

One of the industry's objectives is to increase the funding for the Office of Dietary Supplement Programs (ODSP) within the Center for Food Safety and Nutrition (CFSAN) at the Food and Drug Administration (FDA) to provide adequate resources to fully implement and enforce the Dietary Supplement Health and Education Act (DSHEA); provide appropriate regulatory attention to a growing industry and increase FDA's enforcement activities and priorities.

CRN partnered with the public interest group, Pew Charitable Trusts, to meet with the Appropriations Committee in the House of Representatives and the Senate to build a case and advocate for increased funding for ODSP.

Based on information from FY 2016, CFSAN provided ODSP a budget of \$4.6 million, and a proposed budget of \$5.9 million in FY 2017. CRN's goal is to advocate for an additional \$5 million to be appropriated over the next three years. Despite concerns of extreme cuts in the President's budget proposal, Congress is focused on ensuring that key public health programs continue to function, especially at FDA. In addition, CRN and PEW is requesting Committee Report language be included with the Agriculture Appropriations bills in the Senate and House of Representatives. Language below.

Requested Committee Report Language:

More than half of Americans take at least one dietary supplement each day, with use particularly prevalent among older persons and in children. While dietary supplements enter the market under the assumption that they are safe, the Food and Drug Administration (FDA) has well documented that there are products that are contaminated, either intentionally or unintentionally, with inherently unsafe ingredients, including active pharmaceutical ingredients. These products violate the Dietary Supplement Health and Education Act and pose potential risks to consumers. The Committee applauds FDA's inspection of and enforcement actions against manufacturers with dietary supplement products that contain potentially harmful ingredients. FDA has indicated it conducts roughly 500 inspections a year and issues approximately 70-80 warning letters on cGMP violations. In order to better detect dangerous products in the market, FDA is encouraged to continue to invest resources into oversight and inspection of manufacturing plants that produce dietary supplements. The Committee has been pleased with the interagency collaboration and urges FDA to continue working with the Department of Justice to remove illegal dietary supplements from the market. Therefore, it directs increased resources toward enforcement of DSHEA, including inspection and enforcement activities. In addition, the Committee directs FDA to submit a report no later than 180 days after enactment of this Act, that includes the number of enforcement actions FDA brought against dietary supplement manufacturers and marketers, the number of dietary supplement good manufacturing practice inspections FDA conducted in 2018 and the number of FTEs dedicated to dietary supplement inspections, the number of serious adverse events that were reported to FDA from 2016 to 2018.