and Human Services

Public Health Service
Food and Drug Administration
College Park, MD 20740

NOV 30, 2015
WARNING LETTER

VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

Sean Marszalek
SDC Nutrition, Inc.
d/b/a NVIE Nutrition
170 Industry Drive
Pittsburgh, PA 15275

Re: 483183

Dear Mr. Marszalek:

This letter concerns your product NVIE Edge Pro, which is labeled and/or offered for sale as a dietary supplement. Your product labeling lists the substance Picamilon as a dietary ingredient. This ingredient is also called, among other names, pikatropin, pikamilon, nicotinyl-gamma-aminobutyric acid, and nicotinoyl-GABA (hereinafter referred to as picamilon).

Under section 201(ff)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(ff)(1)], a dietary ingredient is a vitamin; mineral; herb or other botanical; amino acid; dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of the preceding substances. Picamilon is not a vitamin, a mineral, an herb or other botanical, or an amino acid. In addition, according to our research, picamilon is not a dietary substance for use by man to supplement the diet by increasing the total dietary intake. Finally, picamilon is not a concentrate, metabolite, constituent, extract, or combination of a vitamin; mineral; herb or other botanical; amino acid; or dietary substance for use by man to supplement the diet by increasing the total dietary intake. Rather, picamilon is a unique chemical entity synthesized from the dietary ingredients niacin and gamma-aminobutyric acid. As such, it is absorbed into the body, crosses the blood-brain barrier and accumulates in the brain as a separate chemical entity. Because picamilon does not fit in any of the dietary ingredient categories under section 201(ff)(1) of the Act, it is not a dietary ingredient as defined in the Act. Declaring picamilon in your product labeling as a dietary ingredient causes your products marketed as dietary supplements to be misbranded under section 403(a)(1) of the Act [21 U.S.C. § 343(a)(1)] in that the labeling is false or misleading in any particular.

We request that you take prompt action to correct the violation cited above, as well as any other violations associated with your NVIE edge pro product or other products marketed by your firm that list picamilon as a dietary ingredient in the labeling. It is your responsibility to ensure that your firm complies with all requirements of federal law and FDA regulations.

Failure to immediately cease distribution of your NVIE edge pro product, and any other products you market that list picamilon as a dietary ingredient in the labeling, could result in enforcement action by FDA without further notice. Sections 302 and 304 of the Act provide for seizure of violative products and injunction against the manufacturers and distributors of violative products [21 U.S.C. §§ 332 and 334].

Additionally, picamilon is not approved as a food additive or prior sanctioned for use in dietary supplements. Further, FDA's review of this substance does not identify a basis to conclude the substance is GRAS for use in food. If you contend that this substance is GRAS for use in food, please provide your basis for concluding that picamilon is GRAS for use in dietary supplements, including supporting data or other documentation.

We request that you advise us in writing, within 15 days of receipt of this letter, as to the specific steps that have been or will be taken to correct these violations, including any steps taken with respect to product currently in the marketplace. Your response should also include an explanation of each step taken to ensure that similar violations do not recur, as well as documentation to support your response. Your written reply should be directed to Aaron Dotson, United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835. If you have any questions, please contact Aaron Dotson at **aaron.dotson@fda.hss.gov (mailto:aaron.dotson@fda.hss.gov)**.

Sincerely,
/S/
William A. Correll
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

More in 2015 (/ICECI/EnforcementActions/WarningLetters/2015/default.htm)

Top Secret 11/30/15

Department of Health and Human Services

Public Health Service
Food and Drug Administration
College Park, MD 20740

NOV 30, 2015
WARNING LETTER

VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

Augusto Vidaurreta
Top Secret Nutrition, LLC
11490 Interchange Circle North
Miramar, FL 33025

Re: 481420

Dear Mr. Vidaurreta:

This letter concerns your product Pump Igniter, available in Cherry Limeade, Grape, Red Raspberry, Fruit Punch, and Pink Lemonade, which is labeled and/or offered for sale as a dietary supplement. Your product labeling lists the substance Picamilon as a dietary ingredient in your "Nootropic Mood Boosting Combination." This ingredient is also called, among other names, pikatropin, pikamilon, nicotinyl-gamma-aminobutyric acid, and nicotinoyl-GABA (hereinafter referred to as picamilon).

Under section 201(ff)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(ff)(1)], a dietary ingredient is a vitamin; mineral; herb or other botanical; amino acid; dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of the preceding substances. Picamilon is not a vitamin, a mineral, an herb or other botanical, or an amino acid. In addition, according to our research, picamilon is not a dietary substance for use by man to supplement the diet by increasing the total dietary intake. Finally, picamilon is not a concentrate, metabolite, constituent, extract, or combination of a vitamin; mineral; herb or other botanical; amino acid; or dietary substance for use by man to supplement the diet by increasing the total dietary intake. Rather, picamilon is a unique chemical entity synthesized from the dietary ingredients niacin and gamma-aminobutyric acid. As such, it is absorbed into the body, crosses the blood-brain barrier and accumulates in the brain as a separate chemical entity. Because picamilon does not fit any of the dietary ingredient categories under section 201(ff)(1) of the Act, it is not a dietary ingredient as defined in the Act. Declaring picamilon in your product labeling as a dietary ingredient causes your products marketed as dietary supplements to be misbranded under section 403(a)(1) of the Act [21 U.S.C. § 343(a)(1)] in that the labeling is false or misleading in any particular.

