



Beth Rosenshein
Diamond Research Foundation
300 Center Drive, #248
Superior, Colorado 80027

Re: Docket No. FDA-2026-P-1450

Dear Ms. Rosenshein:

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 February 9, 2026. Your petition requests that “. . . section 5.2, Venous Thromboembolism (VTE), of the Full Prescribing Information for Duavee tablets be updated to include pertinent and vital information about the risk of blood clots when taking SERM Bazedoxifene and Premarin together.”

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

Digitally signed by
CAROL BENNETT -S
Date: 2026.08.04
13:28:47 -04'00'

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