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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 172 and 177

[Docket No. FDA–2015–F–4317]

Food Additive Regulations; Synthetic Flavoring Agents and Adjuvants; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA or we) is responding to the submission styled as an objection submitted by Earthjustice on behalf of Breast Cancer Prevention Partners, Center for Environmental Health, Center for Food Safety, Center for Science in the Public Interest, Environmental Defense Fund, Environmental Working Group, and the Natural Resources Defense Council, on the final rule that amended the food additive regulations to no longer authorize the use of benzophenone, ethyl acrylate, eugenyl methyl ether, myrcene, pulegone, and pyridine as synthetic flavoring substances for use in food. The final rule also amended the food additive regulations to no longer provide for the use of benzophenone as a plasticizer in rubber articles intended for repeated use in contact with food. After reviewing the submission, we have concluded that the submission we received is not an objection and consequently does not provide a basis for modifying the regulations.

DATES: Effective date of final rule published in the **Federal Register** of October 9, 2018 (83 FR 50490) confirmed: October 9, 2018.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mical Honigfort, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740–3835, 240–402–1278.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 4, 2016 (81 FR 42), we announced the filing of a food additive petition (FAP 5A4810) (''petition'') submitted jointly by the Center for Science in the Public Interest; Natural Resources Defense Council; Center for Food Safety; Consumers Union; Improving Kids' Environment; Center for Environmental Health; Environmental Working Group; Environmental Defense Fund, and Mr. James Huff (collectively, ''petitioners'') c/o Thomas Neltner, 1875 Connecticut Ave. NW, Suite 600, Washington, DC 20009. Subsequently, the Breast Cancer Fund (now known as the Breast Cancer Prevention Partners) and WE ACT for Environmental Justice joined as co-petitioners.

The petition proposed that we take two separate regulatory actions: (1) Amend the food additive regulations in § 172.515 *Synthetic flavoring substances and adjuvants* (21 CFR 172.515) to no longer authorize the use of seven listed synthetic flavoring food additives and (2) to establish zero tolerances in § 172.515 for these additives. As FDA explained in the filing notice (81 FR 42 at 42 through 43) and the final rule (83 FR 50490 at 50491) for this petition, the food additive regulation is not the appropriate section for a ''zero tolerance,'' and this request is not the proper subject of a food additive petition. A food additive petition must either propose the issuance of a regulation prescribing the conditions under which a food additive may be safely used (see section 409(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348(b)(1)), or propose the amendment or repeal of an existing food additive regulation (see section 409(i) of the FD&C Act). As we explained in the final rule, we interpreted the petitioners' request to establish zero tolerances for these additives as a request to issue a regulation prohibiting a substance from human food under part 189 (21 CFR part 189), a request that is not the proper subject of a food additive petition (83 FR 50490 at 50491). Therefore, because the petitioners' request to establish zero tolerances fell outside the scope of a food additive petition, we focused solely on the request in the petition to amend the food additive regulations pertaining to these seven synthetic flavoring food additives.

The seven food additives that were the subject of the petition are:

1. Benzophenone (also known as diphenylketone) (CAS No. 119–61–9);
2. Ethyl acrylate (CAS No. 140–88–5);
3. Eugenyl methyl ether (also known as 4-allylveratrole or methyl eugenol) (CAS No. 93–15–2);
4. Myrcene (also known as 7-methyl-3-methylene-1,6-octadiene) (CAS No. 123–35–3);
5. Pulegone (also known as p-menth-4(8)-en-3-one) (CAS No. 89–82–7);
6. Pyridine (CAS No. 110–86–1); and
7. Styrene (CAS No. 100–42–5)

Related to FAP 5A4810, in the **Federal Register** of June 15, 2016 (81 FR 38984), we announced that we filed a food additive petition (FAP 6A4817) proposing that we amend § 172.515 to no longer provide for the use of styrene as a synthetic flavoring substance and adjuvant in food because the use has been abandoned. We later issued a final rule in the **Federal Register** of October 9, 2018 (83 FR 50487) granting the petition and amending § 172.515 to no longer authorize the use of styrene as a synthetic flavoring substance and adjuvant in food because its use under § 172.515 had been permanently and completely abandoned.

Additionally, in the **Federal Register** of October 9, 2018 (83 FR 50490), we published a final rule partially granting FAP 5A4810 to amend the food additive regulations in § 172.515 to no longer authorize the use of benzophenone, ethyl acrylate, eugenyl methyl ether, myrcene, pulegone, and pyridine as synthetic flavoring substances for use in food. We also amended the food additive regulation in 21 CFR 177.2600 to no longer provide for the use of benzophenone as a plasticizer in rubber articles intended for repeated use in contact with food. We denied as moot the portions of the petition proposing that the food additive regulations be amended to no longer authorize the use

of styrene as a synthetic flavoring substance because this use has been permanently and completely abandoned (83 FR 50490 at 50492 through 50493). As discussed in detail in section III, we explained in the final rule that we declined to act on the petitioners' request to establish a zero tolerance for the use of these synthetic flavoring substances in food because that issue is not the proper subject of a food additive petition. The final rule advised that objections and requests for a hearing on the final rule were due by November 8, 2018.

