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Comments On Petition As Good As Public Hearing On NAC's Use As Dietary Ingredient – US FDA

Agency Tells Sen. Lee 'Other Mechanisms At Stakeholders' Disposal To Interact With FDA'

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Executive Summary

Agency "does not believe a hearing is necessary at this time given the other mechanisms at stakeholders' disposal to interact with FDA on this issue, including submission of comments" for citizen petition CRN submitted on NAC, Andrew Tantillo, acting associate commissioner for legislative affairs, tells Sen. Mike Lee.

Source: Alamy

A citizen petition asking the US Food and Drug Administration to clarify that amino acid N-acetyl-L-cysteine can be used in in dietary supplements should be ample opportunity for public comment to guide the agency, the FDA tells a senator.

Supplement industry trade groups that have submitted citizen petitions encouraging the FDA to clarify that acid N-acetyl-L-cysteine (NAC) is lawful as a dietary ingredient differed on whether the agency's calculation equating submitting comments on a petition with conducting a part 15 public hearing to consider questions FDA officials would draft in a separate docket.

In its response to a request by Sen. Mike Lee, R-UT, for a public hearing, the FDA disagreed that one is needed.

"FDA denies the hearing request because the Agency does not believe that such a hearing is necessary at this time given the other mechanisms at stakeholders' disposal to interact with FDA on this issue, including submission of comments to the docket for the citizen petition, FDA-2021-P-0523," wrote Andrew Tantillo, the FDA's acting associate commissioner for legislative affairs, in a letter submitted to Lee on 19 August.

The agency has begun warning firms that the ingredient, although used in supplements available in the US for decades, is not a lawful dietary ingredient because it is used as a drug ingredient.

"We agree no hearing is needed on NAC as it's clear from a legal perspective what the outcome should be, however the preclusion issue is likely to arise again with other ingredients." – CRN VP Megan Olsen

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The docket FDA-2021-P-0523 is for a petition the Council for Responsible Nutrition submitted in June after first asking the FDA six months earlier to reverse the position it revealed in July 2020 warnings, "a sudden and drastic

departure from past Agency practice," that products containing NAC cannot be marketed as dietary supplements. The petition came after Amazon Inc. stopped allowing sales of products with the ingredient in May. (Also see "US FDA Put On The Clock About NAC's Use As Dietary Ingredient After Amazon Ends Sales" - HBW Insight, 2 Jun, 2021.)

No Explanation Or Answers

Lee didn't note in his letter, and Tantillo didn't address in his reply that the agency previously conducted public hearings on regulatory questions that also have been topics of petitions.

"FDA has had citizens petitions open on a number of the part 15 hearings they've had," said Daniel Fabricant, president and CEO of Natural Products Association, which also submitted a petition asking the FDA to reverse the position on NAC it stated in the 2020 warnings.

"More importantly, how do you not answer Sen. Lee's questions? How is that skirted by a citizen's petition?" he told HBW Insight.

The CRN, on the other hand, sees the FDA's mention of the open docket for comments as acknowledgement of the trade group's argument stated in its petition. However, a public hearing is needed on the FDA's use of regulations under the Dietary Supplement Health and Education Act that preclude ingredients from use in dietary supplements.

"We hope FDA's response signals that the agency understands the strength of the legal arguments put forth in CRN's Citizen Petition and is poised to act promptly to restore full consumer access to NAC as a dietary ingredient," said Megan Olsen, CRN associate general counsel/vice president, in a statement to HBW Insight.

"In that case, we agree no hearing is needed on NAC as it's clear from a legal perspective what the outcome should be, however the preclusion issue is likely to arise again with other ingredients. CRN believes FDA should hold a public hearing on how FDA should interpret the drug preclusion provision overall."

DSHEA Anticipated Drug, Dietary Coexistence

Like the CRN and the NPA, the senator, in addition to posing questions about the FDA's position on NAC as a dietary ingredient, explained to the agency that that DSHEA deemed as lawful for use in dietary supplements, ingredients that had been available in supplements and had been approved for use in drugs prior to the act's passing in October 1994. (Also see "NAC's Future In US As Dietary Ingredient Should Have Public Hearing, Senator Urges FDA" - HBW Insight, 23 Aug, 2021.)

"DSHEA was not intended to allow the FDA to remove products marketed as supplements from the marketplace in order to create an arguable advantage for any company marketing a drug with a previously used dietary supplement, such as NAC, as the active ingredient," Lee stated in his letter.

In its petition, the CRN noted the language Congress included in DSHEA to allow continued use of dietary ingredients already available also was intended to benefit drug development. But the FDA will impede drug development with actions such as deeming NAC unlawful as a dietary ingredient.

"A retroactive application of this section does nothing to incentivize new drug development because drugs and supplements that were both on the market prior to DSHEA's passage already co-existed and drug companies developed these products with no expectation of DSHEA's protections," wrote Olsen and CRN president and CEO

Steve Mister.

"Congress's objective to preserve incentives for drug research would not be advanced by FDA's award of a monopoly to the drug industry for an ingredient that has co-existed in both drug and supplement forms for decades."

The attention Lee suggests the FDA show for NAC as a dietary ingredient previously has been devoted to the use of hemp-derived cannabinoids in non-drug products subject to its oversight (Also see "FDA Decision On CBD Use Could Run Up Against Chicken Or Egg Question " - HBW Insight, 5 Jun, 2019.); and to compliance with new dietary ingredient notification requirements, the agency's tool for imposing a limited level of pre-market approval for ingredients not used in supplements before DSHEA was passed. (Also see "'Innovation' Meeting Shows FDA-Industry Gap On NDI Guidance Details Remains " - HBW Insight, 20 May, 2019.)

The FDA also has conducted public hearings on overhauling its supplement industry regulatory framework and its Rx-to-OTC switch process; a part 15 hearing was a key early step in overhauling the OTC monograph drug program, a process that led to Congress passing legislation authorizing changes.