**Contact Your Member of Congress About NAC**

*Last Updated: October 6, 2021*

**Instructions for companies, healthcare practitioners, and consumers:**

* Use the relevant sections of CRN’s sample letter to contact your member of Congress or create your own letter.
	+ If creating your own letter, be sure to include your “ask” -- Urging the federal Food and Drug Administration (FDA) to provide a substantive response to legal positions raised in a [Council for Responsible Nutrition (CRN) Citizen Petition](https://www.crnusa.org/sites/default/files/Daily/2021-06/CRN%20NAC%20Citizen%20Petition%20--%206.1.21%20Final.pdf) calling for resolution to an issue affecting consumer access to a legal and safe dietary supplement ingredient, N-acetyl-l-cysteine (NAC).
	+ Click here for an editable Word file
* Sections marked as “FOR EVERYONE” can be used regardless of whether you are a company, healthcare practitioner, or consumer.
* If using CRN’s sample letter, fill-in text prompts and email or mail this correspondence to your Congressional Representative and/or Senator.
	+ [Find your U.S. House of Representative Member](https://www.house.gov/representatives/find-your-representative)
	+ [Find your U.S. Senators](https://www.senate.gov/senators/senators-contact.htm)
* Send a copy of your email/letter to CRN WDumais@crnusa.org.

**FOR EVERYONE:**

[Company Banner if applicable]

(Date)

(The Honorable Jane Doe)

(U.S. House of Representatives/Senate)

(WASHINGTON, DC OFFICE)

(CITY, STATE, ZIP)

Dear Congress(wo)man Doe:

On behalf of (COMPANY/FIRM NAME/NAME), I/we ask you and your Congressional colleagues to urge the federal Food and Drug Administration (FDA) to provide a substantive response to legal positions raised in a Council for Responsible Nutrition (CRN) Citizen Petition[[1]](#footnote-1) calling for resolution to an issue affecting consumer access to a legal and safe dietary supplement ingredient, N-acetyl-l-cysteine (NAC).[[2]](#footnote-2) Senator Mike Lee (R-UT) wrote to the agency in July expressing concerns about FDA’s action, and received a response in mid-August that the agency was reviewing CRN’s Citizen Petition and a hearing on the matter was not necessary. FDA has still not issued a response nearly a year after CRN first raised issues regarding the agency’s position.

**V1 - FOR COMPANIES:**

(Company Name) is the (manufacturer)/(supplier) of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (brands or products), with \_\_\_\_\_\_\_\_\_\_\_\_\_ employees located in \_\_\_\_\_\_\_\_\_\_\_\_\_\_ (enter town or city). **If a CRN member company add the following:** Our company is a proud member of the Council for Responsible Nutrition (CRN)[[3]](#footnote-3), a membership-based trade association representing the mainstream and responsible dietary supplement and functional food industry. CRN’s membership includes suppliers of dietary supplement ingredients, as well as manufacturers and marketers of branded and private label products available to consumers through a variety of distribution channel: mass market, health food stores, mail order, and direct sales.

**V2 - FOR DOCTORS/PRACTITIONERS:**

In addition to being your constituent in (ENTER STATE NAME)’s (XXX) Congressional District, I am a medical professional/naturopathic physician with over (XXX) years of experience and expertise within my field. (Enter any other information about accolades, certifications, etc. that speak to your credentials). As a part of my field and/or practice, I have recommended my patients take NAC dietary supplements for a variety of different purposes. Because of FDA’s actions, my patients have found it difficult to access these safe and beneficial products.

**V3 - FOR CONSUMERS:**

In addition to being one of the nearly 170 million Americans who purchase dietary supplement and functional food products annually, I am also your constituent. I have lived in (ENTER STATE NAME)’s (XXX) Congressional District for (XXX) years, and have purchased NAC dietary supplement products to improve my health and wellbeing. I actively use these products and was very frustrated to learn that retailers like Amazon and others, have removed these products and brands from their shelves and online stores.

