



Azza AbuDagga
Public Citizen's Health Research Group
1600 20th St., N.W.
Washington, DC 20009

May 11, 2026

Re: Docket No. FDA-2025-P-6094

Dear Dr. AbuDagga:

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 November 14, 2025. Your petition requests that the Agency:

1. Update the current general warning regarding the risk of PNAS in all product labels of approved SRIs [serotonin reuptake inhibitors].
2. Add a new general warning indicating that concomitant use of SRIs and benzodiazepines or other CNS depressants during pregnancy increases the risk of PNAS.
3. Add a general warning in SRI labels to consider the use of these drugs during pregnancy only if their potential benefits outweigh their potential risks taking into account the risks associated with untreated mental illness, and highlight the uncertain potential risk of fetal neurobehavioral effects associated with SRI use during pregnancy.
4. Require NDA holders of SRIs to conduct a comprehensive post-marketing safety surveillance study to compare short- and long-term outcomes of prenatal SRI use on the exposed offspring.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. 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 we have reached a decision on your request.

Sincerely,

**CAROL
BENNETT -S**

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CAROL BENNETT -S
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Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research