II. Objections and Requests for Hearing

Section 409(f)(1) of the FD&C Act provides that, within 30 days after publication of an order relating to a food additive regulation, any person adversely affected by such order may file objections, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections.

Under 21 CFR 171.110, objections and requests for a hearing are governed by 21 CFR part 12 of FDA's regulations. Under 21 CFR 12.22(a), each objection must meet the following conditions: (1) Must be submitted on or before the 30th day after the date of publication of the final rule; (2) must be separately numbered; (3) must specify with particularity the provision of the regulation or proposed order objected to; (4) must specifically state each objection on which a hearing is requested; failure to request a hearing on an objection constitutes a waiver of the right to a hearing on that objection; and (5) must include a detailed description and analysis of the factual information to be presented in support of the objection if a hearing is requested; failure to include a description and analysis for an objection constitutes a waiver of the right to a hearing on that objection.

Within the 30-day objection period following publication of the final rule, we received approximately 50 comments concerning the final rule. With the exception of one submission, the comments did not purport to raise objections and did not provide or identify any relevant new evidence. We will not address these comments further.

However, we received one submission that stated it was noting several concerns and raising one ''objection.'' Earthjustice, on behalf of Breast Cancer Prevention Partners, Center for Environmental Health, Center for Food Safety, Center for Science in the Public Interest, Environmental Defense Fund, Environmental Working Group, and the Natural Resources Defense Council, wrote to ''share our objection and concerns'' about the final rule (see Letter from Peter Lehner, Senior Attorney, and Carrie Apfel, Staff Attorney, Earthjustice, to Dockets Management Staff, Food and Drug Administration, dated November 8, 2018). (For the purposes of this document, we will refer to these entities as ''parties.'') The submission stated that the parties ''applaud[ed] FDA for acknowledging that it 'cannot consider these synthetic substances to be safe as a matter of law,'" but indicated that it objected to our ''failure to indicate expressly that these substances no longer qualify in any way as 'safe' for use in food, which amounts to an arbitrary and unlawful failure to protect the safety of food'' (id. at page 1). The submission also noted two concerns about our analyses of the substances (id.). The parties also stated in their submission that they waived their right to a hearing (id.).

As discussed in detail in section III, the provision for objections and a hearing under section 409(f) of the FD&C Act does not apply to this ''objection.'' For the purposes of this document, our use of the term ''objection'' does not mean that the provision for objections under section 409(f) of the FD&C Act applies.

III. Analysis of Objection

The submission's ''objection'' is not subject to the objections and hearing procedure in section 409(f) of the FD&C Act. Therefore, we will not address the arguments detailed in the submission.

The submission asserts that FDA's failure to indicate expressly in the final rule that substances found to induce cancer cannot qualify in any way as ''safe'' for use in food is arbitrary and unlawful (Earthjustice submission at pages 2 through 3). The submission further states that, ''To correct this deficiency, FDA must explain that substances found to induce cancer cannot qualify as ''safe'' for use in food, regardless of whether those substances purport to be food additives, GRAS substances, or both'' (id. at page 3). A substance is generally recognized as safe (GRAS) if there is general recognition, among qualified experts, to be safe under the conditions of its intended use. A substance that is GRAS under the conditions of its intended use is excluded from the statutory definition of food additive under section 201(s) of the FD&C Act (21 U.S.C. 321(s)). Thus, given a substance is, by definition, not a food additive if it is GRAS, whether the status of a substance is GRAS is outside the scope of the food additive petition process and the related provision for objections and public hearing.

Section 409(f)(1) of the FD&C Act states that within 30 days after publication of an order made pursuant to section 409(c) or (d) of the FD&C Act, any person adversely affected by such an order may file objections, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds therefor. In the final rule, we stated that we partially granted the petition and partially denied the petition, completely responding to the food additive petition submitted by the petitioners (83 FR 50490 at 50492). FDA partially granted the petition by amending the food additive regulations to no longer authorize the use of benzophenone, ethyl acrylate, eugenyl methyl ether, myrcene, pulegone, and pyridine as synthetic flavoring substances for use in food based on data provided by the petitioners that demonstrated these additives induce cancer in laboratory animals, and, as a result of this finding in animals, FDA cannot as a matter of law maintain the listing of these synthetic flavoring substances in the food additive regulations (21 U.S.C. 348(c)(3)(A)). We further amended the food additive regulations to no longer provide for the use of benzophenone as a plasticizer in rubber articles intended for repeated use in contact with food because of evidence that benzophenone causes cancer in animals. FDA denied as moot the portions of the petition proposing that the food additive regulations be amended to no longer authorize the use of styrene as a synthetic flavoring substance because this use has been permanently and completely abandoned. Further, and most relevant here, FDA denied the petitioners' request to establish zero tolerances for these additives because such a request fell outside the scope of the food additive petition process (83 FR 50490 at 50491).

