



Beth Battaglino
HealthyWomen
1715 State Route, 35 Suite 204
Middletown, NJ 07748

Sent via email to: beth@healthywomen.org

October 16, 2024

Re: Docket No. FDA-2024-P-1988

Dear Ms. Battaglino:

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 April 22, 2024, and submitted on behalf of HealthyWomen. Your petition requests that the Agency revise the labeling of all fenofibrate drugs to clarify that fenofibrates, when used alone or in combination with statins, do not reduce cardiovascular risk, and communicate related information from a recently published pemafibrate clinical study.

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: 2024.10.15
14:19:10 -04'00'

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