NATURAL PRODUCTS ASSOCIATION

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www.npanational.org

Cannabidiol:

There are thousands of Cannabidiol (CBD) products on the market today, including foods and dietary supplements containing CBD. While it's unlawful for foods and supplements to contain CBD, a recent survey showed that nearly half of American consumers incorrectly believe that CBD products are regulated by FDA for safety.

This raises a series of questions:

1. The FDA's current opinion is that CBD cannot be marketed lawfully or as a food or supplement. According to the FDA, CBD does not qualify for the statutory exception for substances marketed in (or as) foods or supplements before they were approved or studied as drugs. Yet FDA and FTC have only issued a handful of warning letters to companies that are marketing foods and supplements containing CBD. As commissioner, how will you improve enforcement of the law?

2. Numerous laboratory studies conducted by state government agencies and media outlets show that a substantial number of products marketed as containing CBD don't actually include any CBD. To make matters worse, some of these products include potentially dangerous substances, such as synthetic marijuana or fentanyl. As commissioner, what immediate steps will you take to protect consumers from adulterated CBD products?

During the Winter Policy Conference of the National Association of State Departments of Agriculture, Dr. Hahn stated:

"*We know one thing, the American people are using CBD products. People are using these products. We are not going to be able to say you can't use these products. It's a fool's game to try to even approach that.*" You went on to say *"We have to be open to the fact that there might be some value in these products and certainly Americans think that's the case. But we want to get them information to help them make the right decisions. What do we need to do?* We need to fill in the information gaps."

3. Despite the acknowledgment that the CBD market is incredibly large, in 2018, the Food and Drug Administration (FDA) tested only 4 facilities that manufacture CBD for the presence of THC and only 3 products claiming to contain hemp/CBD for the presence of THC. Has there ever been funding for laboratories, such as the National Center for Natural Products Research (NCNPR) to test products that claim to contain CBD for the presence of THC?

4. There are many respected manufacturers and retailers who are interested in the CBD market, but they are on the sidelines waiting for FDA to create a pathway for the lawful marketing of CBD-containing products. FDA previously allowed an exception for a supplement ingredient that was first studied and marketed as a drug prior to being incorporated into a dietary supplement (red yeast rice, which contains monacolin K, a substance that is chemically identical to the active ingredient in the cholesterol-lowering

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drug, lovastatin). As a result, FDA would not be establishing a new precedent in this area.

As with any supplement containing a "new dietary ingredient," this regulatory pathway would require a company to notify FDA that it intends to market a dietary supplement that contains CBD, and to demonstrate to FDA how the CBD incorporated into their supplement is reasonably expected to be safe under the conditions of use on the label, and commit to FDA's current good manufacturing practices that ensure the identity, purity, quality, strength and composition of dietary supplements.

5. Without such a pathway, American consumers will be left in the dark about the safety and lawfulness of CBD products for the foreseeable future. As commissioner, will you commit to expediting the consideration of this regulatory pathway (e.g., that already established for Monocolin K) for CBD-containing foods and dietary supplements and the development of a plan to actively enforce against products marketed by companies who are unwilling or unable to follow FDA laws and regulation?

New Dietary Ingredient Notifications

6. The Food Safety and Modernization Act (FSMA) included a provision that directed the Agency to create a guidance document pertaining to new dietary ingredients and set a deadline for publication of the guidance. FSMA stated that the guidance should clarify that "when a dietary supplement ingredient is a new dietary ingredient, the manufacturer or distributor of a dietary ingredient or dietary supplement should provide the Secretary with information as described in section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act, the evidence needed to document the safety of new dietary ingredients and appropriate methods for establishing the identity of a new dietary ingredient." When an American firm's NDI is acknowledged, their valuable intellectual property for their ingredient is supposed to be protected from copycat ingredients that are rendered adulterated. What are some of the ways the Food and Drug Administration uses their current enforcement structure to protect American firms' IP after they receive an NDIN for counterfeit ingredients that pose not only an intellectual property threats but also legitimate safety concerns to American consumers?

