

United States Senate

SPECIAL COMMITTEE ON AGING
WASHINGTON, DC 20510-6400
(202) 224-5364

November 9, 2015

Mr. Jeffrey Bezos
CEO
Amazon.com, Inc.
410 Terry Avenue N.
Seattle, WA 98109

Dear Mr. Bezos,

As you are aware, under the law, dietary supplements may only contain “dietary ingredients,” or substances that are a vitamin, a mineral, an herb or other botanical, an amino acid, a substance that supplements the total dietary intake, or a concentrate, metabolite, constituent extract, or combination of any of the aforementioned ingredients.¹ As a retailer of dietary supplements, I understand that Amazon may be selling dietary supplements containing picamilon, a substance which does not appear to meet the definition of a dietary ingredient.

On October 22, 2015, the Oregon Attorney General filed a complaint against General Nutrition Corporation (GNC) alleging that GNC knowingly sold products containing ingredients that were not appropriate for inclusion in dietary supplements.² One of the ingredients in products alleged to have been sold by GNC is a substance called picamilon, which GNC allegedly learned—almost nine years before— “was a synthetic drug created by Soviet investigators and was not a lawful dietary ingredient in the United States.”³

In connection with the Oregon Attorney General’s investigation, a representative of the Food and Drug Administration (FDA) submitted an affidavit stating that picamilon is not a dietary ingredient.⁴ A recent article published in the *New England Journal of Medicine* further

¹ Dietary Supplement Health and Education Act of 1994, Public Law 103-417.

² *Oregon AG Accuses Retailer GNC of Selling Drug-Spiked Dietary Supplements*, USA Today (Oct. 23, 2015) (online at <http://www.usatoday.com/story/news/2015/10/22/oregon-lawsuit-gnc-supplements/74344318/>).

³ *State of Oregon v. General Nutrition Corporation*, Complaint Para. 24, 15CV28591 (Or. October 23, 2015).

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confirmed that picamilon, a substance that is classified as a prescription drug in other countries, may not fit the definition of a dietary ingredient.⁵

To date, the FDA, however, has failed to prevent the inclusion of this ingredient in dietary supplements. In October, I requested that the FDA take appropriate steps to determine whether picamilon is appropriate for sale, and to remove it from store shelves if it is not. Despite my repeated requests, the FDA has failed to produce any response to my inquiry and remains silent on whether products containing picamilon should be recalled or removed from sale in dietary supplements.

As one of the leading retailers offering dietary supplements to senior citizens and other American consumers, Amazon plays a pivotal role in determining which supplements these consumers use and trust. For this reason, and given FDA's failure to respond, I request that you voluntarily remove any and all products containing picamilon that you may carry from your stores and from your website. While I understand that some retailers have taken reasonable steps to remove these products, in the absence of FDA action with regard to this ingredient, I feel it necessary to reach out and make this request to ensure that these products are entirely removed from shelves. In addition, I also request that you review your policies for ensuring that all dietary supplements that you carry are safe for consumption and comply with all applicable laws.

Ensuring the health and safety of our seniors is one of the most important aspects of my role as Ranking Member on the Special Committee on Aging. As such, I appreciate your assistance with this matter. Please contact Caitlin Warner at (202) 224-0185 with any questions. Please send any official correspondence related to this request to caitlin_warner@aging.senate.gov and matt_lawrence@aging.senate.gov.

Sincerely,



Claire McCaskill
Ranking Member

Cc: Susan Collins
Chairman

⁵ Avula, B., Chittiboyina, A. G., Sagi, S., Wang, Y.-H., Wang, M., Khan, I. A., and Cohen, P. A. *Identification and quantification of vinpocetine and picamilon in dietary supplements sold in the United States* (Oct. 2015) (online at <http://onlinelibrary.wiley.com/doi/10.1002/dta.1853/full>).

