



Julie McCoy, PharmD
Providence St. Peter Hospital/Centralia Hospital
413 Lily Road NE, MS: LLH10
Olympia, WA 98506

December 19, 2022

Re: Docket No. FDA-2022-P-1409

Dear Ms. McCoy:

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 28, 2022. Your petition requests that the Agency amend the boxed warning on droperidol products to remove certain information that you assert is better suited for the Warnings and Precautions or Contraindications sections of labeling.

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
Date: 2022.12.19 12:14:36 -05'00'

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