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FDA Releases Draft Guidance on NAC Enforcement

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- On April 21, 2022 FDA announced the issuance of draft guidance on FDA's policy regarding dietary supplements containing N-acetyl cysteine (NAC). The guidance details the agency's intent to exercise enforcement discretion on the sale and distribution of such products.

- In 2020 FDA sent warning letters to several companies regarding the use of NAC in dietary supplements. In the letters, FDA warned against the use of drug claims, but also noted that NAC could not be marketed as a dietary supplement because there was no evidence that NAC had been marketed as a food or dietary supplement prior to its approval as a drug in 1963. More recently, we reported that FDA had confirmed in response to citizen petitions that NAC is excluded from the definition of a dietary supplement. FDA had not yet reached a decision, however, regarding a petitioner's request to issue a regulation that would permit the use of NAC in dietary supplements.

- FDA is still considering whether to issue such a rule. In the meantime, it has published this draft guidance with the acknowledgment that NAC has been sold as a dietary supplement for over 30 years and that consumers seek access to such products. FDA notes that while its full safety review is ongoing, there are no safety concerns at this point with respect to the use of NAC as an ingredient or dietary supplement. Thus, the draft guidance explains that unless safety-related concerns are identified, the agency intends to exercise enforcement discretion until either 1) the agency completes notice-and-comment rulemaking to allow NAC in or as a dietary supplement, or 2) FDA decides to deny the request for rulemaking.

- FDA is accepting comments on the draft guidance. Comments may be submitted by mail or electronically at Regulations.gov using Docket No. FDA-2022-D-0490.

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