N-Acetyl-L-Cysteine (NAC)

Legal and Regulatory Update

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Is NAC a Legal Ingredient?

FDA Position:
July 2020 Warning Letters

FDA Sends Warning Letters to Seven Companies Illegally Selling Hangover Products

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Constituent Update

July 29, 2020

Based on the product label on your website, it appears that you intend to market your Happy Hour Vitamins (H2V) product, which contains N-acetyl-L-cysteine (NAC), as a dietary supplement. However, even if your product labeling did not have therapeutic claims that make your product an unapproved new drug, your product could not be a dietary supplement, because it does not meet the definition of dietary supplement under section 201(ff) of the Act [21 U.S.C. § 321(ff)]

Drug Preclusion Provision – 21 USC 321(ff)(3)(B)

(ff) The term "dietary supplement"—
* * * * *

(3) does —

(B) not include—

(i) an article that is approved as a new drug under section 355 of this title, certified as an antibiotic under section 357 of this title, or licensed as a biologic under section 262 of title 42, or

(ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval, certification, licensing, or authorization 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.

The Drug Preclusion Clause

FDA's position: NAC is precluded from being a dietary supplement under 21 U.S.C. § 321(ff)(3)(b) because the article was first approved as a new drug in September 1963.

- Is it really the same "article" that is prohibited from sale?
- Does delivery form count? Inhaled v. ingested?
- Was DSHEA intended to be retroactive—or to wipe the slate clean?
- Pre-1994, what expectation of exclusivity could a drug mfr. have had?
- What about FDA's silence for 27 years? Can it change the rules now?
- When should FDA use its discretion to override the general rule?

Ancillary issue: Retailer Reliance on Warning Letters

- Warning letters are not final agency action. *i.e., You can't sue the agency for a warning letter you don't agree with.*

- The agency takes postures in warning letters that may not be grounded in the law:
  - Remember FDA announcing the Kind Bar wasn't "healthy"?

- Company responses are not made public; close-out letters are hard to come by; and some issues languish for years without resolution.

- Meanwhile, retailers and other stakeholders rely on these warning letters as official positions of the agency.

Repercussions from the NAC Warning Letters

- Amazon has decided to prohibit the sale of NAC products based on the warning letters.
- Some smaller retailers have removed NAC products from their stores.
- These actions have created panic buying and out of stocks at other retailers.
- At least one major contract manufacturer is declining to manufacture supplements containing NAC
- Healthcare practitioners are contacting companies to inquire if NAC supplements are still legal and what liability they have if they sell them.

CRN Action on NAC

- December 2020 Letter to FDA
  - FDA has acknowledged review of this letter
- CRN Citizen Petition submitted June 1, 2021
  - FDA 180 response deadline ~ early December 2021
- Called on legislators to tell FDA to stop limiting consumer access to NAC
- Documents and background available: https://www.crnusa.org/NAC

Call to Action

- Contact your Congressional representatives
- Submit comments to FDA docket for CRN's Citizen Petition
  - Docket FDA-2021-P-0523
- Encourage your patients to contact their Congressional representatives and submit comments to FDA
- Sample letters and additional information on CRN website
  - https://www.crnusa.org/NAC

Questions?

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