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(202) 224-5364

November 9, 2015

Mr. Colin Watts
CEO
The Vitamin Shoppe
2101 91st Street
North Bergen, NJ 07047

Dear Mr. Watts,

As you are aware, under the law, dietary supplements may only contain “dietary ingredients,” or substances that are a vitamin, a mineral, an herb or other botanical, an amino acid, a substance that supplements the total dietary intake, or a concentrate, metabolite, constituent extract, or combination of any of the aforementioned ingredients.¹ As a retailer of dietary supplements, I understand that The Vitamin Shoppe may be selling dietary supplements containing picamilon, a substance which does not appear to meet the definition of a dietary ingredient.

On October 22, 2015, the Oregon Attorney General filed a complaint against General Nutrition Corporation (GNC) alleging that GNC knowingly sold products containing ingredients that were not appropriate for inclusion in dietary supplements.² One of the ingredients in products alleged to have been sold by GNC is a substance called picamilon, which GNC allegedly learned—almost nine years before— “was a synthetic drug created by Soviet investigators and was not a lawful dietary ingredient in the United States.”³

In connection with the Oregon Attorney General’s investigation, a representative of the Food and Drug Administration (FDA) submitted an affidavit stating that picamilon is not a dietary ingredient.⁴ A recent article published in the *New England Journal of Medicine* further

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To date, the FDA, however, has failed to prevent the inclusion of this ingredient in dietary supplements. In October, I requested that the FDA take appropriate steps to determine whether picamilon is appropriate for sale, and to remove it from store shelves if it is not. Despite my repeated requests, the FDA has failed to produce any response to my inquiry and remains silent on whether products containing picamilon should be recalled or removed from sale in dietary supplements.

As one of the leading retailers offering dietary supplements to senior citizens and other American consumers, The Vitamin Shoppe plays a pivotal role in determining which supplements these consumers use and trust. For this reason, and given FDA's failure to respond, I request that you voluntarily remove any and all products containing picamilon that you may carry from your stores and from your website. While I understand that some retailers have taken reasonable steps to remove these products, in the absence of FDA action with regard to this ingredient, I feel it necessary to reach out and make this request to ensure that these products are entirely removed from shelves. In addition, I also request that you review your policies for ensuring that all dietary supplements that you carry are safe for consumption and comply with all applicable laws.

Ensuring the health and safety of our seniors is one of the most important aspects of my role as Ranking Member on the Special Committee on Aging. As such, I appreciate your assistance with this matter. Please contact Caitlin Warner at (202) 224-0185 with any questions. Please send any official correspondence related to this request to caitlin_warner@aging.senate.gov and matt_lawerence@aging.senate.gov.

Sincerely,



Claire McCaskill
Ranking Member

Cc: Susan Collins
Chairman

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WASHINGTON, DC 20510-6400
(202) 224-5364

November 9, 2015

Mr. Larry J. Merlo
CEO
CVS Health
One CVS Drive,
Woonsocket, Rhode Island 02895

Dear Mr. Merlo,

As you are aware, under the law, dietary supplements may only contain “dietary ingredients,” or substances that are a vitamin, a mineral, an herb or other botanical, an amino acid, a substance that supplements the total dietary intake, or a concentrate, metabolite, constituent extract, or combination of any of the aforementioned ingredients.¹ As a retailer of dietary supplements, I understand that CVS may be selling dietary supplements containing picamilon, a substance which does not appear to meet the definition of a dietary ingredient.

On October 22, 2015, the Oregon Attorney General filed a complaint against General Nutrition Corporation (GNC) alleging that GNC knowingly sold products containing ingredients that were not appropriate for inclusion in dietary supplements.² One of the ingredients in products alleged to have been sold by GNC is a substance called picamilon, which GNC allegedly learned—almost nine years before— “was a synthetic drug created by Soviet investigators and was not a lawful dietary ingredient in the United States.”³

In connection with the Oregon Attorney General’s investigation, a representative of the Food and Drug Administration (FDA) submitted an affidavit stating that picamilon is not a dietary ingredient.⁴ A recent article published in the *New England Journal of Medicine* further

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To date, the FDA, however, has failed to prevent the inclusion of this ingredient in dietary supplements. In October, I requested that the FDA take appropriate steps to determine whether picamilon is appropriate for sale, and to remove it from store shelves if it is not. Despite my repeated requests, the FDA has failed to produce any response to my inquiry and remains silent on whether products containing picamilon should be recalled or removed from sale in dietary supplements.

