August 19, 2021

The Honorable Michael S. Lee
United States Senate
Washington, D.C. 20510

Dear Senator Lee:

Thank you for your letter of July 27, 2021, to the Food and Drug Administration (FDA or the Agency) regarding N-acetyl-L-cysteine (NAC). Your letter requests, among other things, that "in accordance with Code of Federal Regulations (CFR) Title 21 Part 15 Subpart B, . . . a public hearing be scheduled to clarify the Food and Drug Administration's position on the use of N-acetyl-L-cysteine (NAC) in dietary supplements."

On June 1, 2021, the Council for Responsible Nutrition submitted a citizen petition[1] to FDA regarding the regulatory status of NAC, which the Agency is currently reviewing. Pursuant to 21 CFR 10.30(d), an interested person may submit comments on a filed petition. The Agency will consider all comments submitted to the open docket in making a determination on the citizen petition. FDA denies the hearing request because the Agency does not believe that such a hearing is necessary at this time given the other mechanisms at stakeholders' disposal to interact with FDA on this issue, including submission of comments to the docket for the citizen petition, FDA-2021-P-0523.

Thank you again for contacting us regarding this matter. Given your interest, I commit that we will provide your staff more information after we have addressed the petition regarding NAC.

Sincerely,

Digitally signed by
Andrew M. Tantillo -S
Date: 2021.08.19
14:28:43 -04'00'

Andrew Tantillo
Acting Associate Commissioner for
Legislative Affairs

[1]Council for Responsible Nutrition Citizen Petition; *https://www.regulations.gov/docket/FDA-2021-P-0523*.

U.S. Food & Drug Administration
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