James Love, Director, et al.
Knowledge Ecology International
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Washington, DC 20009

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

Dear Petitioners:

This letter responds to your citizen petition received on August 3, 2020 (Petition). Your Petition requests that the Food and Drug Administration (FDA or the Agency) amend FDA regulations in § 202.1 (21 CFR 202.1) to include a provision that bans background music during the presentation of risk information in direct-to-consumer (DTC) prescription drug advertising.[1]

We have carefully considered the Petition, the comments submitted to the docket, and the studies and examples of advertisements (ads) referenced. The Agency shares the Petition's aim that important information, including the side effects and risks associated with prescription drugs, be effectively communicated in DTC ads. However, at this time, the Agency declines to take the action requested by the Petition, i.e., initiating new rulemaking to propose an absolute regulatory prohibition on all background music during the presentation of risk information. As further explained below, the Agency's approach under existing regulations already includes assessment of background music, where present, as part of determining whether risk information in a specific ad is communicated effectively in light of all of the elements used in the particular ad. Furthermore, for certain DTC ads in television and radio format, a newly-promulgated final regulation will add to existing regulatory provisions to help ensure that the major statement relating to side effects and contraindications of the advertised drug is presented in a clear, conspicuous, and neutral manner. This regulation, too, will take account of background music, where present, among other factors. We will continue monitoring the overall prescription drug advertising landscape, including overseeing the implementation of the new final regulation. If FDA in the future undertakes further proposals to revise its regulations, it would need to account for policy and legal considerations, including constitutional ones, in shaping its approach. However, we are not persuaded to undertake new rulemaking of the kind you request at this time.

I. BACKGROUND — RELEVANT STATUTORY AND REGULATORY FRAMEWORK

Communication of a prescription drug's risks, in addition to its benefits, is a key element of legal requirements for prescription drug ads under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its implementing regulations. For example, section 502(n) of the FD&C Act (21 U.S.C. 352(n)) mandates that prescription drug ads issued or caused to be issued by the drug's manufacturer, packer, or distributor include "a true statement of . . . other information in brief summary relating to side effects,

[1] See Petition at 4.

contraindications, and effectiveness as shall be required in regulations. . . ."[2] Accordingly, a regulatory requirement to convey a prescription drug's risks in its advertising has been in place since 1963.[3] Since 1969, the prescription drug advertising regulations have specifically addressed the use of a statement of the advertised drug's major side effects and contraindications (known as the "major statement") in ads broadcast through media such as radio, TV, or telephone communications systems, requiring this risk disclosure in the audio or audio and visual parts of the presentation.[4]

In addition, section 201(n) of the FD&C Act (21 U.S.C. 321(n)) reflects the principle that disclosing material facts that include the "consequences" of using the drug to which advertising relates is key to ensuring that such communications are not misleading. Specifically, the section states that, when determining whether advertising is misleading, the Agency shall take into account (among other things) "the extent to which the . . . advertising fails to reveal facts . . . material with respect to consequences which may result from the use of the article . . . ."[5]

Consistent with both sections 201(n) and 502(n) of the FD&C Act, prescription drug advertising regulations further specify that an ad does not satisfy the statutory requirement of containing a "true statement" of information in brief summary relating to side effects, contraindications, and effectiveness if it: (1) is false or misleading with respect to side effects, contraindications, or effectiveness; or (2) fails to present a fair balance between information relating to side effects and contraindications and information relating to effectiveness of the drug; or (3) fails to reveal facts that are material in light of the representations made in the ad or with respect to the consequences that may result from the use of the drug as recommended or suggested in the ad.[6] In the 1980s, FDA confirmed that DTC advertising was subject to these established prescription drug advertising regulations.[7]

In addition to these provisions, Congress amended section 502(n) of the FD&C Act through the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110–85) to add a requirement that in DTC ads for human prescription drugs in TV or radio format that state the name of the drug and its conditions of use, the "major statement relating to side effects and contraindications" be presented in a clear, conspicuous, and neutral manner.[8] This week, FDA published a final regulation in the Federal Register to help implement this requirement by establishing standards that, independently and collectively, help ensure that the major statement is presented in a clear, conspicuous, and neutral manner. This final rule adds to existing prescription drug advertising regulations for the ads within its scope, leaving unchanged the existing requirements on which FDA has long relied to ensure that risk presentation for all ads is not undermined by other presentational elements.

