July 31, 2026

Office of the Assistant Secretary for Health
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

RE: OASH Request for Information Temporary Placement of 7-Hydroxymitragynine Above a Specified Threshold in Schedule I [Docket No. HHS-OASH-2026-0232]

The **Consumer Choice Center** is an independent, non-partisan consumer advocacy organization that represents the interests of consumers who value lifestyle freedom, access to innovative products, and evidence-based regulation. We submit these comments in response to the request for information published at **91 Fed. Reg. 41049** (July 6, 2026).

We confine these comments to the two questions the Office of the Assistant Secretary for Health (OASH) has actually asked: whether data exist supporting the proposed threshold or an alternative threshold, and whether data exist supporting alternative measurement expressions.

OASH has stated that this docket is not open to the permanent scheduling question or to the general merits of kratom-derived products or their more appropriate regulation, which we would otherwise gladly provide.

Our position is straightforward. The proposed threshold — 0.050 percent 7-hydroxymitragynine (7-OH) on a dry-weight basis, or 1.00 milligram of 7-OH in an article — is not calibrated to hazard. It is calibrated to the market. It does not draw a line between dangerous products and safe ones. It draws a line between products that exist and products that do not, and it does so using a measurement expression that cannot be applied consistently across the product forms it purports to cover.

I. The statute confines the threshold to what three empirical factors can support

As OASH notes, when the Attorney General acts under 21 U.S.C. 811(h)(1), he is required to consider, with respect to the finding of an imminent hazard to public safety, only the factors set forth in 21 U.S.C. 811(c)(4), (5), and (6): the substance's history and current pattern of abuse; the scope, duration, and significance of abuse; and what, if any, risk there is to the public health, including actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution.

That limitation matters enormously for a threshold determination, and we do not think it has been given its due weight. Every one of those three factors is empirical and backward-looking. They ask what has actually happened with this substance, not what a pharmacological profile suggests might happen. Congress deliberately excluded the more speculative factors — relative potential for abuse under 811(c)(1), dependence liability under 811(c)(7) — from the emergency-scheduling inquiry.

A threshold derived under 811(h) must therefore be a threshold the actual-use record can support. The question is not whether some quantity of 7-OH could theoretically be hazardous. It is whether the pattern and scope of actual abuse identify a concentration or quantity above which harm has in fact occurred. If no such quantity can be identified on the existing record, that is not a gap for the agency to fill with a conservative estimate.

II. On the factors available, the record does not identify a hazardous concentration

Americans have consumed on the order of two billion servings of 7-OH since 2023. Over that period, FDA's Adverse Event Reporting System logged roughly 100 reports — approximately one per 20 million servings. America's Poison Centers has reported no confirmed overdose deaths from 7-OH consumed in isolation. Dr. Edward Boyer, a medical toxicologist who reviewed nationwide poison-center data, testified before the Ohio House Agriculture Committee in March 2026 that "a signal arising from overdose death from 7-hydroxymitragynine is absent."

Critically for a threshold determination, none of the reports in that record are associated with a stated 7-OH concentration or per-serving quantity. There is

no dose-response curve in the federal adverse-event data because there is no reported cluster to build one from. We are not aware of any published analysis — and OASH has cited none — identifying a per-serving 7-OH quantity above which reported harm increases. Without that, 0.050 percent and 1.00 milligram are not findings. They are selections.

The internal consistency problem is yet more serious. FDA's database contains more than 700 reports tied to leaf mitragynine — roughly seven times the volume associated with 7-OH — and the proposed threshold leaves those products untouched by design. A threshold genuinely calibrated to the scope and significance of actual abuse would not exempt the product category carrying the larger share of reported adverse events. Whatever else the proposed threshold tracks, it does not track the factors 811(h)(3) permits the Attorney General to consider.

The record on diversion and clandestine distribution points the same direction, and in fact points against the threshold. 7-OH products are sold openly at retail. They are not diverted from legitimate medical channels, because there are none. They are not clandestinely imported. The compounds that are clandestinely imported — the synthetic analogs MGM-15 and MGM-16, manufactured primarily in China — entered the U.S. market through states that had already restricted 7-OH, using the same gray-market import networks that carried fentanyl into American communities. A threshold set low enough to eliminate the domestic retail market would create the clandestine-importation problem that 811(c)(6) exists to measure. That is a consequence OASH should weigh before recommending a figure, because the factor cuts in the opposite direction from the one assumed.

III. The pharmacology bears directly on where any threshold can sit

Threshold-setting is a dose question, so the pharmacokinetic and pharmacodynamic literature is directly responsive to OASH's first question, and it does not support the proposed figures.