7. China is the single largest global supplier of cost-effective raw materials for the nutritional supplement industry's products. The industry's reliance on Chinese ingredient suppliers is further illustrated by the fact over 60% of the ingredients supplied for finished product manufacturing in the nutritional supplement industry originates from China. Furthermore, in the last several years, thousands of dietary supplements have flooded the American market while the number of NDIs submitted to the FDA to establish the safety of new dietary ingredients in supplements have dropped. As Commissioner, will the agency use their authority to issue Import Alerts and Import Bulletins for new dietary ingredients that have failed to comply with the NDIN regulations to ensure that finished products originating from countries, like China?

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8. During the May 16th Center for Food Safety and Applied Nutrition meeting on FDA's Modernization of Dietary Supplements, the Director of FDA's Office of Dietary Supplement Programs, stated "It is not all uncommon for stakeholders to say that FDA needs to do a better job of enforcing NDIN. There is a degree of sympathy to that view, but we don't know what we don't know." He went on to note that when DSHEA was passed in 1994 there were an estimated 4,000 products on the market. Today, there are between 50,000 and 80,000. It is safe to assume that about 90% of these products don't need an NDI, but that still leaves about 4,600 products on the market and the agency has only received 1,100 NDINs. These are the counterfeit ingredients that are rendered adulterated as they have failed to file an NDI consistent with 402 (f)(1)(B), meaning the agency has no idea of the specifications on the product when they arrive in the US, or a chance to review if the ingredient is actually going to meet the reasonable expectation of safety standard. What methods will the agency use to ensure that the thousands of remaining ingredients (based upon the previously mentioned calculations) have complied with NDI regulations? How will the Agency enforce on violations of NDI regulations?

FDA Accountability

1. Vitamin supplementation has been the topic of conversation during the global pandemic. It seems as if there has been a growing consensus, including a number of studies that highlight the importance of vitamin D status during the pandemic. Do the current statutory authorities on dietary supplements give you adequate ability to regulate the industry as well as promote the industry?

2. In a *Los Angeles Times* article from November 2020, a spokesperson from the FDA stated, "the FDA has no systematic way of knowing what dietary supplement products are on the market, when new products are introduced or what they contain." I would hope you find this comment especially troubling since Congress put in place a strong regulatory framework nearly 26 years ago. The framework established by the Dietary Supplement Health and Education Act (DSHEA) provides a clear pathway for new products and ingredients through the NDI process. Since 2013, the National Institutes of Health has maintained a database of supplement labels that is available to the public. This system works well and has delivered consumers the safest food and supplement supply in the world. As Commissioner, how will you ensure the Agency is using its enforcement and regulatory authorities to continue providing consumers with the safest supplements in the world?

3. DSHEA 2.0 has been the topic of conversation since DSHEA celebrated its 25th anniversary in 2019. Everyone agrees that the market has evolved significantly since 1994 when DSHEA was enacted; it has grown from a $4 billion market to

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over $40 billion; expanded from 4,000 products on the market to over 40,000 products. In the FY20 budget request, FDA provided language that spelled their request to "Strengthen FDA's Implementation and Enforcement of DSHEA." I would like to see DSHEA fully enforced before providing the additional agency authorities. In 2017, the Office of the Inspector General published a report about the agency's progress toward food facility inspection goals. The annual number of food facilities inspected dropped from 29% in 2004 to 19% in 2015. The report highlighted the fact that despite an increase in spending for domestic food facility inspections, the number of inspections proportionately, decreased. The OIG report indicates that the agency was unable to effectively utilize an increase in both resources and authorities in a manner that was directly applicable to enhanced enforcement of their regulatory authorities. Would you support the agency provide to Congress and the public an annual report of their activities related to?

A. Current Good Manufacturing Practice (cGMP) Inspections
B. Structure Function Claim (SFC) Notifications
C. New Dietary Ingredient (NDI) Notifications