We request that you take prompt action to correct the violation cited above, as well as any other violations associated with your Pump Igniter product or other products marketed by your firm that list picamilon as a dietary ingredient in the labeling. It is your responsibility to ensure that your firm complies with all requirements of federal law and FDA regulations. Failure to immediately cease distribution of your Pump Igniter product, and any other products you market that list picamilon as a dietary ingredient in the labeling, could result in enforcement action by FDA without further notice. Sections 302 and 304 of the Act provide for seizure of violative products and injunction against the manufacturers and distributors of violative products [21 U.S.C. §§ 332 and 334].

Additionally, picamilon is not approved as a food additive or prior sanctioned for use in dietary supplements. Further, FDA's review of this substance does not identify a basis to conclude the substance is GRAS for use in food. If you contend that this substance is GRAS for use in food, please provide your basis for concluding that picamilon is GRAS for use in dietary supplements, including supporting data or other documentation.

We request that you advise us in writing, within 15 days of receipt of this letter, as to the specific steps that have been or will be taken to correct these violations, including any steps taken with respect to product currently in the marketplace. Your response should also include an explanation of each step taken to ensure that similar violations do not recur, as well as documentation to support your response. Your written reply should be directed to Aaron Dotson, United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835. If you have any questions, please contact Aaron Dotson at **aaron.dotson@fda.hss.gov (mailto:aaron.dotson@fda.hss.gov)**.

Sincerely,
/S/
William A. Correll
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

More in 2015 (/ICECI/EnforcementActions/WarningLetters/2015/default.htm)

Train Naked Labs LLC 4/22/15

Department of Health and Human Services

Public Health Service
Food and Drug Administration
College Park, MD 20740

WARNING LETTER
APR 22, 2015

VIA ELECTRONIC MAIL
VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

Christopher A. Conrad, Manager
Train Naked Labs LLC
431 Plant Ave
Palm Bay, FL 32907

cc:
965 Westwinds Blvd
Tarpon Springs, FL 34689

Re: 456792

Dear Mr. Conrad:

This letter concerns your products Critical FX and Sudden Impact, which are labeled and/or offered for sale as dietary supplements. Your product labeling lists the substance R-beta-methylphenethylamine HCl as a dietary ingredient in your “Critical FX Proprietary Blend” and “Impact Proprietary Blend,” respectively. This ingredient is also called, among other names, Beta-methylphenethylamine, βMePEA, or BMPEA (hereinafter referred as BMPEA).

Under section 201(ff)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(ff)(1)], a dietary ingredient is a vitamin; mineral; herb or other botanical; amino acid; dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of the preceding substances. BMPEA is not a vitamin, a mineral, an herb or other botanical, or an amino acid. In addition, BMPEA is not a dietary substance for use by man to supplement the diet by increasing the total dietary intake. Finally, BMPEA is not a concentrate, metabolite, constituent, extract, or combination of a vitamin; mineral; herb or other botanical; amino acid; or dietary substance for use by man to supplement the diet by increasing the total dietary intake. Accordingly, BMPEA is not a dietary ingredient within the definition set forth in section 201(ff)(1) of the Act [21 U.S.C. § 321(ff)(1)]. Declaring BMPEA in your product labeling as a dietary ingredient causes your products

marketed as dietary supplements to be misbranded under section 403(a)(1) of the Act [21 U.S.C. § 343(a)(1)] in that the labeling is false or misleading in any particular.

We request that you take prompt action to correct the violation cited above, as well as any other violations associated with your Critical FX and Sudden Impact products or other products marketed by your firm that contain BMPEA. It is your responsibility to ensure that your firm complies with all requirements of federal law and FDA regulations.

Failure to immediately cease distribution of your Critical FX and Sudden Impact products, and any other products you market that contain BMPEA, could result in enforcement action by FDA without further notice. Sections 302 and 304 of the Act provide for seizure of violative products and injunction against the manufacturers and distributors of violative products [21 U.S.C. §§ 332 and 334].

Additionally, BMPEA is not approved as a food additive or prior sanctioned for use in dietary supplements. Further, FDA's review of this substance does not identify a basis to conclude the substance is GRAS for use in food. If you contend that this substance is GRAS for use in food, please provide your basis for concluding that BMPEA is GRAS for use in dietary supplements, including supporting data or other documentation.

We request that you advise us in writing, within 15 days of receipt of this letter, as to the specific steps that have been or will be taken to correct these violations, including any steps taken with respect to product currently in the marketplace. Your response should also include an explanation of each step taken to ensure that similar violations do not recur, as well as documentation to support your response. Your written reply should be directed to Mabel Lee, United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835. If you have any questions, please contact Ms. Lee at **BMPEATaskforce-CFSAN@fda.hhs.gov (mailto:BMPEATaskforce-CFSAN@fda.hhs.gov)**.

