4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 170, 177, and 189

[Docket No. FDA-2015-F-0537]

Natural Resources Defense Council et al.: Response to the Objections and Denial of the Requests for a Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; response to objections and denial of public hearing requests.

SUMMARY: The Food and Drug Administration (FDA or we) is overruling the objections and is denying the requests for a public hearing, submitted by the Environmental Defense Fund, Natural Resources Defense Council, Center for Food Safety, Clean Water Action, Center for Science in the Public Interest, Breast Cancer Prevention Partners, Center for Environmental Health, Environmental Working Group, and Improving Kids' Environment.

DATES: [insert date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Hui-Chen (Anita) Chang, Center for Food Safety and Applied Nutrition (HFS-275), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740-3835, 240-402-1161.

SUPPLEMENTARY INFORMATION:

I. Background

In the *Federal Register* of March 16, 2015 (80 FR 13508), we announced the filing of a food additive petition (FAP 4B4808) ("petition") submitted by the Natural Resources Defense Council, 1152 15th St. NW, Suite 300, Washington, DC 20005; the Center for Food Safety, 303

Sacramento St., Second Floor, San Francisco, CA 94111; Clean Water Action, 1444 I St. NW, Suite 400, Washington, DC 20005; the Center for Science in the Public Interest, 1220 L St. NW, Suite 300, Washington, DC 20005; Children's Environmental Health Network, 110 Maryland Ave. NE, Suite 402, Washington, DC 20002; the Breast Cancer Fund (now known as Breast Cancer Prevention Partners), 1388 Sutter St., Suite 400, San Francisco, CA 94109-5400; the Center for Environmental Health, 2201 Broadway, Suite 302, Oakland, CA 94612; Environmental Working Group, 1436 U St. NW, Suite 100, Washington, DC 20009; and Improving Kids' Environment, 1915 West 18th St., Indianapolis, IN 46202 (collectively, "petitioners"). The petition asked FDA to take three separate regulatory actions: (1) revoke our 2005 approval of Threshold of Regulation (TOR) exemption No. 2005-006 allowing as much as 1.2 percent sodium perchlorate monohydrate in dry food packaging; (2) issue a new regulation under part 189 (21 CFR part 189) prohibiting the use of perchlorate as a conductivity enhancer in the manufacture of antistatic agents to be used in food contact articles; and (3) remove potassium perchlorate as an allowed additive in sealing gaskets for food containers in existing § 177.1210 (21 CFR 177.1210).

In the *Federal Register* of June 30, 2016 (81 FR 42585), we announced that we filed a food additive petition (FAP 6B4816) ("abandonment petition") submitted on behalf of Society of the Plastics Industry, Inc. (SPI) by Keller and Heckman LLP, 1001 G Street NW, Suite 500 West, Washington, DC 20001. The abandonment petition proposed to amend § 177.1210 to no longer provide for the use of potassium perchlorate as an additive in closure sealing gaskets for food containers because the use has been intentionally and permanently abandoned.

In response to the abandonment petition, we issued a final rule in the *Federal Register* on May 4, 2017 (82 FR 20829), to no longer provide for the use of potassium perchlorate as an

additive in closure-sealing gaskets for food containers because this use has been abandoned. The final rule removed the entry for "Potassium perchlorate" from § 177.1210(b)(5), table 1.

Additionally, in the *Federal Register* of May 4, 2017 (82 FR 20847), we announced that we were denying the petition ("2017 denial"). The 2017 denial advised that objections and requests for a hearing were due by June 4, 2017. The 2017 denial explained that the requests to revoke TOR exemption No. 2005-006 and issue a regulation under part 189 prohibiting the use of perchlorate in the manufacture of antistatic agents to be used in food-contact articles are not directed at regulations issued under the food additive petition process and are not subject to the statutory processes for food additive petitions (82 FR 20847 at 20858). Because the requests to revoke TOR exemption No. 2005-006 and issue a regulation under part 189 are not within the scope of a food additive petition, the provision for objections and a hearing under section 409(f) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348(f)) does not apply to these two requests (Id.). The 2017 denial also explained that the petitioners' request to remove potassium perchlorate as an allowed additive in closure-sealing gaskets for food containers in § 177.1210 was moot when we amended § 177.1210 to no longer authorize this use of potassium perchlorate because it had been abandoned (see 82 FR 20847 at 20849).

