

United States Senate

WASHINGTON, DC 20510

August 24, 2023

Robert M. Califf, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

On June 27, 2023, the Food and Drug Administration (FDA) provided an update on its plans to reorganize the Human Foods Program (HFP) and the Office of Regulatory Affairs (ORA), in which we learned that the new Deputy Commissioner for Human Foods will have authorities over “all budget and resource allocations for the HFP, including ORA resources.” We welcome this announcement and appreciate FDA’s attentiveness to the reorganization. However, we have concerns about the proposed changes to the Office of Dietary Supplement Programs (ODSP).

In 1994, the *Dietary Supplement Health and Education Act* (DSHEA) established a framework to regulate dietary supplements in the United States. It included provisions to outline the ingredients that could—and could not—be included in a supplement. DSHEA also provided FDA with authorities to oversee the market to ensure that consumers would have access to safe supplements. However, oversight and enforcement at FDA has not kept pace, while the market has seen significant growth over the past 29 years.

In 1994, there were 4,000 supplements on the market in the United States. Now, there are more than 95,000 supplements on the market—and most adults—and a third of children—use one. At the same time, FDA has documented instances in which supplements have included potentially dangerous or otherwise illegal ingredients in violation of DSHEA, such as Selective Androgen Receptor Modulators, which are substances similar to testosterone or anabolic steroids.

ODSP is the lead office at FDA responsible for oversight of the \$50 billion supplement market in the United States. With a little more than \$13 million in funding, it sets strategic priorities, and ensures that limited resources are used in the best manner possible to protect the health and well-being of consumers. According to the June 27, 2023, announcement, ODSP will be merged into the “Office of Food Chemical Safety, Dietary Supplements, and Innovation.” We are concerned that these changes could divert resources, funding, and attention from the supplement market at a time when it is needed more than ever.

We request that answers to the following questions by **September 8, 2023**.

1. In December 2015, FDA recognized the growth of the supplement market in the United States and elevated the former Division of Dietary Supplement Programs to its

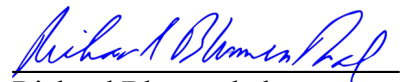
- own office. Since then, the market has continued to grow. How will the proposed changes lead to greater oversight and enforcement of the supplement market?
2. How many full-time equivalents (FTEs) in the Office of Food Chemical Safety, Dietary Supplements, and Innovation will support the regulation of the supplement market?
 - a. Who will set the goals, priorities, and budget for FDA's dietary supplement activities?
 - b. Will FTEs be dedicated to one market or split their time between the regulation of the supplement market and other markets (*i.e.*, food chemical safety, innovation)?
 - c. If FTEs will split their time, how will this result in greater oversight and enforcement of the supplement market?
 - d. Does FDA plan to hire additional FTEs to support the regulation of the supplement market?
 3. What are the metrics that FDA will use to evaluate the effectiveness of the Office of Food Chemical Safety, Dietary Supplements, and Innovation, with regard to regulation of the supplement market?
 4. In Fiscal Year 2023, ODSP received \$13.1 million in funding to oversee the \$50 billion supplement market. In the future, will FDA request that the House and Senate Appropriations Committees provide dedicated funding for the regulation of the supplement market or general funding for the Office of Food Chemical Safety, Dietary Supplements, and Innovation?

We appreciate FDA's consideration of this letter. You have stated that the regulation of the supplement market is one of FDA's priorities. We hope that commitment will ensure the health and well-being of Americans and their families who use a supplement.

Sincerely,



Richard J. Durbin
United States Senator



Richard Blumenthal
United States Senator