Sincerely,
/S/
William A. Correll
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

More in 2015 (/ICECI/EnforcementActions/WarningLetters/2015/default.htm)

Tribravus Enterprises, LLC dba iForce Nutrition 4/22/15

Department of Health and Human Services

Public Health Service
Food and Drug Administration
College Park, MD 20740

WARNING LETTER
APR 22, 2015

VIA ELECTRONIC MAIL
VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

David Nelson, Manager
Tribravus Enterprises, LLC dba iForce Nutrition
1305 Hot Spring Way #103
Vista, CA 92081

cc:
Tribravus Enterprises, LLC dba iForce Nutrition
1330 Specialty Drive, Suite A
Vista, CA 92081

Re: 456725

Dear Mr. Nelson:

This letter concerns your products Conquer™ (Fruit Punch Slam and Raspberry Lemonade flavors) which are labeled and/or offered for sale as dietary supplements. Your product labeling lists the substance R-beta-methylphenethylamine as a dietary ingredient in the form of an extract of *Acacia rigidula* (leaves). This ingredient is also called, among other names, Beta-methylphenethylamine, βMePEA, or BMPEA (hereinafter referred to as BMPEA).

Under section 201(ff)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(ff)(1)], a dietary ingredient is a vitamin; mineral; herb or other botanical; amino acid; dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of the preceding substances. BMPEA is not a vitamin, a mineral, an herb or other botanical, or an amino acid. In addition, BMPEA is not a dietary substance for use by man to supplement the diet by increasing the total dietary intake. Finally, BMPEA is not a concentrate, metabolite, constituent, extract, or combination of a vitamin; mineral; herb or other

botanical; amino acid; or dietary substance for use by man to supplement the diet by increasing the total dietary intake. Although your product labeling asserts that BMPEA is an extract of the botanical *Acacia rigidula*, we are aware of no evidence to support an assertion that BMPEA is, in fact, a constituent of this botanical. Accordingly, BMPEA is not a dietary ingredient within the definition set forth in section 201(ff)(1) of the Act [21 U.S.C. § 321(ff)(1)]. Declaring BMPEA in your product labeling as a dietary ingredient causes your products marketed as dietary supplements to be misbranded under section 403(a)(1) of the Act [21 U.S.C. § 343(a)(1)] in that the labeling is false or misleading in any particular.

We request that you take prompt action to correct the violation cited above, as well as any other violations associated with your Conquer™ (Fruit Punch Slam and Raspberry Lemonade flavors) products or other products marketed by your firm that contain BMPEA. It is your responsibility to ensure that your firm complies with all requirements of federal law and FDA regulations.

Failure to immediately cease distribution of your Conquer™ (Fruit Punch Slam and Raspberry Lemonade flavors) products, and any other products you market that contain BMPEA, could result in enforcement action by FDA without further notice. Sections 302 and 304 of the Act provide for seizure of violative products and injunction against the manufacturers and distributors of violative products [21 U.S.C. §§ 332 and 334].

Additionally, BMPEA is not approved as a food additive or prior sanctioned for use in dietary supplements. Further, FDA's review of this substance does not identify a basis to conclude the substance is GRAS for use in food. If you contend that this substance is GRAS for use in food, please provide your basis for concluding that BMPEA is GRAS for use in dietary supplements, including supporting data or other documentation.

We request that you advise us in writing, within 15 days of receipt of this letter, as to the specific steps that have been or will be taken to correct these violations, including any steps taken with respect to product currently in the marketplace. Your response should also include an explanation of each step taken to ensure that similar violations do not recur, as well as documentation to support your response. Your written reply should be directed to Mabel Lee, United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835. If you have any questions, please contact Ms. Lee at **BMPEATaskforce-CFSAN@fda.hhs.gov (mailto:BMPEATaskforce-CFSAN@fda.hhs.gov)**.

Sincerely,
/S/
William A. Correll
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

More in 2015 (/ICECI/EnforcementActions/WarningLetters/2015/default.htm)

Achieve Health, LLC 3/7/16

Department of Health and Human Services

Public Health Service
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

March 7, 2016

WARNING LETTER

VIA OVERNIGHT DELIVERY, RETURN RECEIPT REQUESTED
VIA EMAIL

Nathan Barrett, Member
Achieve Health, LLC
1636 Popps Ferry Road
Biloxi, MS 39532

Re: 486997

Dear Mr. Barrett:

This letter concerns your product Achieve Energy, which is labeled and/or offered for sale as a dietary supplement. The ingredient list on your product labeling declares *Acacia rigidula* ext as a dietary ingredient. *Acacia rigidula* is also called, among other names, *Vachellia rigidula*, chaparro prieto, or blackbrush, and will be referred to in the rest of this letter as *A. rigidula*.

As an extract of an herb or other botanical, *A. rigidula* extract is a dietary ingredient under section 201(ff)(1)(F) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 321(ff)(1)(F)]. Further, as a dietary ingredient that was not marketed in the United States before October 15, 1994, *A. rigidula* extract is a "new dietary ingredient" under section 413(d) of the Act [21 U.S.C. § 350b(d)].