As one of the leading retailers offering dietary supplements to senior citizens and other American consumers, CVS plays a pivotal role in determining which supplements these consumers use and trust. For this reason, and given FDA's failure to respond, I request that you voluntarily remove any and all products containing picamilon that you may carry from your stores and from your website. While I understand that some retailers have taken reasonable steps to remove these products, in the absence of FDA action with regard to this ingredient, I feel it necessary to reach out and make this request to ensure that these products are entirely removed from shelves. In addition, I also request that you review your policies for ensuring that all dietary supplements that you carry are safe for consumption and comply with all applicable laws.

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Sincerely,



Claire McCaskill
Ranking Member

Cc: Susan Collins
Chairman

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(202) 224-5364

November 9, 2015

Mr. Doug McMilon
President and CEO
Wal-Mart Stores Inc.
702 SW 8th Street
Bentonville, Arkansas 72716

Dear Mr. McMilon,

As you are aware, under the law, dietary supplements may only contain “dietary ingredients,” or substances that are a vitamin, a mineral, an herb or other botanical, an amino acid, a substance that supplements the total dietary intake, or a concentrate, metabolite, constituent extract, or combination of any of the aforementioned ingredients.¹ As a retailer of dietary supplements, I understand that Wal-Mart may be selling dietary supplements containing picamilon, a substance which does not appear to meet the definition of a dietary ingredient.

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To date, the FDA, however, has failed to prevent the inclusion of this ingredient in dietary supplements. In October, I requested that the FDA take appropriate steps to determine whether picamilon is appropriate for sale, and to remove it from store shelves if it is not. Despite my repeated requests, the FDA has failed to produce any response to my inquiry and remains silent on whether products containing picamilon should be recalled or removed from sale in dietary supplements.

As one of the leading retailers offering dietary supplements to senior citizens and other American consumers, Wal-Mart plays a pivotal role in determining which supplements these consumers use and trust. For this reason, and given FDA's failure to respond, I request that you voluntarily remove any and all products containing picamilon that you may carry from your stores and from your website. While I understand that some retailers have taken reasonable steps to remove these products, in the absence of FDA action with regard to this ingredient, I feel it necessary to reach out and make this request to ensure that these products are entirely removed from shelves. In addition, I also request that you review your policies for ensuring that all dietary supplements that you carry are safe for consumption and comply with all applicable laws.

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Sincerely,



Claire McCaskill
Ranking Member

Cc: Susan Collins
Chairman

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November 9, 2015

Mr. Sundar Pichai
CEO
Google Inc.
1600 Amphitheatre Parkway
Mountain View, CA 94043

Dear Mr. Pichai,

As you are aware, under the law, dietary supplements may only contain “dietary ingredients,” or substances that are a vitamin, a mineral, an herb or other botanical, an amino acid, a substance that supplements the total dietary intake, or a concentrate, metabolite, constituent extract, or combination of any of the aforementioned ingredients.¹ As a retailer of dietary supplements, I understand that Google Shopping may be selling dietary supplements containing picamilon, a substance which does not appear to meet the definition of a dietary ingredient.

On October 22, 2015, the Oregon Attorney General filed a complaint against General Nutrition Corporation (GNC) alleging that GNC knowingly sold products containing ingredients that were not appropriate for inclusion in dietary supplements.² One of the ingredients in products alleged to have been sold by GNC is a substance called picamilon, which GNC allegedly learned—almost nine years before— “was a synthetic drug created by Soviet investigators and was not a lawful dietary ingredient in the United States.”³

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To date, the FDA, however, has failed to prevent the inclusion of this ingredient in dietary supplements. In October, I requested that the FDA take appropriate steps to determine whether picamilon is appropriate for sale, and to remove it from store shelves if it is not. Despite my repeated requests, the FDA has failed to produce any response to my inquiry and remains silent on whether products containing picamilon should be recalled or removed from sale in dietary supplements.

