

United States Senate

WASHINGTON, DC 20510

February 18, 2015

The Honorable Margaret Hamburg
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 Hampshire Avenue
Silver Spring, MD 20093

Dear Commissioner Hamburg:

Earlier this month, New York Attorney General Eric Schneiderman requested four major retailers stop sales of herbal supplements after alleging that, using DNA barcode testing, 19 out of 24 products did not contain the ingredients listed on the label. However, even as this matter escalates, Attorney General Schneiderman has refused to make the test results and the details of the study methodology public, and questions about the appropriateness of DNA testing for herbal extracts have been raised that merit consideration.

The question at the heart of this matter is whether DNA barcoding methodology is fit for the purpose of identifying DNA in botanical extracts found in dietary supplements. It is our understanding that the process of extracting an herb's phytochemicals for use in finished products can either damage, destroy or simply leave behind the DNA this testing protocol is designed to find, which has left many scientists – both inside and outside the industry – to question whether DNA barcoding technology is an appropriate or validated method for determining the presence of herbal ingredients in finished botanical products.

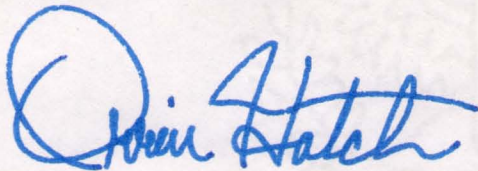
As the FDA has enforcement authority ensuring that dietary supplements accurately reflect their ingredients in product labeling, we request that the FDA respond to the following questions in light of the apparent discrepancies between the New York Attorney General's report and federal requirements:

1. Do federal regulations require that dietary supplement manufacturers conduct at least one appropriate test or examination on the incoming material used in a finished dietary supplement to confirm the identity of those ingredients? Do these regulations further require that finished dietary supplement manufacturers, such as the manufacturers of herbal extracts, perform testing on their finished products intended for sale to consumers to verify the identity, purity, strength and composition of these products and to assure that the contents are consistent with their labeling?
2. Does the FDA recognize DNA barcode testing as an appropriate test or examination for the positive identification of botanical materials in finished extract dietary supplements? Does the performance of DNA barcode testing by a manufacturer, without additional confirmatory methods, satisfy these requirements?


3. Does FDA use or recommend the use of DNA barcode testing for confirming the identity of phytochemicals found in herbal extract dietary supplements? Does FDA believe the current state of DNA barcode technology, and the existing validated libraries of DNA reference materials, provide sufficient certainty to permit the use of this methodology, in the absence of separate confirmatory testing, to determine the absence of particular phytochemicals in a finished herbal extract?
4. Do federal laws and regulations require food labeling (including dietary supplements) to identify all ingredients? Do these laws and regulations permit the inclusion, either intentionally or unintentionally, of trace amounts of agricultural materials without labeling of these substances? Do federal laws and regulations permit the use of plant materials as excipients in dietary supplements provided such ingredients are listed on the labeling?

Thank you for your attention to this important matter. Given the potential uncertainties for public health and safety created by the New York Attorney General's allegations, we would appreciate your responses as soon as possible, but certainly on or before Friday, February 27, 2015. Should you have any questions, please direct your staff to contact Matthew Richardson (matthew_richardson@hatch.senate.gov; 202-224-2185) with Senator Hatch or Louis Agnello (louis_agnello@heinrich.senate.gov; 202-224-0175) with Senator Heinrich.

Sincerely,



Orrin G. Hatch
U.S. Senator



Martin Heinrich
U.S. Senator