Under section 413 of the Act (21 U.S.C. 350b), a dietary supplement that contains a new dietary ingredient shall be deemed adulterated under section 402(f) of the Act [21 U.S.C. § 342(f)] unless it meets one of two requirements:

1. The dietary supplement contains only dietary ingredients that have been present in the food supply as an article used for food in a form in which the food has not been chemically altered; or

2. There is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides FDA with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

To the best of FDA's knowledge, there is no information demonstrating that *A. rigidula* or its extract was lawfully marketed as a dietary ingredient in the United States before October 15, 1994, nor is there information demonstrating that this ingredient has been present in the food supply as an article used for human food in a form in which the food has not been chemically altered. In the absence of such information, *A. rigidula* extract is subject to the notification requirement in section 413(a)(2) of the Act [21 U.S.C. § 350b(a)(2)] and 21 CFR 190.6. Because the required notification has not been submitted, your product is adulterated under sections 402(f)(1)(B) and 413(a) of the Act [21 U.S.C. §§ 342(f)(1)(B) and 350b(a)].

Even if the required notification had been submitted, we know of no evidence that would establish that your product is not adulterated. In the absence of a history of use or other evidence of safety establishing that *A. rigidula* extract, when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe, Achieve Energy is adulterated under sections 402(f)(1)(B) and 413(a) of the Act [21 U.S.C. §§ 342(f)(1)(B) and 350b(a)] because it contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such product into interstate commerce is prohibited under section 301(a) and (v) of the Act [21 U.S.C. §§ 331(a) and (v)]. To the best of FDA's knowledge, there is no history of use or other evidence of safety establishing that *A. rigidula* extract will reasonably be expected to be safe when used as a dietary ingredient.

We request that you take prompt action to correct the violations cited above, as well as any other violations associated with your Achieve Energy product or other dietary supplement products marketed by your firm, including any that contain *A. rigidula* or *A. rigidula* extract. We also remind you that the new dietary ingredient notification requirement applies to all dietary supplements that contain new dietary ingredients that have not been present in the food supply as articles used for food in a form in which the food has not been chemically altered. It is your responsibility to ensure that your firm complies with all requirements of federal law and FDA regulations.

Failure to immediately cease distribution of your product Achieve Energy and any other products you market that contain *A. rigidula* or *A. rigidula* extract could result in enforcement action by FDA without further notice. Sections 302 and 304 of the Act provide for seizure of violative products and injunction against the manufacturers and distributors of violative products [21 U.S.C. §§ 332 and 334].

We request that you advise us in writing, within 15 days of receipt of this letter, as to the specific steps that have been or will be taken to correct these violations, including any steps taken with respect to product currently in the marketplace. Your response should also include an explanation of each step taken to ensure that similar violations do not recur, as well as documentation to support your response. Your written reply should be directed to Marjorie Davis, United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835. If you have any questions, please contact Ms. Davis at **Marjorie.Davis@fda.hhs.gov (mailto:Marjorie.Davis@fda.hhs.gov)**.

Sincerely,
/S/
William A. Correll
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

cc:
achieve@achievehealth.com

(b)(6)gmail.com

Nathan Barrett
Achieve Health, LLC
10117 Skyhawk Ct
Biloxi, MS 39532

More in 2016 (/ICECI/EnforcementActions/WarningLetters/2016/default.htm)

Journey Health USA, LLC 3/7/16

Department of Health and Human Services

Public Health Service
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

March 7, 2016

WARNING LETTER

VIA OVERNIGHT DELIVERY, RETURN RECEIPT REQUESTED
VIA EMAIL

Anthony Shaw, Owner
Journey Health USA, LLC
4044 Weletka Drive, Suite B
Austin, TX 78734

Re: 486996

Dear Mr. Shaw:

This letter concerns your product Journey To Weight Control, which is labeled and/or offered for sale as a dietary supplement. The Supplement Facts panel on your product labeling declares *Acacia rigidula* extract as a dietary ingredient. *Acacia rigidula* is also called, among other names, *Vachellia rigidula*, chaparro prieto, or blackbrush, and will be referred to in the rest of this letter as *A. rigidula*.

As an extract of an herb or other botanical, *A. rigidula* extract is a dietary ingredient under section 201(ff)(1)(F) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 321(ff)(1)(F)]. Further, as a dietary ingredient that was not marketed in the United States before October 15, 1994, *A. rigidula* extract is a "new dietary ingredient" under section 413(d) of the Act [21 U.S.C. § 350b(d)].

Under section 413 of the Act [21 U.S.C. § 350b], a dietary supplement that contains a new dietary ingredient shall be deemed adulterated under section 402(f) of the Act [21 U.S.C. § 342(f)] unless it meets one of two requirements:

1. The dietary supplement contains only dietary ingredients that have been present in the food supply as an article used for food in a form in which the food has not been chemically altered; or

2. There is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides FDA with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

To the best of FDA's knowledge, there is no information demonstrating that *A. rigidula* or its extract was lawfully marketed as a dietary ingredient in the United States before October 15, 1994, nor is there information demonstrating that this ingredient has been present in the food supply as an article used for human food in a form in which the food has not been chemically altered. In the absence of such information, *A. rigidula* extract is subject to the notification requirement in section 413(a)(2) of the Act [21 U.S.C. §350b(a)(2)] and 21 CFR 190.6. Because the required notification has not been submitted, your product is adulterated under sections 402(f)(1)(B) and 413(a) of the Act [21 U.S.C. §§ 342(f)(1)(B) and 350b(a)].