As one of the leading retailers offering dietary supplements to senior citizens and other American consumers, Google Shopping plays a pivotal role in determining which supplements these consumers use and trust. For this reason, and given FDA's failure to respond, I request that you voluntarily remove any and all products containing picamilon that you may carry from your stores and from your website. While I understand that some retailers have taken reasonable steps to remove these products, in the absence of FDA action with regard to this ingredient, I feel it necessary to reach out and make this request to ensure that these products are entirely removed from shelves. In addition, I also request that you review your policies for ensuring that all dietary supplements that you carry are safe for consumption and comply with all applicable laws.

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Sincerely,



Claire McCaskill
Ranking Member

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Chairman

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United States Senate

SPECIAL COMMITTEE ON AGING
WASHINGTON, DC 20510-6400
(202) 224-5364

November 9, 2015

Mr. Jack Krause
President
Vitamin World
105 Orville Drive
Bohemia, NY 11716

Dear Mr. Krause,

As you are aware, under the law, dietary supplements may only contain “dietary ingredients,” or substances that are a vitamin, a mineral, an herb or other botanical, an amino acid, a substance that supplements the total dietary intake, or a concentrate, metabolite, constituent extract, or combination of any of the aforementioned ingredients.¹ As a retailer of dietary supplements, I understand that Vitamin World may be selling dietary supplements containing picamilon, a substance which does not appear to meet the definition of a dietary ingredient.

On October 22, 2015, the Oregon Attorney General filed a complaint against General Nutrition Corporation (GNC) alleging that GNC knowingly sold products containing ingredients that were not appropriate for inclusion in dietary supplements.² One of the ingredients in products alleged to have been sold by GNC is a substance called picamilon, which GNC allegedly learned—almost nine years before— “was a synthetic drug created by Soviet investigators and was not a lawful dietary ingredient in the United States.”³

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To date, the FDA, however, has failed to prevent the inclusion of this ingredient in dietary supplements. In October, I requested that the FDA take appropriate steps to determine whether picamilon is appropriate for sale, and to remove it from store shelves if it is not. Despite my repeated requests, the FDA has failed to produce any response to my inquiry and remains silent on whether products containing picamilon should be recalled or removed from sale in dietary supplements.

As one of the leading retailers offering dietary supplements to senior citizens and other American consumers, Vitamin World plays a pivotal role in determining which supplements these consumers use and trust. For this reason, and given FDA's failure to respond, I request that you voluntarily remove any and all products containing picamilon that you may carry from your stores and from your website. While I understand that some retailers have taken reasonable steps to remove these products, in the absence of FDA action with regard to this ingredient, I feel it necessary to reach out and make this request to ensure that these products are entirely removed from shelves. In addition, I also request that you review your policies for ensuring that all dietary supplements that you carry are safe for consumption and comply with all applicable laws.

Ensuring the health and safety of our seniors is one of the most important aspects of my role as Ranking Member on the Special Committee on Aging. As such, I appreciate your assistance with this matter. Please contact Caitlin Warner at (202) 224-0185 with any questions. Please send any official correspondence related to this request to caitlin_warner@aging.senate.gov and matt_lawrence@aging.senate.gov.

Sincerely,



Claire McCaskill
Ranking Member

Cc: Susan Collins
Chairman

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United States Senate

SPECIAL COMMITTEE ON AGING

WASHINGTON, DC 20510-6400

(202) 224-5364

November 9, 2015

Mr. Stefano Pessina
CEO
Walgreen Co.
200 Wilmot Road
Deerfield, IL 60015

Dear Mr. Pessina,

As you are aware, under the law, dietary supplements may only contain “dietary ingredients,” or substances that are a vitamin, a mineral, an herb or other botanical, an amino acid, a substance that supplements the total dietary intake, or a concentrate, metabolite, constituent extract, or combination of any of the aforementioned ingredients.¹ As a retailer of dietary supplements, I understand that Walgreens may be selling dietary supplements containing picamilon, a substance which does not appear to meet the definition of a dietary ingredient.

