MERCOLA
Take Control of Your Health

NAC Banned From Amazon, FDA Says It's Medication

Analysis by Dr. Joseph Mercola ✔ Fact Checked

STORY AT-A-GLANCE

- After sending warning letters to several manufacturers, the FDA invoked the Drug Exclusion Provision in U.S. code Title 21 to ban the sale of n-acetylcysteine (NAC)
- According to one attorney, this is legally questionable and, according to counsel for the Council for Responsible Nutrition (CRN), for several reasons it is "legally invalid"
- The FDA used this same tactic on supplements infringing on the financial gain of pharmaceutical companies and may have done the same with NAC since the supplement may effectively reduce the incidence of severe COVID-19
- NAC has multiple health benefits as it reduces oxidative stress in the body, which plays a significant role in the development of Alzheimer's and Parkinson's disease, cancer, stroke, diabetes and liver disease

N-acetylcysteine (NAC) has made the news, not because scientists discovered a new health benefit, but because the U.S. Food and Drug Administration decided after 57 years of over-the-counter sales the compound is now a medication that requires a physician's prescription.

Like ibuprofen (Advil)[1] and acetaminophen (Tylenol),[2] NAC has been available both over the counter and in prescription form.[3] Doctors prescribe ibuprofen, acetaminophen and NAC in the hospital for specific uses. Historically, people could purchase all three over the counter.

Recently, the FDA decided that, unlike ibuprofen and acetaminophen, NAC should be removed from public sale. NAC is an antioxidant compound made up of three amino acids — glutamic acid, glycine and cysteine.[4]

However, N-acetylcysteine is available only in supplement form and cannot be found as such in foods. But the precursors to NAC can be found in foods high in cysteine, including pork, beef, chicken, eggs, swiss cheese and sunflower seeds.[5] NAC is valued as a precursor to glutathione, also called the "master antioxidant."[6]

NAC is useful in the treatment of acetaminophen poisoning, helping to lower the risk of mortality and liver damage. Despite a long history of concurrent use as an over-the-counter supplement and prescription medication in the hospital, the FDA has not been interested in removing the status as a dietary supplement — not, that is, until recently when NAC showed promise in the fight against COVID-19.[7]

FDA Invokes a Legally Questionable Drug Exclusion Provision

The law defines dietary supplements specifically. In the U.S. code Title 21,[8] the law uses specific definitions of what a dietary supplement is and is not. According to experts, the actions of the FDA in banning the sale of NAC and finding it a "medication" is illegal under the law.

Attorney Dan Soper[9] writes that under Title 21 §321 paragraph (ff)(3)(b)[10] the actions of the FDA do not meet the Drug Exclusion Provision. In the code, it defines what a dietary supplement is not. Specifically, it says that a dietary supplement (article) does not include:

- An article approved as a new drug, certified as an antibiotic, or licensed as a biologic under specific sections of the title.
- An article authorized for investigation as a new drug, antibiotic or biologic for which there have been substantial clinical trials and for which the existence of all of these investigations has been made public.

In addition, the article was not before approved, certified, licensed or authorized, marketed as a dietary supplement or as a food "unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this chapter."

According to Soper,[11] the exclusion provision has only been invoked a few times, specifically when used to keep red yeast rice, vitamin B6 and cannabidiol (CBD) from being sold as supplements. In each of these cases there was a potential pharmaceutical financial loss that triggered the assertion the supplement was illegal.

In the case of red yeast rice, it contains a naturally occurring substance that acts in a similar manner to Lovastatin, a statin medication.[12] In 2005, drug manufacturer Biostratum filed an investigational new drug (IND) application with the FDA to use vitamin B6 in the treatment of diabetic kidney disease.

Their argument was there was "no evidence that it was marketed as a dietary supplement or food prior to its IND and Phase II investigations."[13] In 2009 the FDA declared vitamin B6 was not a dietary supplement despite documentation that it had been sold as such before the IND application.

The FDA has also invoked the Drug Exclusion Provision against CBD, warning that it is not a legal dietary supplement since there was no meaningful evidence it was marketed as such before drug investigations were approved for Sativex and Epidiolex, which are drugs that contain CBD.

After the **2018 Farm Bill** was signed legalizing hemp, then-FDA secretary Scott Gottlieb made the statement that it was illegal to introduce CBD into the food supply or market it as a supplement.[14] Soper postulates[15] that the use of the Drug Exclusion Provision against CBD may have opened the door for the FDA to use it against NAC.

Others Hold the FDA Is Using a 'Legally Invalid' Position

In 1994, Congress enacted the Dietary Supplement Health and Education Act

(DSHEA).[16] This gave the FDA regulatory authority and enforcement tools to protect consumers. The Council for Responsible Nutrition (CRN) supports enforcement of the law,[17] but the recent FDA move against NAC appears to step well beyond the letter and intent of the Act.

December 4, 2020, the CRN wrote an open letter[18] to Steve Tave, director of the FDA's office of dietary supplement programs, and sent a copy to Douglas Stearn, deputy director for regulatory affairs. In the eight-page letter, the CRN outlined why they believe the position the FDA has taken is "legally invalid."[19]

In December 2020, a journalist from Natural Products Insider[20] outlined the arguments CRN used in their letter to Tave, stating why the FDA's actions were not legally defensible. The points the CRN made included:

- Through a Freedom of Information Act request, CRN learned the FDA's claim that NAC had been approved as a drug in 1963 was nothing more than a handwritten notation. The CRN notes this raises questions about the reliability of the record, true approval date and who made the notation.