Even if the required notification had been submitted, we know of no evidence that would establish that your product is not adulterated. In the absence of a history of use or other evidence of safety establishing that *A. rigidula* extract, when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe, Journey To Weight Control is adulterated under sections 402(f)(1)(B) and 413(a) of the Act [21 U.S.C. §§ 342(f)(1)(B) and 350b(a)] because it contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such product into interstate commerce is prohibited under section 301(a) and (v) of the Act [21 U.S.C. §§ 331(a) and (v)]. To the best of FDA's knowledge, there is no history of use or other evidence of safety establishing that *A. rigidula* extract will reasonably be expected to be safe when used as a dietary ingredient.

We request that you take prompt action to correct the violations cited above, as well as any other violations associated with your Journey To Weight Control product or other dietary supplement products marketed by your firm, including any that contain *A. rigidula* or *A. rigidula* extract. We also remind you that the new dietary ingredient notification requirement applies to all dietary supplements that contain new dietary ingredients that have not been present in the food supply as articles used for food in a form in which the food has not been chemically altered. It is your responsibility to ensure that your firm complies with all requirements of federal law and FDA regulations.

Failure to immediately cease distribution of your product Journey To Weight Control and any other products you market that contain *A. rigidula* or *A. rigidula* extract could result in enforcement action by FDA without further notice. Sections 302 and 304 of the Act provide for seizure of violative products and injunction against the manufacturers and distributors of violative products [21 U.S.C. §§ 332 and 334].

We also note that your product label lists Ephedra extract as a dietary ingredient. To the extent that dietary supplement products contain Ephedra extract from which Ephedrine alkaloids have not been removed, such dietary supplements are adulterated under section 402(f)(1)(A) of the Act [21 U.S.C. § 342(f)(1)(A)] because they present an unreasonable risk of illness or injury under the conditions of use recommended or suggested in labeling, or if no conditions of use are suggested or recommended in labeling, under ordinary conditions of use.**[1]**
We request that you advise us in writing, within 15 days of receipt of this letter, as to the specific steps that have been or will be taken to correct these violations, including any steps taken with respect to product currently in the marketplace. Your response should also include an explanation of each step taken to ensure that similar violations do not recur, as well as documentation to support your response. Your written reply should be directed to Marjorie Davis, United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835. If you have

any questions, please contact Marjorie Davis at **Marjorie.Davis@fda.hhs.gov (mailto:Marjorie.Davis@fda.hhs.gov)**.

Sincerely,
/S/
William A. Correll
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

cc:
(b)(6)@gmail.com

support@journeyhealthusa.com

---

[1] See Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk, **69 FR 6788 (http://www.lexis.com/research/xlink?app=00075&view=full&searchtype=get&search=69+FR+6788)** (Feb. 11, 2014).

More in 2016 (/ICECI/EnforcementActions/WarningLetters/2016/default.htm)

Legendary Nutrition, LLC 3/7/16

Department of Health and Human Services

Public Health Service
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

March 7, 2016

WARNING LETTER

VIA OVERNIGHT DELIVERY, RETURN RECEIPT REQUESTED
VIA EMAIL

Dave Rodely
Legendary Nutrition, LLC
361 Southwest Drive #136
Jonesboro, Arkansas 72401

Re: 486995

Dear Mr. Rodely:

This letter concerns your product Thermotropin, which is labeled and/or offered for sale as a dietary supplement. The Supplement Facts panel on your product labeling declares *Acacia rigidula* Bark Powder as a dietary ingredient. This ingredient is also called, among other names, *Vachellia rigidula*, chaparro prieto, or blackbrush, and will be referred to in the rest of this letter as *A. rigidula*.

As an herb or other botanical, *A. rigidula* is a dietary ingredient under section 201(ff)(1)(C) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 321(ff)(1)(C)]. Further, as a dietary ingredient that was not marketed in the United States before October 15, 1994, *A. rigidula* is a “new dietary ingredient” under section 413(d) of the Act [21 U.S.C. § 350b(d)].

Under section 413 of the Act [21 U.S.C. §350b], a dietary supplement that contains a new dietary ingredient (i.e., a dietary ingredient not marketed in the United States before October 15, 1994) shall be deemed adulterated under section 402(f) of the Act [21 U.S.C. § 342(f)] unless it meets one of two requirements:

1. The dietary supplement contains only dietary ingredients that have been present in the food supply as an article used for food in a form in which the food has not been chemically altered; or

2. There is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides FDA with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

To the best of FDA's knowledge, there is no information demonstrating that *A. rigidula* was lawfully marketed as a dietary ingredient in the United States before October 15, 1994, nor is there information demonstrating that this ingredient has been present in the food supply as an article used for human food in a form in which the food has not been chemically altered. In the absence of such information, *A. rigidula* is subject to the notification requirement in section 413(a)(2) of the Act [21 U.S.C. § 350b(a)(2)] and 21 CFR 190.6. Because the required notification has not been submitted, your product is adulterated under sections 402(f)(1)(B) and 413(a) of the Act [21 U.S.C. §§ 342(f)(1)(B) and 350b(a)].