A 2025 study in the European Journal of Drug Metabolism and Pharmacokinetics (Chiang et al.) found that only 2.7 to 3 percent of an oral 7-OH dose survives first-pass metabolism. A threshold expressed as

milligrams present in an article therefore overstates systemic exposure by a factor of roughly thirty to forty. If OASH intends the 1.00-milligram figure to correspond to a physiologically meaningful dose, it is off by more than an order of magnitude. Any threshold that is meant to describe hazard must be expressed in terms of bioavailable dose, or it is describing something other than exposure.

Two further findings bear on whether milligram-quantity cutoffs transfer to this compound at all. A 2021 study in the Journal of Pharmacology and Experimental Therapeutics (Obeng et al.) found 7-OH's binding activity at the mu-opioid receptor closely mirrors buprenorphine, the medication physicians use to treat opioid dependence.

Department of Defense–funded research at Memorial Sloan Kettering, conducted under a grant for non-addicting analgesics, found that 7-OH does not produce respiratory depression. Respiratory depression is the dose-dependent mechanism that makes milligram thresholds meaningful for conventional opioids. If it is absent here, the analytical basis for importing an opioid-style quantity cutoff is absent with it, and OASH should say so rather than adopt the form of an opioid threshold without its rationale.

IV. On measurement: the proposed expression cannot be applied consistently

OASH's second question asks whether data support alternative measurement expressions. Our answer is that the proposed expression should not be adopted in its current form regardless of what figure is chosen, for four reasons.

First, the term "article" is undefined. A 1.00-milligram-per-article limit produces entirely different results depending on whether an article is a serving, a tablet, a sealed unit, a retail container, or a shipping case. A multi-serving container at a low per-serving concentration exceeds the limit; a single high-concentration serving may not. A threshold whose application turns on packaging rather than concentration is not measuring what OASH says it wants to measure.

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Second, the notice expresses the percentage prong as weight/weight, weight/volume, or volume/volume in the alternative. These are not interchangeable. For a solid alkaloid in a liquid preparation, a volume/volume expression has no coherent meaning, and weight/volume and weight/weight results diverge with formulation density. Permitting three expressions invites three different compliance determinations for the same product.

Third, there is no consensus validated analytical method for quantifying 7-OH consistently across raw botanical material, semi-synthetic derivatives, and finished consumer dosage forms. Laboratories, manufacturers, and regulators have not had the opportunity to test the proposed threshold against real products using a common method. A threshold announced before its measurement method is validated will be enforced inconsistently, and disputes over compliance will be disputes about instrumentation rather than about safety.

Fourth, OASH should address analyte stability before fixing any figure. 7-OH arises as an oxidation product of mitragynine. If measured 7-OH content in a finished product varies over its shelf life, a product compliant at manufacture may test out of compliance at retail through no act of the manufacturer. We are not aware that this question has been resolved, and it should be answered before a criminal threshold depends on the answer.

V. What a hazard-calibrated threshold would require

We do not ask OASH to leave this question unanswered. We ask that the answer be derived rather than assumed. A defensible threshold would have the following characteristics.

It would be expressed per labeled serving, not per article, so that the figure describes what a consumer actually takes. It would be adjusted for first-pass metabolism, so that it describes bioavailable dose rather than article content. It would rest on an identified per-serving quantity above which reports of actual abuse and harm demonstrably increase — the showing 811(c)(4) and (5) require. And it would apply consistently across kratom product categories, because a threshold that exempts the products generating the larger share of adverse-event reports cannot be described as calibrated to public health risk.

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Where the evidence of clandestine manufacture and importation is actually strongest is with the truly novel synthetic analogs — mitragynine pseudoindoxyl, MGM-15, and MGM-16 — which the Drug Enforcement Administration has addressed in a separate notice published the same day. To the extent the 7-OH threshold is aimed at those compounds, it is redundant of an action already underway. To the extent it reaches beyond them, it reaches the roughly one million Americans who use these products for chronic pain, anxiety, or to stay off prescription opioids and street fentanyl, and it does so without the evidentiary showing the statute requires.

If OASH cannot identify a per-serving quantity supported by the factors available under 811(h)(3), we respectfully submit that the correct advice to the Secretary and the Attorney General is that the record does not presently support a threshold.

VI. Conclusion

The Consumer Choice Center does not contend that 7-OH is harmless, that no product on the market warrants control, or that concentrated preparations should be sold to children. We contend that a threshold is a factual finding, that the statute limits the facts that may support it, and that the facts currently before OASH do not identify 0.050 percent or 1.00 milligram as the point at which an imminent hazard to public safety begins.

We renew the request in our July 10, 2026 letter that OASH extend this comment period, and that it coordinate with the Drug Enforcement Administration to pause the temporary scheduling order.

We appreciate OASH's attention to this request and look forward to participating constructively in this process.

Respectfully,

Yaël Ossowski
Deputy Director
Consumer Choice Center

consumerchoicecenter.org
yael@consumerchoicecenter.org

Sources cited

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