As a result of responding to these two food additive petitions, FDA revoked the uses of all seven synthetic flavoring substances either: (1) As a matter of law because data demonstrated that six of the seven synthetic flavoring substances have been shown to cause cancer in animals or (2) based on a determination that the use had been completely and permanently abandoned; we further made clear that the petitioners' ''zero tolerance'' request was not the proper subject of a food additive petition (83 FR 50487; 83 FR 50490).

Thus, when the parties state in their ''objection'' that FDA's ''failure to indicate expressly that these substances no longer qualify in any way as 'safe' for use in food.. . . amounts to an arbitrary and unlawful failure to protect the safety of food,'' it does not appear the parties have stated with particularity a specific provision of the synthetic flavoring substances order that they deem objectionable. The parties do not object to our determination to revoke the uses of the synthetic flavoring substances, and in fact in their submission, the parties stated they ''applaud FDA for acknowledging that it 'cannot consider these synthetic flavoring substances to be safe as a matter of law' '' (Earthjustice submission, page 1). Rather, by asserting in their submission that FDA is being arbitrary and unlawful by failing to indicate expressly in the final rule that substances found to induce cancer cannot qualify in any way as ''safe'' for use in food, we interpret the parties' ''objection'' to be related to the petitioners' request to establish zero tolerances for these synthetic flavoring additives, a request we declined to act on in the final rule because such a request was not the proper subject of a food additive petition.

As explained in the final rule (83 FR 50490 at 50491), a food additive petition must either propose the issuance of a regulation prescribing the conditions under which a food additive may be safely used or propose the amendment or repeal of an existing food additive regulation (sections 409(b)(1) and (i) of the FD&C Act). We explained in the final rule that we interpreted the request to establish zero tolerances for these flavoring additives as a request to issue a regulation prohibiting a substance from human food under part 189 and that this request fell outside the scope of a food additive petition because it does not propose the issuance of a new food additive regulation or the amendment or repeal of an existing food additive regulation (id.). Consequently, we did not address the zero tolerance request further in the final rule and thus this issue was not considered part of the order by regulation that revoked the uses for these synthetic flavoring additives, pursuant to section 409(c) of the FD&C Act. Therefore, because the parties failed to identify a provision of the order deemed objectionable and have also failed to raise an objection regarding the order made pursuant to section 409(c) or (d) of the FD&C Act, the provision for objections and public hearing under section 409(f) of the FD&C Act does not apply.[1]

Finally, even though we do not think the parties' submission legally rises to an objection under 409(f) of the FD&C Act, even if the submission was a properly raised objection, we would deny such an objection because the parties' request amounts to the same outcome as the petitioners' zero tolerance request and such a request falls outside the scope of the food additive petition process.

IV. Conclusion

After evaluating the submission from Earthjustice et al., we have concluded that the ''objection'' is not within the scope of the objections and hearing provision under section 409(f) of the FD&C Act. Therefore, we do not address the arguments related to this ''objection.'' We are confirming October 9, 2018, as the effective date of this regulation. FDA still intends to not enforce applicable requirements of the final rule with regard to food products manufactured (domestically and internationally) prior to October 9, 2020, that contain one or more of these six synthetic flavoring substances, to provide an opportunity for companies to reformulate products prior to enforcing the requirements of this final rule.

Dated: January 16, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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[1] We note that the parties' submission did not present any argument or evidence that FDA's determination that the petitioners' zero tolerance request was not the proper subject of a food additive petition, and was thus outside the scope of section 409 of the FD&C Act, was erroneous.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–558]

Schedules of Controlled Substances: Placement of Lasmiditan in Schedule V

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Interim final rule with request for comments.

SUMMARY: On October 11, 2019, the U.S. Food and Drug Administration approved a new drug application for Reyvow (lasmiditan) tablets for oral use. Lasmiditan is chemically known as [2,4,6-trifluoro-*N*-(6-(1-methylpiperidine-4-carbonyl)pyridine-2-yl-benzamide]. Thereafter, the Department of Health and Human Services provided the Drug Enforcement Administration (DEA) with a scheduling recommendation to place lasmiditan in schedule V of the Controlled Substances Act (CSA). In accordance with the CSA, as revised by the Improving Regulatory Transparency for New Medical Therapies Act, DEA is hereby issuing an interim final rule placing lasmiditan, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule V of the CSA.

DATES: The effective date of this rulemaking is January 31, 2020. Interested persons may file written comments on this rulemaking in accordance with 21 U.S.C. 811(j)(3) and 21 CFR 1308.43(g). Electronic comments must be submitted, and written comments must be postmarked, on or before March 2, 2020. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Interested persons may file a request for hearing or waiver of hearing in accordance with 21 U.S.C. 811(j)(3) and 21 CFR 1308.44. Requests for hearing and waivers of an opportunity for a hearing or to participate in a hearing must be received on or before March 2, 2020.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–558'' on all correspondence, including any attachments.

- *Electronic comments:* The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on *Regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

- *Paper comments:* Paper comments that duplicate the electronic submission are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu of* an electronic comment, it should be sent via regular