



Kai Deusch, MD, PhD
Dsquare LLC
P.O. Box 9618
Caguas, PR 00725-9618

December 10, 2024

Re: Docket No. FDA-2024-P-2955

Dear Dr. Deusch:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on June 19, 2024. Your petition requests that the Agency amend the labeling of sodium containing N-acetylcysteine products to “include a statement regarding the high sodium content” and “a Black Box Warning for the ‘sodium sensitive population’ and for subjects with pre-existing cardiovascular or CNS disease.”

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Carol Bennett -S

Digitally signed by Carol
Bennett -S
Date: 2024.12.10 10:47:19
-05'00'

Carol J. Bennett
Acting Director
Office of Regulatory Policy
Center for Drug Evaluation and Research