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[2] See section 502(n) of the FD&C Act.

[3] See 28 FR 6375 at -6376 (June 20, 1963) (establishing what was then 21 CFR 1.105(e)); see also current 21 CFR 202.1(e). There are a few regulatory exemptions from the requirements to provide risk information. In particular, "reminder ads" (ads that call attention to the name of a drug but do not include indications, dosage recommendations, or other information) are exempted by regulation from the requirements under the FD&C Act for the disclosure of risk information. See 21 CFR 202.1(e)(2)(i).

[4] See 34 FR 7802 (May 16, 1969); (requirement subsequently recodified at 21 CFR 202.1(e)(1)).

[5] See section 201(n) of the FD&C Act.

[6] See 21 CFR 202.1(e)(5).

[7] See 50 FR 36677 at 36678 (September 9, 1985).

[8] See section 901(d)(3) of FDAAA, section 502(n) of the FD&C Act.

II. DISCUSSION

Current prescription drug advertising authorities—even without the additional regulation provisions recently finalized regarding the manner of presentation of the major statement—reach ads that fail to effectively communicate risks of the advertised drugs, including through their use of music, among other factors. Examples where FDA has addressed music, among other things, include:

- FDA Compliance Letter for ParaGard T380A intrauterine copper contraceptive MA 578, NDA 018680, dated July 25, 2019,[9] pp. 2-3 (presentation of certain risk information in the major statement of risks was undermined by the simultaneous presentation of fast-paced visuals that feature choreographed dancing to instrumental background music, i.e., dancing to background music through a crowded street forming a pattern in the street while people hold letters that spell the name of the product in bold letters).

- FDA Compliance Letter for Toujeo (insulin glargine injection) U-300, for subcutaneous use, NDA 206538, dated December 12, 2016,[10] p. 2 (TV ad presenting, at the same time as the major statement, fast-paced visuals featuring a man continuously dancing to music from the song "Let's Groove" throughout multiple scene changes — while cooking, working in an office, mowing his lawn, picking tomatoes with his children, and walking his dog — undermined the communication of the important risk information and thereby misleadingly minimized the risks associated with the use of the drug).

- FDA Compliance Letter for Otezla (apremilast) tablets, for oral use, NDA 205437, dated December 12, 2016,[11] pp. 2-3 (ad presenting in conjunction with audio risk disclosures, a rooftop dance party scene --- featuring a woman who raises music volume way up, then the scene cuts to her grabbing her friend's hands and dancing with her, then it cuts again to a man setting up the lights stopping and reacting to the dancing women with a smile — made it difficult for consumers to adequately process and comprehend the risk information).

As illustrated by these examples, FDA already uses its existing legal authorities to address specific ads where music is a factor (including with other creative elements) that interferes with communication of risk information.[12] Unlike the Petition's request for a total ban on background music, however, the Agency's

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[9] Note that the original compliance action letter was issued on July 19, 2019, and a revised final letter was issued on July 25, 2019. A public version of the letter is posted, available at https://www.fda.gov/media/129526/download.

[10] Available at http://wayback.archive-it.org/7993/20170112030751/http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/UCM533300.pdf.

[11] Available at http://wayback.archive-it.org/7993/20170112030757/http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM533292.pdf.

