U.S. FOOD & DRUG ADMINISTRATION

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Re: Docket No. FDA-2016-P-1874

Dear Petitioners:

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 29, 2016. Your petition requests that the Agency immediately require a boxed warning and risk evaluation and mitigation strategy (REMS) for dopamine agonist drug products due to an alleged risk of developing certain impulse-control problems and compulsive behaviors.

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

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