

United States Senate

SPECIAL COMMITTEE ON AGING

WASHINGTON, DC 20510-6400

(202) 224-5364

June 15, 2015

The Honorable Stephen Ostroff, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Ostroff:

Thank you for providing the Committee staff with a briefing regarding the Food and Drug Administration's (FDA) role in regulating dietary supplements as requested by Ranking Member McCaskill's letter on February 26, 2015. While we appreciate the information that your staff provided, we continue to have questions about FDA's efforts to protect seniors and other American consumers who take dietary supplements in order to protect and improve their health. Currently, many types of "healthy aging" supplements are marketed to seniors and are widely available for purchase in the marketplace. Examples of the conditions these supplements claim to improve are dementia, Alzheimer's disease, cancer, cardiovascular support, arthritis, and osteoarthritis.

As demonstrated by recent reports regarding the presence of β -Methylphenethylamine (BMPEA), a potentially harmful stimulant and which does not meet the statutory definition of a dietary ingredient, in several supplements currently on the market, questions have been raised about consumer protection and access to information, as well as FDA's oversight and authority.¹

In light of this and other recent developments regarding dietary supplements, we are interested in learning what steps FDA is taking to exercise current authority and improve the process for systematically ensuring the safety and accuracy of labeling of supplements on the market to protect consumers from tainted products, mislabeled ingredients, and fraudulent health claims, including guidelines to address the new dietary ingredient notification process.² In 2013, the GAO recommended that the FDA explore options to obtain poison center data; collect

¹ *Study Warns of Diet Supplement Dangers Kept Quiet by F.D.A.*, The New York Times (April 7, 2015) (online at: <http://well.blogs.nytimes.com/2015/04/07/study-warns-of-diet-supplement-dangers-kept-quiet-by-f-d-a/>).

² *Chains Pull Dietary Aids Off Shelves After Inquiry*, The New York Times (February 12, 2015) (online at: http://well.blogs.nytimes.com/2015/02/12/chains-pull-dietary-aids-off-shelves-after-inquiry/?_r=1).

information on how the FDA uses Adverse Event Reports (AERs); and determine what additional information the agency is able to provide to the public about AERs and how to make readily available on its website. The FDA generally concurred with each of GAO's recommendations, but the GAO considers these recommendations open.³

While we understand that FDA undertakes periodic reviews and targeted investigations of dietary supplements currently on the market, concerns have been raised that the FDA's current regulatory authorities lack a systematic approach to preventing adulterated, mislabeled, and fraudulent products from entering the market.

Additionally, we are concerned that the FDA may not be effectively using its existing regulatory authority to adequately enforce the pre-market notification requirements for supplements containing new dietary ingredients. The new dietary ingredient process represents one of the FDA's only opportunities to perform a pre-market review of dietary supplements to ensure reasonable expectations of safety, yet questions have been raised about how the FDA is utilizing this authority.

To examine and better understand the role of the FDA in protecting seniors and other consumers from adulterated or fraudulent dietary supplements, we request that you provide the information and documents enumerated below.

1. The Dietary Supplement Health and Education Act of 1994 requires the manufacturer or distributor of a new dietary ingredient, defined as ingredients not on the market in the United States prior to October 15, 1994, to notify the FDA before introducing a new dietary ingredient into interstate commerce. The manufacturer or distributor must provide information supporting the basis on which it has determined the ingredient will reasonably be expected to be safe. Those ingredients marketed in the United States prior to October 15, 1994 are not subject to this requirement. However the FDA does have authority to take enforcement action against companies for the use of these ingredients if the agency can prove a dietary supplement or one of its ingredient is adulterated.
 - a. Provide a list of all new dietary ingredients of which the FDA has been notified of during the past five years.
 - b. Provide a list of all dietary supplements and/or dietary ingredients that were on the market prior to October 15, 1994 and have since been deemed adulterated as defined by 21 USC 342(f).
 - c. Describe the FDA's processes and procedures used to ensure that companies are reporting new dietary ingredients as required, as well as any penalties that the FDA has the authority to impose for non-compliance.
 - d. Provide a summary of each enforcement action taken in the past five years against a manufacturer or distributor for failure to notify the FDA of a new dietary ingredient.
 - e. Section 113 of the Food Safety Modernization Act required the FDA to publish guidance relating to new dietary ingredients. Draft guidance was distributed for comment in July 2011, but was not finalized. Provide an update on the status of this guidance.

³ GAO-13-244.