Even if the required notification had been submitted, we know of no evidence that would establish that your product is not adulterated. In the absence of a history of use or other evidence of safety establishing that *A. rigidula*, when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe, Thermotropin is adulterated under sections 402(f)(1)(B) and 413(a) of the Act [21 U.S.C. §§ 342(f)(1)(B) and 350b(a)] because it contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such product into interstate commerce is prohibited under section 301(a) and (v) of the Act [21 U.S.C. §§ 331(a) and (v)]. To the best of FDA's knowledge, there is no history of use or other evidence of safety establishing that *A. rigidula* will reasonably be expected to be safe when used as a dietary ingredient.

We request that you take prompt action to correct the violations cited above, as well as any other violations associated with your Thermotropin product or other dietary supplement products marketed by your firm, including any that contain *A. rigidula*. We also remind you that the new dietary ingredient notification requirement applies to all dietary supplements that contain new dietary ingredients that have not been present in the food supply as articles used for food in a form in which the food has not been chemically altered. It is your responsibility to ensure that your firm complies with all requirements of federal law and FDA regulations.

Failure to immediately cease distribution of your product Thermotropin and any other products you market that contain *A. rigidula* could result in enforcement action by FDA without further notice. Sections 302 and 304 of the Act provide for seizure of violative products and injunction against the manufacturers and distributors of violative products [21 U.S.C. §§ 332 and 334].

We request that you advise us in writing, within 15 days of receipt of this letter, as to the specific steps that have been or will be taken to correct these violations, including any steps taken with respect to product currently in the marketplace. Your response should also include an explanation of each step taken to ensure that similar violations do not recur, as well as documentation to support your response. Your written reply should be directed to Marjorie Davis, United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835. If you have any questions, please contact Marjorie Davis at **Marjorie.Davis@fda.hhs.gov (mailto:Marjorie.Davis@fda.hhs.gov)**.

Sincerely,
/S/
William A. Correll
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

cc:
info@legendarynutrition.org

Dave Rodely
NXS, LLC
10710 Otter Creek East Blvd
Mabelvale, AR 72103

Web.com—eWorks xl
12808 Gran Bay Parkway West
Jacksonville, FL 32258

More in 2016 (/ICECI/EnforcementActions/WarningLetters/2016/default.htm)

Nubreed Nutrition, Inc 3/7/16

Department of Health and Human Services

Public Health Service
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

March 7, 2016

WARNING LETTER

VIA OVERNIGHT DELIVERY, RETURN RECEIPT REQUESTED
VIA EMAIL

Jeff Thomas
Nubreed Nutrition, Inc.
318 John R Rd., Ste 310
Troy, MI 48083

Re: 486998

Dear Mr. Thomas:

This letter concerns your product "UNDISPUTED," which is labeled and/or offered for sale as a dietary supplement. The Supplement Facts panel on "UNDISPUTED" declares *Acacia rigidula* as a dietary ingredient. This ingredient is also called, among other names, *Vachellia rigidula*, chaparro prieto, and blackbrush, and will be referred to in the rest of this letter as *A. rigidula*.

As an herb or other botanical, *A. rigidula* is a dietary ingredient under section 201(ff)(1)(C) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 321(ff)(1)(C)]. Further, as a dietary ingredient that was not marketed in the United States before October 15, 1994, *A. rigidula* is a "new dietary ingredient" under section 413(d) of the Act [21 U.S.C. § 350b(d)].

Under section 413 of the Act [21 U.S.C. § 350b], a dietary supplement that contains a new dietary ingredient shall be deemed adulterated under section 402(f) of the Act [21 U.S.C. § 342(f)] unless it meets one of two requirements:

1. The dietary supplement contains only dietary ingredients that have been present in the food supply as an article used for food in a form in which the food has not been chemically altered; or

2. There is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides FDA with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

To the best of FDA's knowledge, there is no information demonstrating that *A. rigidula* was lawfully marketed as a dietary ingredient in the United States before October 15, 1994, nor is there information demonstrating that this ingredient has been present in the food supply as an article used for human food in a form in which the food has not been chemically altered. In the absence of such information, *A. rigidula* is subject to the notification requirement in section 413(a)(2) of the Act [21 U.S.C. § 350b(a)(2)] and 21 CFR 190.6. Because the required notification has not been submitted, your product is adulterated under sections 402(f)(1)(B) and 413(a) of the Act [21 U.S.C. §§ 342(f)(1)(B) and 350b(a)].

Even if the required notification had been submitted, we know of no evidence that would establish that your product is not adulterated. In the absence of a history of use or other evidence of safety establishing that *A. rigidula*, when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe, "UNDISPUTED" is adulterated under sections 402(f)(1)(B) and 413(a) of the Act [21 U.S.C. §§ 342(f)(1)(B) and 350b(a)] because it contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such product into interstate commerce is prohibited under section 301(a) and (v) of the Act [21 U.S.C. §§ 331(a) and (v)]. To the best of FDA's knowledge, there is no history of use or other evidence of safety establishing that *A. rigidula* will reasonably be expected to be safe when used as a dietary ingredient.

