

United States Senate

WASHINGTON, DC 20510

April 14, 2015

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

Dear Acting Commissioner Ostroff:

We call on the Food and Drug Administration (FDA) to launch an investigation into manufacturers of dietary supplements containing *Acacia rigidula* plant extracts and to take swift, appropriate, regulatory action against these mislabeled and deceptive dietary supplements. Last week, the journal *Drug Testing and Analysis* published an alarming study in which researchers found a deceptively labeled synthetic stimulant, known as β -methylphenylethylamine (BMPEA), in 11 of 21 over-the-counter dietary supplements included in the analysis. Yet, the FDA has not taken any action to protect consumers from these potentially dangerous products.

For too long, dietary supplement manufacturers have either failed to list BMPEA on product labels or have listed the stimulant as a "natural botanical," which the Food and Drug Administration's own scientists have disproved. In their own 2013 study published in *Journal of Pharmaceutical and Biomedical Analysis*, FDA scientists concluded that it is nearly impossible for the amounts of BMPEA present in dietary supplements to be derived from *A. rigidula* plant extracts. Thus, BMPEA cannot be considered synonymous with *A. rigidula*, and dietary supplement manufacturers that list *A. rigidula*, but not BMPEA, on their product label are in violation of the Dietary Supplement Health and Education Act of 1994. Accordingly, we urge the FDA to use its authority to remove these products from the market. While FDA has remained silent on this issue, the percentage of brands of *A. rigidula* supplements that contain BMPEA have increased from 42.9% in 2012 to 52.4% in 2014.

BMPEA has been described by researchers as an alternative to amphetamine, a potent central nervous system stimulant. Amphetamines themselves have been attributed to a wide range of side effects, including increased blood pressure, heart rate and body temperature; serious cardiovascular complications, including stroke at high doses; suppressed sleep and appetite; and the potential to be addictive. While the direct effects of BMPEA in the human body are not known, FDA should not wait for tragedy to strike before taking action to warn consumers and to remove this mislabeled product.

Other countries and entities have already taken note of *A. rigidula* and BMPEA's potential danger. The European Food Standards Agency and the Danish Veterinary and Food Administration have both cautioned against the consumption of *A. rigidula* products, while Canadian health authorities have called BMPEA "a serious health risk" and pulled supplements that contain it from store shelves. Furthermore, the chemical is classified as a doping agent by the World Anti-Doping Agency.

We are very troubled by FDA's inaction on this issue and appreciate your cooperation in answering the following questions regarding FDA's process for regulating dietary supplements and making sure consumers are safe:

1. When did it first come to the FDA's attention that products labeled as *A. rigidula* may contain BMPEA?
2. Does the FDA consider a New Dietary Ingredient (NDI) Notification necessary for *A. rigidula* or BMPEA? Please explain FDA's reasoning.
3. Has FDA ever received a NDI Notification for *A. rigidula* or BMPEA? If yes, please provide NDI Notification submission(s) and FDA's response(s).
4. What communications, if any, did FDA have with manufacturers of *A. rigidula* supplements before and after its 2013 study? Please describe.
5. What kind of follow-up did FDA conduct or plan to conduct, in the wake of its 2013 study on *A. rigidula*?
6. Please describe any adverse event cases the FDA has received regarding *A. rigidula* supplements or products containing BMPEA through MedWatch or other channels.
7. How many staff does the FDA have overseeing the regulation of dietary supplements?

FDA should move quickly to conduct a thorough inspection of all dietary supplements containing *A. rigidula* plant extracts and other BMPEA amphetamine-like substances. By calling your attention to studies like the one released last week, we hope your agency will take action to protect consumers from the deceptive practices of these dietary supplement manufacturers. We also hope this gives your agency an opportunity to reevaluate internal procedures to ensure there is robust oversight of dietary supplements.

Sincerely,



Richard J. Durbin
United States Senator



Richard Blumenthal
United States Senator