



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

Re: Docket No. FDA-2025-P-6074

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 November 12, 2025. Your petition requests that the Agency revise the “INDICATIONS and USAGE section of the Full Prescribing Label for Premarin tablets for dosages 0.30 mg and 0.45 mg.”

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: 2026.05.08  
12:51:52 -04'00'

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