NATURAL PRODUCTS ASSOCIATION

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"COVID-19 and Beyond: Oversight of the FDA's Foreign Drug Manufacturing Inspection Process"
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Introduction

The Natural Products Association (NPA) was founded in 1936 to ensure that Americans have access to safe and affordable natural products, and also to promote and protect the interests of retailers and suppliers of natural nutritional foods and natural products. We are the oldest and largest trade association in our industry. While the industry has existed for many years, it has only recently – since the late 1980s – transformed into a major engine of economic growth, customer satisfaction, and job creation throughout the United States.

When the Dietary Supplement Health and Education Act of 1994 (DSHEA) was passed there were an estimated 4,000 dietary supplement products on the market. Twenty-five years later, there are between 50,000 and 80,000 products on the market. This is in large part because more and more consumers are turning to these products to maintain their health and wellness. But the recent outbreak of COVID-19 also reaffirms the importance of consistency from the Food and Drug Administration when regulating imported finished products.

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) requires that manufacturers and distributors who wish to market dietary supplements that contain "new dietary ingredients" notify the FDA about these ingredients. The notification must include information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing a new dietary ingredient will reasonably be expected to be safe under the conditions of use recommended or suggested.

Issue

China is the single largest global supplier of cost-effective raw materials for the nutritional supplement industry, responsible for 60% of the ingredients supplied for finished product manufacturing in the nutritional supplement. Furthermore, in the last several years, thousands of dietary supplements have flooded the American market while the number of New Dietary Ingredients (NDI) submitted to the FDA to establish the safety of new dietary ingredients in supplements has dropped.

The FDA recently received a budget increase of $3 million to modernize its regulatory process for dietary supplements. Despite recent budget increases, FDA has failed to take significant action to protect consumers from adulterated products and from the proliferation of CBD products, which still remain illegal in the U.S. NPA has repeatedly requested action from the FDA on CBD, including establishing a safe level of daily consumption.

By neglecting its enforcement obligations on NDIs and CBD products, the FDA has allowed unsafe and untested dietary supplement products into the country, and potentially unsafe products on store

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shelves. Adulterated ingredients that have not completed the NDI notification process are entering our country at an alarming rate. This puts American consumers at risk and compliant U.S. supplement-makers at a terrible disadvantage.

According to industry estimates, about 90% of dietary supplement products on the market are not required to file an NDI because they have been generally recognized as safe. Meaning, they contain dietary ingredients which have been present in the food supply and are generally recognized as safe. However, that means approximately 4,600 products on the market have not received FDA scrutiny. Furthermore, the Agency has only received 1,100 NDINs, highlighting concerns that these products contain counterfeit ingredients.

When a dietary ingredient is introduced into the food supply for the first time, manufacturers are required to notify the FDA of their intent to market an NDI-containing supplement at least 75 days before the supplement is marketed in the United States. The NDI notification must thoroughly identify the ingredient, how it is used in the supplement, and present evidence the manufacturer relied upon to determine the ingredient is reasonably safe. This provides the FDA with significant oversight on the dietary supplement manufacturers' safety assessment of the NDI-containing dietary supplement.

The Food Safety and Modernization Act (FSMA) directed the Agency to issue guidance pertaining to new dietary ingredients. Specifically, Congress directed the Agency to clarify *"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, its valuable intellectual property is supposed to be protected. However, the Director of FDA's Office of Dietary Supplement Programs admitted that this is not always the case, stating that "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."

Unfortunately, the practice of adulterated products NDIs is all too common, and it harms legitimate manufacturers. Imported dietary supplements are considered adulterated when they purport to contain ingredients that have not gone through the NDIN process or are misrepresenting the ingredients that the dietary supplements actually contain. In 2008, Mitsubishi Gas & Chemical Inc. (MGC) received a successful 2008 NDIN submitted to CFSAN. In 2010, a piggybacked ingredient began to appear on the market before engaging in the FDA's NDIN compliance process for safety concerns. Testing of the product revealed differences between MGC's product and the non-compliant products, including product impurities. When the piggybacked product finally filed NDIs, the FDA questioned the safety of these products, including that the notifier failed to address organ damage after consumption in an experimental animal model. Yet, this product remains on the market. Members of the Natural Products Association, including, Natural Alternatives International, Lonza, and others all face similar scenarios.

Proposed Solution

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NPA proposes a two-pronged public-private partnership approach to ensure the safety of the global dietary supplement supply chain:

Import Alerts: The Agency has not published an import alert for dietary supplements in several years. The agency last used this authority in 2014 in response to safety concerns related to the importation of Kratom. Creating an import alert for new dietary ingredients that have failed to comply with the NDIN regulations would provide the Agency with the ability to police the market in a way that is resource-efficient and consistent with the goals of protecting the public's health, and provide the intellectual property protection the industry desperately needs. This process would restore integrity to the NDIN process, protect intellectual property, and provide the necessary safety net our consumers rely on. Since the FDA is prioritizing resources and only performing "for-cause inspections" during the COVID-19 crisis, issuing an import alert for products that are adulterated would require no additional resources and would be an effective measure that would provide important information to the Agency to facilitate their enforcement of current dietary supplement regulations. Placing responsibility back on the importer to ensure that products being imported to the United States are in compliance with the FDA's laws and regulations is more than an appropriate step providing a necessary safety net for American consumers.

Stronger Self-Regulatory Collaboration: The second recommendation is to expand the number of companies who agree to meet industry specific quality assurance standards in NPA's Supplement Safety and Compliance Initiative (SSCI) SCI is an industry-driven initiative led by the nation's leading retailers to provide a harmonized benchmark to recognize various safety standards throughout the entire dietary supplement supply chain. SSCI is a bold step forward in providing quality assurance from harvest to retailer shelf. Dietary supplements must meet or exceed the SSCI benchmark to be accepted in major retailers, all with the goal of providing quality products and increasing consumer confidence.