\*\*\* **FOR EVERYONE**

NAC has safely been on the market for over 25 years. However, in July 2020, FDA took unprecedented action to prohibit sales of NAC as a dietary supplement by enacting a sudden policy change in the manner in which the agency treats this ingredient. This was done by issuing multiple warning letters, asserting that products containing NAC cannot be marketed as dietary supplements under section 201(ff)(3)(B)(i) of the Food, Drug, and Cosmetic Act. Section 201(ff)(3)(B)(i) prohibits manufacturers from marketing products as dietary supplements if they contain an article that FDA has approved as a drug, unless that article was marketed in dietary supplements or food before it’s drug approval(often called the “drug preclusion clause”). FDA’s warning letters assert that NAC was approved as a new drug in 1963 and, to FDA’s knowledge, was not marketed as a dietary supplement prior to that date. As such, FDA claims that products containing NAC cannot be marketed as dietary supplements. FDA has failed to provide any rationale for this policy change other than the basic assertions made in these warning letters.

FDA’s actions are concerning and are contrary to existing legal, regulatory, and scientific precedent. For decades, manufacturers have safely marketed products containing NAC as dietary supplements in the United States. There are currently hundreds of dietary supplements containing NAC on the market, and thousands of consumers have come to rely on these products as a crucial source of nutrients. The safety of NAC has been widely recognized, including by authoritative government bodies, such as the National Institutes of Health. NAC is also naturally found in foods, like onions and garlic, and it is the precursor to the amino acid l-cysteine, which FDA considers to be generally recognized as safe (GRAS). The safety of NAC dietary supplements is not in dispute.

FDA cites a section of the landmark law, the Dietary Supplement Health and Education Act (DSHEA), which prohibits an ingredient from being used in a supplement if that ingredient was first approved as a drug. This provision has no application here for several reasons. For example, the form of NAC first approved, as a drug is different from the form of NAC found in supplements. Further, FDA is applying DSHEA in a retroactive manner that Congress never intended and courts likely would not support. NAC as a supplement coexisted with NAC as a drug well before DSHEA was enacted. Drugs and supplements commonly coexist in the market today – drugs and supplements coexisting is not a safety issue. For example, omega-3 is commonly found in dietary supplements, but is also used in the prescription drug Vascepa. For over 25 years, since the passage of DSHEA, FDA has not objected to the continued use of NAC in dietary supplements – the agency has had amble opportunity to object. The only objection in 25 years that FDA can point to is an objection sent to one company for a form of NAC that appears to be different from the form that is the subject of FDA’s current enforcement actions. Subsequent to that objection, FDA affirmatively stated in another communication to another company that NAC was a legal dietary ingredient.[[4]](#footnote-4)

In sum, FDA should revert to its longstanding policy of allowing manufacturers to market dietary supplements containing NAC and rescind the legally invalid position included in warning letters that NAC is precluded by section 201(ff)(3)(B)(i) of the FDCA from being a legal dietary ingredient in dietary supplements. Since it appears FDA is unlikely and unwilling to provide a timely and effective resolution to this challenge on their own, we urge you to push FDA towards action on this important precedent-shattering issue facing the entire dietary supplement industry.

Thank you in advance for your consideration of this request. I look forward to hearing your response on action you will take to urge the FDA to answer CRN’s Citizen Petition, and reverse its effective “ban’ on safe and reliable dietary supplements.

Sincerely,

(Enter Name/Company Executive Name Here)

cc: Council for Responsible Nutrition

1. Citizen Petition submitted by the Council for Responsible Nutrition to the U.S. Food and Drug Administration, June 1, 2021, available at: <https://www.crnusa.org/sites/default/files/Daily/2021-06/CRN%20NAC%20Citizen%20Petition%20--%206.1.21%20Final.pdf> [↑](#footnote-ref-1)
2. For more information on N-acetyl-l-cysteine (NAC), go to: <https://www.crnusa.org/congress-tell-fda-stop-limiting-consumer-access-safe-beneficial-dietary-supplements> [↑](#footnote-ref-2)
3. The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement and functional food manufacturers, marketers and ingredient suppliers. CRN companies produce a large portion of the functional food ingredients and dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug stores and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. CRN represents more than 180 companies that manufacture dietary ingredients, dietary supplements and/or functional foods, or supply services to those suppliers and manufacturers. Our member companies are expected to comply with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control and safety. Our supplier and manufacturer member companies also agree to adhere to additional voluntary guidelines as well as to CRN’s Code of Ethics. Learn more about us at [www.crnusa.org](http://www.crnusa.org). [↑](#footnote-ref-3)
4. Letter to Sevo Nutraceuticals, Inc. from FDA responding to April 27, 2016 petition (available at <https://www.fda.gov/media/119441/download>). [↑](#footnote-ref-4)