Tell FDA to Stop Limiting Consumer Access to Safe, Beneficial Dietary Supplements

Congress should require 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 calling for resolution to an issue affecting consumer access to a legal dietary supplement ingredient, N-acetyl-l-cysteine (NAC).

BACKGROUND:

In July 2020, FDA took unprecedented action to prohibit sales of NAC as a dietary supplement, which has safely been on the market for over 25 years, is found in hundreds of products, and that thousands of consumers rely on.

What is NAC?

- NAC is an abbreviation for the nutritional ingredient n-acetyl-l-cysteine, and is a form of the amino acid L-cysteine.
- NAC increases levels of glutathione, a major antioxidant, and helps thin and loosen mucus in the respiratory tract.
- The safety of NAC supplements have been widely recognized, including by authoritative government bodies, such as the National Institutes of Health (NIH).
- NAC also is 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).

Why is FDA prohibiting the sale of NAC as a dietary supplement?

- FDA cites a section of the Dietary Supplement Health and Education Act (DSHEA) that 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.
    - The form of NAC first approved as a drug is different from the form of NAC found in supplements.
    - 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.

Are there other concerns with FDA's position?

- NAC also is naturally found in foods, like onions and garlic, and it is the precursor to the amino acid l-cysteine
- For over 25 years, since the passage of DSHEA, FDA has not objected to the continued use of NAC in dietary supplements. FDA 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.[1]

What can Congress do?

CRN contacted FDA over six months ago to reverse its legally indefensible position and, after no meaningful response, filed a Citizen Petition on June 1, 2021. Part of the problem is that NAC, as an ingredient, is caught in the regulatory quagmire waiting for FDA to issue final agency action.[2] CRN is calling on Congress to require that FDA provide a substantive response to the legal positions CRN raised in its Citizen Petition to give industry a resolution that will either allow NAC to continue to be sold as supplements or ask a court to review this matter.

Council for Responsible Nutrition **www.crnusa.org/NAC**

[1] Letter to Sevo Nutraceuticals, Inc. from FDA responding to April 27, 2016 petition (available at www.fda.gov/media/119441/download).

[2] The FDA enforcement tool used against NAC – Warning Letters – are not considered to be final agency action reviewable by courts, giving companies that sell NAC no avenue to have their concerns heard outside of the Agency.