[12] Additional examples include FDA Compliance Letters for:

- Strattera (atomoxetine hydrochloride), NDA 021411, dated June 21, 2005, (revision of letter issued June 14, 2005), available at http://wayback.archive-it.org/7993/20170112064726/http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm054820.pdf,

regulations do not categorically prohibit any one type of element, such as background music, during the presentation of risk information. Instead, the Agency considers the whole set of elements presented by a specific ad to determine whether the ad satisfies the applicable legal obligations, including that the ad reveals material facts about the consequences of using the drug and that it presents a "true statement" of information in brief summary relating to side effects and contraindications (as well as effectiveness). (See FD&C Act sections 201(n) and 502(n).) These obligations are not satisfied if presentational elements, alone or in combination, undermine the effective communication of risk information. FDA's regulations apply to all ads and include – but are not solely focused on -- an assessment of background music, where present.

The Petition requests that FDA take action to initiate new rulemaking proposing to ban the use of music categorically, despite implicitly acknowledging that music is not inevitably a problem. The Petition suggests music may contribute positively to message reception, including both ad recall and recognition, particularly when there is high congruency between music and words.[13] However, the Petition is skeptical of what it *expects* advertisers to choose, expressing the view that "[a]dvertisers' use of background music is a distraction from the presentation of risks because the type of music they choose is incongruent with the message presented and it bombards the viewer with excess stimuli making it difficult for them to retain the information."[14] As a result, it requests that *all* background music be banned. Instead of examining whether the music in a specific ad is in fact "incongruent" or "bombards" the audience with excess stimuli—looking at the facts presented—the Petition advocates for a "bright line" categorical ban on all music because it asserts that approach is easy to enforce.[15]

At this time, however, FDA declines to pursue the approach advocated by the Petition. As a matter of regulatory policy, we believe that the best course of action at this time is to continue the approach in our longstanding regulations that considers all of the elements in each specific ad, to determine whether risk information is communicated effectively, without a total ban on background music or any other particular

- Seasonale (levonorgestrel/ethinyl estradiol) Tablets, new drug application (NDA) 021544, dated December 29, 2004, available at http://wayback.archive-it.org/7993/20170112064846/http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm054665.pdf.
- Paxil CR (paroxetine HCl) Controlled-Release Tablets**,** NDA 020936, dated June 9, 2004, available at http://wayback.archive-it.org/7993/20170112064944/http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm055293.pdf
- Lamisil (terbinafine hydrochloride), NDA 020539, dated August 22, 2003, available at http://wayback.archive-it.org/7993/20170112065341/http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM168904.pdf
- Prevacid (lansoprazole) Delayed-Release Capsules, NDA 020406, dated August 2, 2002, available at http://wayback.archive-it.org/7993/20170112065845/http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM164803.pdf.

[13] See Petition at 8.

[14] Id. at 7; see also id. at 8 (asserting that "the background music chosen for most drug commercials often distracts from the risks by being incongruent with its messaging.") (underlining added)

[15] Id. at 12. ("Banning music during discussions of side effects has the advantage also of being a clear bright line that is easy to enforce.") Comments in support of the Petition's request make a similar argument. (See FDA-2020-P-1725-0006.)

element.[16] In addition, FDA expects the new regulatory provisions addressing the manner of presentation of the major statement in certain DTC ads to further enhance its ability to ensure effective risk communications.

Thus, FDA at this time chooses not to initiate new rulemaking to seek to institute the ban on all background music requested by the Petition, but instead chooses to apply already-promulgated regulations to the specific facts of each ad — which includes an assessment of background music, if any, along with other creative elements —to help ensure that important information about prescription drugs, including the risk information, is effectively communicated in DTC ads.

III. CONCLUSION

For the reasons described in this response, the Petition is denied.

Sincerely,

Douglas C. Throckmorton -S

Digitally signed by Douglas C. Throckmorton -S
Date: 2023.11.21 10:28:48 -05'00'

Patrizia Cavazzoni, M.D.
Director
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[16] This approach also takes account of the impact of other elements beyond music, which the Petition acknowledges also can impact risk comprehension. See Petition at 15-16 ("[t]here are similar and serious concerns about the distracting and incongruent nature of the use of images in pharmaceutical ad discussions of side effects and risks. Regulating the use of images is important, but beyond the scope of this petition."; see also [Petitioner's supplemental] submission FDA-2020-P-1725-0007.