FDA Finalizes NAC Enforcement Discretion Guidance

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- FDA issued final guidance regarding its decision to exercise enforcement discretion with respect to the sale and distribution of dietary supplements containing N-acetyl-L-cysteine (NAC). The final guidance is substantively identical to the draft guidance issued in April 2022.

- As we have previously reported, FDA concluded that NAC was excluded from the definition of a dietary supplement because it was approved as a drug before being marketed as a dietary supplement and because no regulation authorizing its use in dietary supplements has been promulgated.

- Nevertheless, the Agency determined that enforcement discretion is appropriate because (1) it has not identified any safety issues thus far in its (ongoing) review of the safety of NAC in dietary supplements, (2) NAC has been used in dietary supplements for over 30 years, and (3) a strong demand for such use continues. FDA intends to continue exercising enforcement discretion until it either completes notice-and-comment rulemaking authorizing the use of NAC.
in dietary supplements, determines that rulemaking is not appropriate, or identifies safety issues in its ongoing review. We will continue to monitor and report on any developments related to the regulatory status of NAC in dietary supplements.

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