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The Relevance of FDA Import Alert 54-15 on Kratom's Regulatory Status in the United States

There has been a recent uptick in anti-kratom advocates asserting that, per FDA Import Alert 54-15, FDA has banned the importation of the natural botanical into the United States. The point of the assertion, which is sometimes inferred and other times directly stated, is that because kratom is grown in southeast Asia the FDA's alleged importation ban necessarily means that kratom cannot be lawfully sold in the United States. As explained below, FDA has not banned the importation of kratom into the United States, and the natural botanical, grown and harvested in southeast Asia, can be lawfully sold in the United States.

By way of background, I am the FDA-regulatory attorney for Botanicals for Better Health and Wellness (BBHW). BBHW advocates for evidence-based regulation of plant-derived products. Before entering private practice, I served as Chief Counsel of the United States Food and Drug Administration. Among other duties, I advised the FDA's senior leadership on issues related to both botanicals and import alerts.

For a recent example of an anti-kratom advocate discussing alleged importation bans of kratom, I would point the reader to Dr. Andrew Kolodny. While Dr. Kolodny has spent much of his professional career as a psychiatrist advocating for responsible opioid prescribing, he is not an expert on the FDA in general or on the Agency's use of import alerts in particular.¹ Nevertheless, in testimony before the Suffolk County Legislature on June 23, 2026, Dr. Kolodny asserted that kratom "[i]s not legally imported into the United States. There is an FDA import alert, which means all of the kratom that's coming into the United States is coming in illegally."² When questioned on the issue, he asserted that kratom "comes in[to the United States] because it's either labeled as something not intended for human consumption, or it comes in simply by luck."³ He further stated that it was his understanding that when kratom "comes to the border, if the FDA catches it, it is immediately seized."⁴

As an initial matter, an FDA import alert does not operate as a ban. As the name suggests, the document is an "alert". Specifically, it is FDA's way of alerting the United States Customs and Border Protection (Customs) of specific companies that may be out of compliance with the Food, Drug and Cosmetic Act (FD&C Act). Having been alerted, Customs can then detain the imports of said companies when they enter the country to confirm whether they are compliant. That Dr. Kolodny asserted that "FDA" was immediately "seizing" kratom that it saw at the border pursuant to an import

¹ See [Andrew Kolodny, MD - Kaiser Permanente Institute for Health Policy](#).

² Dr. Kolodny's testimony on June 23, 2026, begins at 2:22:54. See [Video Broadcast and Gallery | Suffolk County Legislature, NY](#).

³ *Id.*

⁴ *Id.*



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alert nicely illustrates that Dr. Kolodny doesn't understand what an import alert is or who is responsible for examining imports at the border.

While Dr. Kolodny did not specifically reference Import Alert 54-15⁵, it is the only import alert that specifically references kratom. IA 54-15 was issued by FDA on February 28, 2014, the relevance of which will be discussed below. Like other import alerts, IA 54-15 flagged specific firms in the kratom trade that may be out of compliance with the FD&C Act. Customs, in turn, can use the import alert as the basis to detain those firms' products at the border to confirm whether they are in fact compliant.

Importantly, notwithstanding IA 54-15, I am aware of only one case over the course of the last 12 plus years in which Customs detained kratom products at the border and found them to be noncompliant with the FD&C Act. In that case from 2020, Customs testing found that more than a half ton of kratom detained at a port of entry in Detroit was laced with salmonella.⁶ Of note, the kratom at issue was denied entry to the United States because it was contaminated with a dangerous pathogen and not because it could not be lawfully imported (as Dr. Kolodny asserted).

In addition, since 2012 I am aware of only one occasion in which IA 54-15 was cited in an enforcement action by the federal government. Specifically, it was cited in a DOJ press release discussing an action against a kratom importer that was falsifying import-related documents as part of a money laundering scheme.⁷ In short, to date IA 54-15 has only been cited in one enforcement action, and that was when the importation was directly tied to an independent (and serious) violation of federal law.

Based on his testimony, Dr. Kolodny would have people believe (without citing supportive evidence) that the lack of enforcement is due to two reasons: (1) kratom imports are falsely labeled for non-human uses and (2) luck. As explained in the next paragraph, FDA is fully aware that kratom products are currently being distributed and sold throughout the United States for use in humans (and that the kratom in such products was grown in southeast Asia and imported into the United States). And, while not a statistician, it strikes me as highly improbable that over the course of 12 years kratom importers are lucky 99.9% of the time. The alternative explanation, i.e., that Customs tests kratom products and only rarely finds them to be noncompliant, is supported by the above-referenced case in Detroit.

FDA's awareness that kratom is being sold in the United States for human use is nicely illustrated by the fact that FDA has issued Warning Letters to, and requested recalls by, several kratom manufacturers. Those actions, however, were for reasons unrelated to the fact that the products contained kratom. For example, FDA has issued Warning Letters to manufacturers that make drug claims for their supplements that contain kratom.⁸ Likewise, FDA has requested recalls from kratom

⁵ [Import Alert 54-15](#).

