

# POLICY BRIEF



AMERICAN  
KRATOM  
ASSOCIATION

## THE AKA TRUTH IN LABELING PROGRAM. WHY IS IT NECESSARY?

The FDA has ramped up its War on Kratom using a new tactic that is evidenced in the announcement by the Ohio Department of Agriculture (ODA) Food Safety Division that they would embargo and ultimately destroy any kratom product if sold to consumers in capsule, pill, or beverage form. This shift in tactics by the FDA in aggressively reaching out to states is obvious in the documentation provided by the ODA in justifying its ban on kratom sold for human consumption that included two FDA documents:

1. An FDA report on kratom published on February 21, 2020 that highlighted the FDA position that there “are no FDA-approved uses for kratom.” The FDA statement went on to describe the prevailing Import Alert and the seizure actions taken on kratom products.
2. An FDA News Release dated on June 25, 2019 citing warnings issued by the FDA to two kratom vendors for “illegally selling unapproved, misbranded kratom-containing drug products with unproven claims about their ability to treat or cure opioid addiction and withdrawal symptoms. The companies also make claims about treating pain, as well as other medical conditions like depression, anxiety and cancer.”

The Federal Food, Drug & Cosmetic (FD&C) Act specifically bans any food, dietary ingredient, or dietary supplement vendor from making therapeutic claims about any product that has not been approved by the FDA as a drug pursuant to a properly filed new drug application. This new strategy by the FDA clearly targets the argument that kratom is being widely marketed as a drug and is therefore subject to seizure and destruction.

The AKA fully supports the freedom of individual consumers to use any food, dietary ingredient, or dietary supplement, including kratom products, to maintain their health and well-being and, where it works for them individually, to use kratom as an alternative to an FDA-approved drug. However, the FDA has the legal authority and therefore should stop vendors who have an inherent economic interest from making such illegal therapeutic claims in the marketing of their kratom products.

## WHY CAN INDIVIDUAL CONSUMERS AND THE AKA TALK ABOUT THE THERAPEUTIC BENEFITS OF KRATOM, BUT VENDORS CANNOT?

The answer to this question lies in decades of complex case law on the scope of the FDA’s statutory authority to regulate the use of words that explicitly limit speech that most of us believe is protected by the U.S. Constitution. Congress has given the FDA the authority to limit impermissible health claims on

unapproved drug products, and the Courts have drawn the lines between commercial and non-commercial speech. Those lines, however, are not always crystal clear.

In the critical *Bolger v. Youngs Drug Products* case (463 U.S. 60, 66-67 (1983)), the Court established a “totality of circumstances test” to determine whether the speech is an advertisement, whether it refers to a specific product, and whether the speaker has an economic motive. While none of these factors alone would allow the FDA to classify the speech as “commercial,” together they would.

The question on whether speech is commercial or noncommercial is key to the FDA exercising the authority Congress gave them in the FD&C Act. If the speech by a regulated firm is commercial, then the FDA can enforce regulations on whether the claim is false or misleading; it can require or compel certain speech (i.e., label requirements); and it can even limit truthful speech.

However, if the speech is noncommercial, the FDA cannot do any of those things and that distinction determines the extent to which the government can regulate, if at all. That is why individual kratom consumers and the AKA can openly discuss the science, policy, and consumer experiences on the potential therapeutic benefits of kratom.

## WHY DOES THE AKA BELIEVE IT IS IMPORTANT TO REPORT INTENTIONAL VIOLATORS TO THE FDA?

The FDA is clearly switching its tactics. When they focused on the adverse events and deaths the alleged to be associated with kratom, and the contaminants and adulterants that were present in many kratom products, the AKA created the GMP standards program that asked vendors to voluntarily adhere to the GMP standards for food and dietary ingredient products. This has been welcomed as a powerfully positive step by many elected officials, public health officials, and policy makers at all levels of government. It clearly demonstrates the kratom industry is both willing and capable of self-regulation and condemns the kratom manufacturers to fail to use GMPs or who deliberately adulterate their products for profit.

The FDA is now focusing on the health claims made by vendors that are clearly intended to spike sales and create economic benefits for those vendors. The FDA is attempting to make the argument that the number of vendors making such claims are so pervasive in the industry that there is no reasonable way for the Agency to identify and stop each bad actor. That is why it is critically important for the AKA to demonstrate the commitment of the kratom consumer community to protecting kratom purchasers from false and misleading therapeutic health claims, and to clearly demonstrate the vast majority of kratom vendors already adhere to the law on health claims. When we eliminate the bad actors, the FDA’s argument is diminished or goes away entirely.

Most important, we undermine the FDA’s claim they don’t have the resources to regulate the kratom industry to identify and weed out the bad actors. This is exactly the model that is used by the dietary supplement industry today and the FDA works cooperatively with thousands of vendors in that marketplace to identify the bad actors through self-regulation.

## WHAT ABOUT THE ARGUMENT MADE BY CRITICS THAT AKA IS DOING THE BIDDING OF LARGE KRATOM COMPANIES TO ELIMINATE SMALLER KRATOM VENDORS?

That claim is false. The AKA is a consumer advocacy organization, and we do not represent vendors.

It is true that a kratom vendor must comply with FDA regulations governing the manufacturing and marketing of food products. Look at a bottle of water you buy at a convenience store and you can see the label that is required by FDA regulations even for water. Small kratom vendors can and will continue to thrive in the kratom marketplace if they make the required investments in equipment needed to safely manufacture kratom products; to train their employees on how to properly run the equipment to maintain a sustainable quality manufacturing facility; and to correctly label and market their kratom products.

The days of kratom vendors packaging kratom powder in kitchens, bathrooms, or bedrooms are over. The days of unscrupulous kratom marketers making illegal health claims is also over.

## HOW WILL THE AKA TRUTH IN LABELING PROGRAM ACTUALLY WORK?

If a consumer chooses to make a report on suspected suspicious marketing of a kratom product, they can simply go to the AKA website and fill out the form.

The AKA will then review the complaint and any supporting material (social media posts, websites, blogs, advertisements, etc.) to determine if there is a basis for reaching out to the vendor to advise them to correct or stop the impermissible advertising.

If the vendor voluntarily corrects the problem, the case is closed and no further action will be taken by the AKA.

If the vendor is unreachable, or fails to respond to the notice from the AKA, the information will be sent to the FDA for their investigation.

This program is an essential part of our effort to show the kratom community is committed to protecting consumers and assuring kratom vendors comply with manufacturing and marketing kratom as a food product.