On October 22, 2015, the Oregon Attorney General filed a complaint against General Nutrition Corporation (GNC) alleging that GNC knowingly sold products containing ingredients that were not appropriate for inclusion in dietary supplements.² One of the ingredients in products alleged to have been sold by GNC is a substance called picamilon, which GNC allegedly learned—almost nine years before— “was a synthetic drug created by Soviet investigators and was not a lawful dietary ingredient in the United States.”³

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As one of the leading retailers offering dietary supplements to senior citizens and other American consumers, Walgreens plays a pivotal role in determining which supplements these consumers use and trust. For this reason, and given FDA's failure to respond, I request that you voluntarily remove any and all products containing picamilon that you may carry from your stores and from your website. While I understand that some retailers have taken reasonable steps to remove these products, in the absence of FDA action with regard to this ingredient, I feel it necessary to reach out and make this request to ensure that these products are entirely removed from shelves. In addition, I also request that you review your policies for ensuring that all dietary supplements that you carry are safe for consumption and comply with all applicable laws.

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Sincerely,



Claire McCaskill
Ranking Member

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Chairman

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United States Senate

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WASHINGTON, DC 20510-6400
(202) 224-5364

November 9, 2015

Mr. Brian Cornell
CEO
Target Corporation
Target Plaza North & Target Plaza South
1000 Nicollet Mall
Minneapolis, Minnesota 55403

Dear Mr. Cornell,

As you are aware, under the law, dietary supplements may only contain “dietary ingredients,” or substances that are a vitamin, a mineral, an herb or other botanical, an amino acid, a substance that supplements the total dietary intake, or a concentrate, metabolite, constituent extract, or combination of any of the aforementioned ingredients.¹ As a retailer of dietary supplements, I understand that Target may be selling dietary supplements containing picamilon, a substance which does not appear to meet the definition of a dietary ingredient.

On October 22, 2015, the Oregon Attorney General filed a complaint against General Nutrition Corporation (GNC) alleging that GNC knowingly sold products containing ingredients that were not appropriate for inclusion in dietary supplements.² One of the ingredients in products alleged to have been sold by GNC is a substance called picamilon, which GNC allegedly learned—almost nine years before— “was a synthetic drug created by Soviet investigators and was not a lawful dietary ingredient in the United States.”³

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As one of the leading retailers offering dietary supplements to senior citizens and other American consumers, Target plays a pivotal role in determining which supplements these consumers use and trust. For this reason, and given FDA's failure to respond, I request that you voluntarily remove any and all products containing picamilon that you may carry from your stores and from your website. While I understand that some retailers have taken reasonable steps to remove these products, in the absence of FDA action with regard to this ingredient, I feel it necessary to reach out and make this request to ensure that these products are entirely removed from shelves. In addition, I also request that you review your policies for ensuring that all dietary supplements that you carry are safe for consumption and comply with all applicable laws.

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Sincerely,



Claire McCaskill
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November 9, 2015

Mr. Michael G. Archbold CPA
CEO
General Nutrition Corporation
300 6th Avenue
Pittsburgh, PA 15222

Dear Mr. Archbold,

As you are aware, under the law, dietary supplements may only contain “dietary ingredients,” or substances that are a vitamin, a mineral, an herb or other botanical, an amino acid, a substance that supplements the total dietary intake, or a concentrate, metabolite, constituent extract, or combination of any of the aforementioned ingredients.¹ As a retailer of dietary supplements, I understand that GNC may still be selling dietary supplements containing picamilon, a substance which does not appear to meet the definition of a dietary ingredient.