- The 1963 handwritten notation was for an inhalation drug. However, the code clearly states the chemical cannot be called a dietary supplement if the "article" is the same as the drug. In this case, the FDA is asserting an inhaled drug is the same as an oral supplement. Steve Mister, president and CEO, and Megan Olsen, CRN associate general counsel, wrote:[21]

> *"Further, a dietary supplement, by definition, must be "a product that ... is intended for ingestion." Because of this limitation, a dietary supplement would, by its very nature, differ significantly in the route of administration and dosage form from an inhaled drug.*
>
> *Such significant differences, which will affect a substance's impact on the human body, must preclude an inhaled ingredient from being considered the same "article" as an orally ingested ingredient."*

- The CRN found records to suggest that **NAC** was not approved for drug use until 2016, "well after dietary supplement companies had been marketing NAC as a supplement."[22]

- The FDA's interpretation of the law also conflicts with "the presumption against statutory retroactivity," which Mister and Olsen go on to say, "Even if FDA records reliably demonstrated drug approval before 201(ff)(3)(B)(i) was enacted, it is a well-established canon of statutory interpretation that legislation shall not be read to have a retroactive effect on private rights unless Congress expresses a clear, unambiguous intent to the contrary."[23]

  The CRN also argues that the FDA failed to explain the policy change before sending warning letters to several NAC manufacturers in July 2020. Mister and Olsen wrote:[24]

  > *"In response to the extensive history of NAC being treated by FDA as a dietary supplement, manufacturers have invested substantial resources to develop hundreds of such products, and thousands of consumers have come to rely on such products to meet their daily nutritional needs.*
  >
  > *Now, FDA has decided to not only change its decades-long policy, but to do so through the issuance of warning letters that fail to provide any reasonable explanation for this consequential policy shift."*

- Lastly, the CRN maintains the FDA cannot enforce the policy because they exhibited a lack of diligence, writing:[25]

  > *"First, FDA's decades-long delay in bringing enforcement action against manufacturers of dietary supplements containing NAC indisputably resulted from a lack of diligence by FDA, rather than an unawareness that these products were on the market.*
  >
  > *In fact, there is ample evidence that FDA has long been aware that these products are on the market, and that FDA has actively considered — and*

> *failed to object to — structure/function and qualified health claim petitions regarding products containing NAC. Thus, FDA's long-delayed enforcement against these products resulted from the Agency's own lack of diligence.*"

In an email to Natural Products Insider, Mister said:[26]

> *"CRN is firmly committed to protecting our members' interest in this matter to sell a lawful ingredient. FDA's warning letters on NAC issued earlier this year are not final agency actions, but rather should be viewed as the opening salvo, inviting those with sound legal arguments to respond and present an opposing point of view, which we are doing.*
>
> *CRN is optimistic that FDA will closely consider the legal argumentation we have laid out and evaluate its initial position regarding NAC in light of these arguments."*

Why Is the FDA Taking Aim at NAC?

Using the Drug Exclusion Provision on **CBD** may have opened the door for the FDA to make similar claims against NAC, but there is still the question of timing. Why has the FDA chosen to target NAC now? In the past the provision was used inappropriately in three instances to protect the finances of pharmaceutical companies, and it is likely the motivation to ban NAC as a supplement has the same roots.

As pulmonologist Dr. Roger Seheult succinctly explains in this MedCram video, NAC is a crucial chemical compound necessary to reduce the oxidative stress associated with **severe COVID-19 infections** and thus may significantly impact the sales of antiviral drugs. And, without severe disease, is there truly a need for a vaccine?

Nine months after the FDA issued warning letters with their position that NAC supplements could not legally be sold, Amazon began removing products containing the supplement.[27] In 2020, Amazon adopted polices to improve the quality of the

supplements sold on their platform after knock-off dietary supplements were found[28] and NOW Health Group identified inferior quality supplements from third-party lab tests.[29]

Amazon did not respond to Natural Products Insider[30] to explain why the products were being removed from the platform. One long-time public relations professional in the industry postulated it may have been a result of significant turnover in Amazon's regulatory staff that prompted the move if the new staff believed selling NAC made the company vulnerable.

More Health Benefits of N-acetylcysteine

NAC supplements are well absorbed and can effectively increase levels of glutathione in the body.[31] **Glutathione deficiency** is a key contributor to oxidative stress.[32] In turn, oxidative stress contributes to the pathogenesis of several diseases such as liver disease, **Alzheimer's disease**, **Parkinson's disease**, cancer, **heart attack** and **diabetes**.

NAC contributes cysteine, which one study[33] found is inversely associated with the risk of stroke in women. Two papers[34,35] concluded that NAC shows promise in the treatment of psychiatric conditions, including addiction, compulsive disorders, schizophrenia and bipolar disorder. The treatment may benefit those whose condition has not responded to drugs and medication.

One team of scientists[36] presented a review on different applications NAC may have in a variety of health conditions. This includes reducing **insulin resistance** and providing a therapeutic approach in the treatment of polycystic ovary syndrome.

Based on evidence, they hypothesized that NAC may reduce the number of premature births and recurrent pregnancy losses by exerting an anti-inflammatory effect in women who have bacterial vaginosis, a risk factor of preterm delivery and low birth weight.

They found there were positive influences that NAC exerted in patients who have ulcerative colitis, including decreasing **oxidative stress**, lowering cell apoptosis and improving recovery in the colon. Lab studies and animal models have demonstrated NAC can protect normal cells from radiation therapy and chemotherapy but does not protect cancer cells.

NAC has preventive effects against airway hyperresponsiveness in animal studies using acute exacerbation of asthma. In their review, they found NAC was "safe and well tolerated" without considerable side effects.[37]