⁶ See [CBP Seizes Half Ton of Salmonella-Laced Kratom | U.S. Customs and Border Protection](#).

⁷ See [Southern District of California | Kratom Company and Owner Plead Guilty | United States Department of Justice](#).

⁸ See, e.g., FDA Warning Letters to Cali Botanicals and Kratom NC.



manufacturers whose supplements contained undeclared food allergens⁹ or pathogens¹⁰. These are the types of actions that FDA routinely takes against regulated actors marketing misbranded or adulterated products. Indeed, FDA's limited and narrowly tailored actions were particularly peculiar if Dr. Kolodny is to be believed, i.e., if products containing kratom are per se illegal because they were unlawfully imported into the United States.

Finally, in 2014, when IA 54-15 was issued, FDA held a very different view about the safety of kratom. Those outdated views have given way over time as additional studies on kratom have been conducted. For example, in 2014 FDA was concerned that kratom may cause respiratory depression. A subsequent NIH-funded study, however, found that mitragynine, the primary alkaloid in kratom, actually increased respiratory frequency.¹¹ Similarly, FDA's own Single Ascending Dose Study, which was designed to assess the safety and potential toxicity of kratom, showed that the botanical was well tolerated in human participants even at high doses.

Not surprisingly, given the current body of scientific evidence showing that kratom poses relatively low abuse liability¹², Import Alert 54-15 has never resulted in an enforcement action (apart from the one case cited above where the importation of kratom was part of a larger and more serious money laundering scheme). Tellingly, when statements similar to those provided by FDA in 2014 (in support of IA 54-15) have been challenged, the FDA has disowned the statements. For example, in 2023, the U.S. District Court for the Southern District of California specifically asked that FDA provide the United States Department of Justice (DOJ) with documentation supporting its prior public statements that kratom is a "dangerous substance". According to a statement from DOJ provided to the court, the FDA refused the court's request:

We have been in contact with representatives of the FDA regarding the upcoming sentencing hearing regarding the dangers of kratom. They have refused to provide us with witnesses or documents to support our position, as well as witnesses and documents that might be inconsistent with our position. The reason they gave was that they have not yet made a determination regarding whether kratom is dangerous.¹³

It is not surprising that FDA does not treat IA 54-15 as a ban on kratom in light of its statement, provided under oath in federal court, that it does not have evidence that kratom is dangerous.

Similarly, in 2024, a kratom manufacturer (Marian Sales, d.b.a. OPMS) filed a complaint against FDA challenging a number of "demonstrably false statements" previously made by the Agency about the safety of one of the company's kratom products in a "Safety Alert" issued to the public on July 26,

⁹ See, e.g., Recall of Kula Can – Pina Colada + Kratom Seltzer.

¹⁰ See, e.g., Recall of Powdered Kratom Products by Triangle Pharnaturals.

¹¹ See Zuarth Gonzalez et al., Mitragynine and 7-Hydroxymitragynine: Bidirectional Effects on Breathing in Rats. Posted May 25, 2025.

¹² See Garcia-Romeu, et al. 2020, Todd et al. 2020, Henningfield, Wang et al. 2021, Mongar et al 2024.

¹³ See Ex. 30, Declaration of Andrew P. Young in Support of [Defendant] Guthery's Motion for Issuance of a Pretrial Subpoena Duces Tecum, *United States v. Nine2Five, LLC*, No. 3:23-cr-00179-TWR (S.D. Ca.) (filed Dec. 6, 2023) Dkts. 110-2, 110-6 (emphasis added).



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2024. In its motion to dismiss the complaint, FDA did not defend the accuracy of the Safety Alert, but instead argued that it could not be sued for issuing the Alert because the challenged statements:

- “[H]ad no legal effect and did not purport to impose any obligations on Plaintiff or anyone else.”¹⁴
- “[D]id not consummate any internal decision-making process or determine any right or obligations.”¹⁵
- Were published as part of a “non-binding” Safety Alert and therefore did not constitute “agency action.”¹⁶

For the same reason, FDA does not consider any of the statements made in the preamble to IA 54-15 to represent the FDA’s official views regarding the safety of kratom.

Based on the above, FDA has not banned the importation of kratom into the United States and products containing kratom are not per se illegal by virtue of the fact that the kratom was grown and harvested in southeast Asia.

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¹⁴ See Defendant’s Memorandum in Support of their Motion to Dismiss, *Martian Sales, Inc. v. Food and Drug Administration, et al.*, case 1:24-cv-03031-RBW (DC) (filed on 12/23/24) Dkt 12-1.

¹⁵ *Id.*

¹⁶ *Id.*