We request that you take prompt action to correct the violations cited above, as well as any other violations associated with your "UNDISPUTED" product or other dietary supplement products marketed by your firm, including any that contain *A. rigidula*. We also remind you that the new dietary ingredient notification requirement applies to all dietary supplements that contain new dietary ingredients that have not been present in the food supply as articles used for food in a form in which the food has not been chemically altered. It is your responsibility to ensure that your firm complies with all requirements of federal law and FDA regulations.

Failure to immediately cease distribution of your product "UNDISPUTED" and any other products you market that contain *A. rigidula* could result in enforcement action by FDA without further notice. Sections 302 and 304 of the Act provide for seizure of violative products and injunction against the manufacturers and distributors of violative products [21 U.S.C. §§ 332 and 334].

We request that you advise us in writing, within 15 days of receipt of this letter, as to the specific steps that have been or will be taken to correct these violations, including any steps taken with respect to product currently in the marketplace. Your response should also include an explanation of each step taken to ensure that similar violations do not recur, as well as documentation to support your response. Your written reply should be directed to Mabel Lee, United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835. If you have any questions, please contact Ms. Lee at **mabel.lee@fda.hhs.gov (mailto:mabel.lee@fda.hhs.gov)**.

Sincerely,
/S/
William A. Correll
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

cc:
info@nubreednutrition.com

Domains By Proxy, LLC
14747 N Northsight Blvd, Suite 111, PMB 309
Scottsdale, AZ 85260

More in 2016 (/ICECI/EnforcementActions/WarningLetters/2016/default.htm)

Rightway Nutrition, LLC 3/7/16

Department of Health and Human Services

Public Health Service
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

March 7, 2016

WARNING LETTER

VIA OVERNIGHT DELIVERY, RETURN RECEIPT REQUESTED
VIA EMAIL

Kevin Wright
Rightway Nutrition Marketing, LLC
14513 S Center Point Way, Ste 300
Bluffdale, Utah 84065

Re: 486977

Dear Mr. Wright:

This letter concerns your product “Green Coffee Bean Extract +Energy,” which is labeled and/or offered for sale as a dietary supplement. The Supplement Facts panel on your product declares *Acacia rigidula* Powder as a dietary ingredient. This ingredient is also called, among other names, *Vachellia rigidula*, chaparro prieto, or blackbrush, and will be referred to in the rest of this letter as *A. rigidula*.

As an herb or other botanical, *A. rigidula* is a dietary ingredient under section 201(ff)(1)(C) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 321(ff)(1)(C)]. Further, as a dietary ingredient that was not marketed in the United States before October 15, 1994, *A. rigidula* is a “new dietary ingredient” under section 413(d) of the Act [21 U.S.C. § 350b(d)].

Under section 413 of the Act [21 U.S.C. § 350b], a dietary supplement that contains a new dietary ingredient (i.e., a dietary ingredient not marketed in the United States before October 15, 1994) shall be deemed adulterated under

section 402(f) of the Act [21 U.S.C. § 342(f)] unless it meets one of two requirements:

1. The dietary supplement contains only dietary ingredients that have been present in the food supply as an article used for food in a form in which the food has not been chemically altered; or

2. There is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides FDA with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

To the best of FDA's knowledge, there is no information demonstrating that *A. rigidula* was lawfully marketed as a dietary ingredient in the United States before October 15, 1994, nor is there information demonstrating that this ingredient has been present in the food supply as an article used for human food in a form in which the food has not been chemically altered. In the absence of such information, *A. rigidula* is subject to the notification requirement in section 413(a)(2) of the Act [21 U.S.C. § 350b(a)(2)] and 21 CFR 190.6. Because the required notification has not been submitted, your product is adulterated under sections 402(f)(1)(B) and 413(a) of the Act [21 U.S.C. §§ 342(f)(1)(B) and 350b(a)].

Even if the required notification had been submitted, we know of no evidence that would establish that your product is not adulterated. In the absence of a history of use or other evidence of safety establishing that *A. rigidula*, when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe, "Green Coffee Bean Extract +Energy" is adulterated under sections 402(f)(1)(B) and 413(a) of the Act [21 U.S.C. §§ 342(f)(1)(B) and 350b(a)] because it contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such product into interstate commerce is prohibited under section 301(a) and (v) of the Act [21 U.S.C. §§ 331(a) and (v)]. To the best of FDA's knowledge, there is no history of use or other evidence of safety establishing that *A. rigidula* will reasonably be expected to be safe when used as a dietary ingredient.

We request that you take prompt action to correct the violations cited above, as well as any other violations associated with your "Green Coffee Bean Extract +Energy" product or other dietary supplement products marketed by your firm, including any that contain *A. rigidula*. We also remind you that the new dietary ingredient notification requirement applies to all dietary supplements that contain new dietary ingredients that have not been present in the food supply as articles used for food in a form in which the food has not been chemically altered. It is your responsibility to ensure that your firm complies with all requirements of federal law and FDA regulations.

Failure to immediately cease distribution of your product "Green Coffee Bean Extract +Energy" and any other products you market that contain *A. rigidula* could result in enforcement action by FDA without further notice. Sections 302 and 304 of the Act provide for seizure of violative products and injunction against the manufacturers and distributors of violative products [21 U.S.C. §§ 332 and 334].