2. The FDA is responsible for ensuring the safety and accurate labeling of dietary supplements, as well as quality manufacturing, and is responsible for taking action against any adulterated or mislabeled dietary supplement currently on the market.
 - a. Provide all current regulations and guidance relating to the inspection of dietary supplements and/or facilities that manufacture or distribute dietary supplements.
 - b. Describe the role contractors and/or third-party testing laboratories play in the inspection of dietary supplements and/or facilities that manufacture or distribute dietary supplements. If applicable, please provide a copy of the relevant contract, memorandum of understanding, or agreement currently in effect between the FDA and each contractor and/or third party.
 - c. Provide a summary of all enforcement actions related to a supplement manufacturer's failure to register with the FDA over the past five years. Please use the template attached to this letter to provide your response.
 - d. The Dietary Supplement and Nonprescription Drug Consumer Protection Act requires a manufacturer, packer, or distributor of a dietary supplement to submit all reports of serious adverse events within 15 days. Provide all serious adverse events reported in relation to dietary supplements since December 22, 2007. Please use the template attached to this letter to provide your response.
 - e. Provide a summary of each enforcement action taken against manufacturers, packers, or distributors of dietary supplements since December 22, 2007, for failure to comply with mandatory adverse event reporting requirements. Please use the template attached to this letter to provide your response.
 - f. Consumers can voluntarily submit adverse event reports related to dietary supplements. Provide a description of each adverse event reported by consumers related to dietary supplements during the past 5 years. Please use the template attached to this letter to provide your response.
 - g. In March 2013, the GAO recommended that the FDA determine what additional information it could make public regarding Adverse Event Reports and make that information accessible and publically available. GAO continues to consider this recommendation open. Please describe the FDA's efforts to implement this recommendation, and how the FDA plans to promote transparency related to adverse event reporting.
 - h. Provide all warning letters FDA sent relating to dietary supplements during the past five years.
 - i. Currently, Operation Supplement Safety (OPSS), an organization created as a joint effort between the Department of Defense and the Human Performance Resource Center, maintains a "high risk supplement list" that contains more than 100 supplements believed to be "high risk" because they contain additives such as anabolic agents or stimulants. Please describe the role that these and other outside organizations (governmental and non-governmental) play in the FDA's efforts to oversee the dietary supplement industry, including the efforts the FDA has taken to utilize information gained from other organizations like OPSS.
3. DSHEA requires that a manufacturer of a dietary supplement making a nutritional deficiency, structure/function, or general well-being claim have substantiation that the claim is truthful and not misleading. However dietary supplement manufacturers are prohibited from asserting that a dietary supplement treats or cures a disease.

- a. Describe the FDA's process for evaluating and ensuring the validity of structure/function, general well-being, and nutritional claims or statement made by a dietary supplement label or manufacturer.
 - b. Describe FDA's current authorities or procedures following adverse event reports related to dietary supplements sold online.
 - c. Provide a summary of each enforcement action taken against manufacturers during the past five years for failure to comply with current FDA law and regulatory authority related to structure/function, general well-being, nutritional, or health claims. Please use the template attached to this letter to provide your response.
4. Domestic and foreign facilities that manufacture or process food for human consumption in the United States are required to register with FDA. This includes dietary supplement manufacturers and processors.
- a. Provide a list of dietary supplement manufacturers and processors currently registered with FDA.
 - b. Summarize all actions taken by FDA in the last five years against entities for failure to register.
5. At the briefing that the FDA provided to the Committee staff, the staff asked the FDA about a product sold on Amazon.com called "Brain Armor," which purported to "Provide Protection Against Alzheimer's, Dementia, Stroke, Memory Loss, Cognitive Decline." Following the briefing, I understand that the FDA contacted Amazon and had the product removed.
- a. Please describe FDA's current authority to recall or remove a dietary supplement product from the market.
 - b. Please describe any additional regulatory or enforcement action that the FDA has taken or plans to take with regard to "Brain Armor."

We request that you provide these documents as soon as possible, but no later than July 13, 2015.

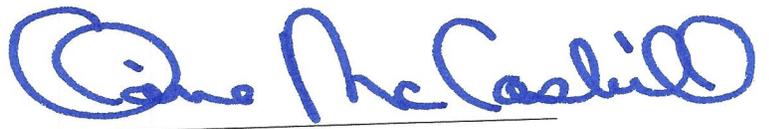
The jurisdiction of the Special Committee on Aging is set forth in Section 104 of S. Res. 4, agreed to February 4, 1977.

Ensuring the health and safety of our aging population is one of the most important aspects of our roles as Chairman and Ranking Member of the Special Committee on Aging. As such, we appreciate your assistance with this matter. Please contact Caitlin Warner of the Minority staff at (202) 224-0185 or Sharon Utz of the Majority staff at (202) 224-5364 with any questions. Please send any official correspondence related to this request to Caitlin_Warner@aging.senate.gov and Sharon_Utz@aging.senate.gov as well as to Matt_Lawrence@aging.senate.gov.

Sincerely,



Susan M. Collins
Chairman



Claire McCaskill
Ranking Member