On October 22, 2015, the Oregon Attorney General filed a complaint against your company alleging that you knowingly sold products containing ingredients that were not appropriate for inclusion in dietary supplements.² One of the ingredients in products alleged to have been sold by GNC is a substance called picamilon, which you allegedly learned—almost nine years before— “was a synthetic drug created by Soviet investigators and was not a lawful dietary ingredient in the United States.”³

In connection with the Oregon Attorney General’s investigation, a representative of the Food and Drug Administration (FDA) submitted an affidavit stating that picamilon is not a dietary ingredient.⁴ A recent article published in the New England Journal of Medicine further

¹ Dietary Supplement Health and Education Act of 1994, Public Law 103-417.

² *Oregon AG Accuses Retailer GNC of Selling Drug-Spiked Dietary Supplements*, USA Today (Oct. 23, 2015) (online at <http://www.usatoday.com/story/news/2015/10/22/oregon-lawsuit-gnc-supplements/74344318/>).

³ *State of Oregon v. General Nutrition Corporation*, Complaint Para. 24, 15CV28591 (Or. October 23, 2015).

⁴ *State of Oregon v. General Nutrition Corporation*, 15CV28591 (Or. October 23, 2015).

confirmed that picamilon, a substance that is classified as a prescription drug in other countries, may not fit the definition of a dietary ingredient.⁵

To date, the FDA, however, has failed to prevent the inclusion of this ingredient in dietary supplements. In October, I requested that the FDA take appropriate steps to determine whether picamilon is appropriate for sale, and to remove it from store shelves if it is not. Despite my repeated requests, the FDA has failed to produce any response to my inquiry and remains silent on whether products containing picamilon should be recalled or removed from sale in dietary supplements.

As one of the leading retailers offering dietary supplements to senior citizens and other American consumers, GNC plays a pivotal role in determining which supplements these consumers use and trust. For this reason, and given FDA's failure to respond, I request that you voluntarily remove any and all products containing picamilon that you may carry from your stores and from your website. While I understand that some retailers have taken reasonable steps to remove these products, in the absence of FDA action with regard to this ingredient, I feel it necessary to reach out and make this request to ensure that these products are entirely removed from shelves. In addition, I also request that you review your policies for ensuring that all dietary supplements that you carry are safe for consumption and comply with all applicable laws.

Ensuring the health and safety of our seniors is one of the most important aspects of my role as Ranking Member on the Special Committee on Aging. As such, I appreciate your assistance with this matter. Please contact Caitlin Warner at (202) 224-0185 with any questions. Please send any official correspondence related to this request to caitlin_warner@aging.senate.gov and matt_lawrence@aging.senate.gov.

Sincerely,



Claire McCaskill
Ranking Member

Cc: Susan Collins
Chairman

⁵ Avula, B., Chittiboyina, A. G., Sagi, S., Wang, Y.-H., Wang, M., Khan, I. A., and Cohen, P. A. *Identification and quantification of vinpocetine and picamilon in dietary supplements sold in the United States* (Oct. 2015) (online at <http://onlinelibrary.wiley.com/doi/10.1002/dta.1853/full>).

United States Senate

SPECIAL COMMITTEE ON AGING
WASHINGTON, DC 20510-6400
(202) 224-5364

November 9, 2015

Mr. John Joseph Donahoe II
President and CEO
eBay Inc.
2145 Hamilton Avenue
San Jose, CA 95125

Dear Mr. Donahoe,

As you are aware, under the law, dietary supplements may only contain “dietary ingredients,” or substances that are a vitamin, a mineral, an herb or other botanical, an amino acid, a substance that supplements the total dietary intake, or a concentrate, metabolite, constituent extract, or combination of any of the aforementioned ingredients.¹ As a retailer of dietary supplements, I understand that eBay may be selling dietary supplements containing picamilon, a substance which does not appear to meet the definition of a dietary ingredient.

On October 22, 2015, the Oregon Attorney General filed a complaint against General Nutrition Corporation (GNC) alleging that GNC knowingly sold products containing ingredients that were not appropriate for inclusion in dietary supplements.² One of the ingredients in products alleged to have been sold by GNC is a substance called picamilon, which GNC allegedly learned—almost nine years before— “was a synthetic drug created by Soviet investigators and was not a lawful dietary ingredient in the United States.”³

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Claire McCaskill
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