We request that you advise us in writing, within 15 days of receipt of this letter, as to the specific steps that have been or will be taken to correct these violations, including any steps taken with respect to product currently in the marketplace. Your response should also include an explanation of each step taken to ensure that similar violations do not recur, as well as documentation to support your response. Your written reply should be directed to Mabel Lee, United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835. If you have any questions, please contact Ms. Lee at **mabel.lee@fda.hhs.gov (mailto:mabel.lee@fda.hhs.gov)**.

Sincerely,
/S/
William A. Correll
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

cc:
info@rightwaynutrition.com

Rightway Nutrition
2150 W Broadway Rd.
Mesa, AZ 85202

More in 2016 (/ICECI/EnforcementActions/WarningLetters/2016/default.htm)

Ronnie Coleman Signature Series/Rcba Nutraceuticals, LLC 3/7/16

Department of Health and Human Services

Public Health Service
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

March 7, 2016

WARNING LETTER

VIA OVERNIGHT DELIVERY, RETURN RECEIPT REQUESTED
VIA EMAIL

Ronnie Coleman
Ronnie Coleman Signature Series
Rcba Nutraceuticals, LLC
2041 High Ridge Rd
Boynton Beach, Florida 33426

Re: 486978

Dear Mr. Coleman:

This letter concerns your product "BETA-STIM 45 SCOOPS," which is labeled and/or offered for sale as a dietary supplement. The Supplement Facts panel on your product labeling declares *Acacia rigidula* as a dietary ingredient. This ingredient is also called, among other names, *Vachellia rigidula*, chaparro prieto, or blackbrush, and will be referred to in the rest of this letter as *A. rigidula*.

As an herb or other botanical, *A. rigidula* is a dietary ingredient under section 201(ff)(1)(C) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 321(ff)(1)(C)]. Further, as a dietary ingredient that was not marketed in the United

States before October 15, 1994, *A. rigidula* is a "new dietary ingredient" under section 413(d) of the Act [21 U.S.C. § 350b(d)].

Under section 413 of the Act [21 U.S.C. § 350b], a dietary supplement that contains a new dietary ingredient (i.e., a dietary ingredient not marketed in the United States before October 15, 1994) shall be deemed adulterated under section 402(f) of the Act [21 U.S.C. § 342(f)] unless it meets one of two requirements:

1. The dietary supplement contains only dietary ingredients that have been present in the food supply as an article used for food in a form in which the food has not been chemically altered; or

2. There is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides FDA with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

To the best of FDA's knowledge, there is no information demonstrating that *A. rigidula* was lawfully marketed as a dietary ingredient in the United States before October 15, 1994, nor is there information demonstrating that this ingredient has been present in the food supply as an article used for human food in a form in which the food has not been chemically altered. In the absence of such information, *A. rigidula* is subject to the notification requirement in section 413(a)(2) of the Act [21 U.S.C. § 350b(a)(2)] and 21 CFR 190.6. Because the required notification has not been submitted, your product is adulterated under sections 402(f)(1)(B) and 413(a) of the Act [21 U.S.C. §§ 342(f)(1)(B) and 350b(a)].

Even if the required notification had been submitted, we know of no evidence that would establish that your product is not adulterated. In the absence of a history of use or other evidence of safety establishing that *A. rigidula*, when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe, "BETA-STIM 45 SCOOPS" is adulterated under sections 402(f)(1)(B) and 413(a) of the Act [21 U.S.C. §§ 342(f)(1)(B) and 350b(a)] because it contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such product into interstate commerce is prohibited under section 301(a) and (v) of the Act [21 U.S.C. §§ 331(a) and (v)]. To the best of FDA's knowledge, there is no history of use or other evidence of safety establishing that *A. rigidula* will reasonably be expected to be safe when used as a dietary ingredient.

We request that you take prompt action to correct the violations cited above, as well as any other violations associated with your "BETA-STIM 45 SCOOPS" product or other dietary supplement products marketed by your firm, including any that contain *A. rigidula*. We also remind you that the new dietary ingredient notification requirement applies to all dietary supplements that contain new dietary ingredients that have not been present in the food supply as articles used for food in a form in which the food has not been chemically altered. It is your responsibility to ensure that your firm complies with all requirements of federal law and FDA regulations.

Failure to immediately cease distribution of your product "BETA-STIM 45 SCOOPS" and any other products you market that contain *A. rigidula* could result in enforcement action by FDA without further notice. Sections 302 and 304 of the Act provide for seizure of violative products and injunction against the manufacturers and distributors of violative products [21 U.S.C. §§ 332 and 334].

We request that you advise us in writing, within 15 days of receipt of this letter, as to the specific steps that have been or will be taken to correct these violations, including any steps taken with respect to product currently in the

marketplace. Your response should also include an explanation of each step taken to ensure that similar violations do not recur, as well as documentation to support your response. Your written reply should be directed to Mabel Lee, United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835. If you have any questions, please contact Ms. Lee at **mabel.lee@fda.hhs.gov (mailto:mabel.lee@fda.hhs.gov)**.

Sincerely,
/S/
William A. Correll
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

cc:
customerservice@ronniecoleman.net

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14747 N Northsight Blvd, Suite 111, PMB 309
Scottsdale, AZ 85260

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