

James Love, Director Knowledge Ecology International 1621 Connecticut Avenue, Suite 500 Washington, DC 20009

January 29, 2021

Sent via email to: James.love@Keionline.org, Harrison.cope@keionline.org, claire.cassedy@keionline.org, Jeff@democraticmedia.org

Re: Docket No. FDA-2020-P-1725

Dear Petitioners:

I am writing to inform you that the Food and Drug Administration (FDA or Agency) has not yet resolved the issues raised in your citizen petition, received on August 3, 2020. Your petition requests that FDA amend § 202.1 of the Code of Federal Regulations Title 21 on Prescription-Drug Advertisements to include a provision that bans background music from the presentation of the risks section of direct to consumer prescription drug advertising. (21 CFR § 202.1).

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 - Digitally signed by Carol Bennett -S DN: c=US. Government, ou=HHS, ou=FDA, ou=People, cn=Carol Bennett -S, 092342.1920300.100.1.1=20000.0495.8 Date: 2021.0128 165.48:32 -0500'

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