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BACKGROUNDER:

FDA's Office of Dietary Supplement Programs (ODSP) Funding, FTEs and Necessary Resources

More than 170 million U.S. consumers use dietary supplements each year as a cost-effective way to take an active role in managing their healthcare and well-being. After the passage of the Dietary Supplement Health and Education Act of 1994 (DSHEA), the dietary supplement industry was estimated at $4 billion in annual sales, but since that time, has grown to $43.2 billion in 2017 [*Nutrition Business Journal –June 2018*]. This robust growth of the industry reflects not only increased interest among consumers for these products, but also significant advancements in the science of health and nutrition. This growth also brings new regulatory responsibilities to appropriately monitor the overall marketplace.

The Office of Dietary Supplement Programs (ODSP), within the Center for Food Safety and Applied Nutrition (CFSAN) at the U.S. Food and Drug Administration (FDA), was elevated from a division in December 2015 to address the growth of the dietary supplement industry and underscore the important role that dietary supplement and functional foods play in public health and the economy. This elevation was widely supported by Congress and the dietary supplement industry. However, the elevation was in name only as there has not been an adequate funding increase devoted to ODSP to monitor, inspect and enforce the growing marketplace.

Frequently Asked Questions:

What is ODSP at FDA?
ODSP is the CFSAN lead for policy development and strategic management of FDA's dietary supplement program. And provides advice and counsel to Congress, states, foreign governments, and to external stakeholders, including the industry on dietary supplement programs and policies.

What does ODSP do?
ODSP plays a central role in FDA's regulation of dietary supplements. It implements and enforces DSHEA and other relevant statutes to ensure appropriate marketing of products, and oversees the implementation of manufacturing and labeling regulations specific to dietary supplements. In addition, it evaluates serious adverse event reports and other signals related to the safety of dietary ingredients and supplements.

How much funding does ODSP receive annually?
Today, ODSP receives $7.6 million a year to fund oversight and regulatory activities for a $40+ billion industry, only a $3M increase since the "Office" was elevated from a "Division" in FY 2016.

How much of a funding increase is industry requesting?
$5 million in addition to the $7.6 million that ODSP currently receives. This could be incrementally achieved by appropriating $1.5 million per year for the next 4 years.

What will ODSP do with more funding?
As the industry has grown, FDA's funding, and therefore its ability to robustly monitor the marketplace, has not kept pace. ODSP would use new funds to engage in greater enforcement of bad actors marketing adulterated substances as dietary supplements, and increase oversight of manufacturing through additional facility inspections. In addition, the Office would focus on policymaking and guidance providing clarity to stakeholders on issues raised in the draft NDI notification guidance, like creating an authoritative list of pre-DSHEA dietary ingredients and developing processes for "master files." Also ODSP would focus more on research, education and communications to enhance its systems to proactively monitor and identify safety signals to minimize and prevent serious adverse events.

How many employees does ODSP currently have?
There are currently 26 full time employee positions (FTEs) at ODSP.

How many offices are under CFSAN at FDA?
ODSP is one of many "offices" within CFSAN. In addition to ODSP, there are a total of 13 "offices" that focus on all of CFSAN's responsibilities related to food, nutrition, labeling, cosmetics and other administrative functions.