II. Objections and Requests for Hearing

Section 409(f) 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. FDA may deny a hearing request if the objections to the regulation do not raise genuine and substantial

issues of fact that can be resolved at a hearing (*Community Nutrition Inst*. v. *Young*, 773 F.2d 1356, 1364 (D.C. Cir. 1985)).

Under the food additive regulations at 21 CFR 171.110, objections and requests for a hearing are governed by part 12 (21 CFR part 12) of FDA's regulations. Under § 12.22(a), each objection must: (1) be submitted on or before the 30th day after the date of publication of the final rule; (2) be separately numbered; (3) specify with particularity the provision of the regulation or proposed order objected to; (4) 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) 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 2017 denial, we received one submission raising objections. The submission, dated June 4, 2017, from most of the petitioners and the Environmental Defense Fund, raised specific objections to the 2017 denial and requested a hearing on the issues raised by each objection. However, as explained in this document, the provision for objections and a hearing under section 409(f) of the FD&C Act does not apply to all objections in the submission. As further explained in this document, for the objections to which this provision does not apply, we do not address the submission's arguments and we do not consider the related requests for a hearing. For purposes of this document, our use of the term "objections" does not mean that the provision for objections and hearing under section 409(f) of the FD&C Act necessarily applies.

III. Standards for Granting a Hearing

Specific criteria for deciding whether to grant or deny a request for a hearing are set out in § 12.24(b). Under that regulation, a hearing will be granted if the material submitted by the requester shows, among other things, the following: (1) there is a genuine and substantial factual issue for resolution at a hearing; a hearing will not be granted on issues of policy or law; (2) the factual issue can be resolved by available and specifically identified reliable evidence; a hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions; (3) the data and information submitted, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the requester; a hearing will be denied if the data and information submitted are insufficient to justify the factual determination urged, even if accurate; (4) resolution of the factual issue in the way sought by the person is adequate to justify the action requested; a hearing will not be granted on factual issues that are not determinative with respect to the action requested (e.g., if the action would be the same even if the factual issue were resolved in the way sought); (5) the action requested is not inconsistent with any provision in the FD&C Act or any FDA regulation; and (6) the requirements in other applicable regulations, e.g., 21 CFR 10.20 and §§ 12.21 and 12.22, and in the document issuing the final regulation or the notice of opportunity for hearing are met.

A party seeking a hearing is required to meet a "threshold burden of tendering evidence suggesting the need for a hearing" (*Costle* v. *Pac. Legal Found*., 445 U.S. 198, 214 (1980), citing *Weinberger* v. *Hynson, Westcott & Dunning, Inc*., 412 U.S. 609, 620-21 (1973)). An allegation that a hearing is necessary to "'sharpen the issues' and 'fully develop the facts' does not meet this test" (*Georgia-Pacific Corp*. v. *U.S. EPA*, 671 F.2d 1235, 1241 (9th Cir. 1982)). If a hearing request fails to identify any factual evidence that would be the subject of a hearing, there is no point in holding one. In judicial proceedings, a court is authorized to issue summary judgment

without an evidentiary hearing whenever it finds that there are no genuine issues of material fact in dispute and a party is entitled to judgment as a matter of law (see Fed. R. Civ. P. 56). The same principle applies in administrative proceedings (see § 12.24).

A hearing request must not only contain evidence, but that evidence should raise a material issue of fact "concerning which a meaningful hearing might be held" (*Pineapple Growers Ass'n* v. *FDA*, 673 F.2d 1083, 1085 (9th Cir. 1982)). Where the issues raised in the objection are, even if true, legally insufficient to alter the decision, an agency need not grant a hearing (see *Dyestuffs and Chem., Inc.* v. *Flemming*, 271 F.2d 281, 286 (8th Cir. 1959)). A hearing is justified only if the objections are made in good faith and if they "draw in question in a material way the underpinnings of the regulation at issue" (*Pactra Indus.* v. *CPSC*, 555 F.2d 677, 684 (9th Cir. 1977)). A hearing need not be held to resolve questions of law or policy (see *Citizens for Allegan Cnty., Inc.* v. *FPC*, 414 F.2d 1125, 1128 (D.C. Cir. 1969); *Sun Oil Co.* v. *FPC*, 256 F.2d 233, 240 (5th Cir. 1958)).

Even if the objections raise material issues of fact, FDA need not grant a hearing if those same issues were adequately raised and considered in an earlier proceeding. Once an issue has been so raised and considered, a party is estopped from raising that same issue in a later proceeding without new evidence. The various judicial doctrines dealing with finality, such as collateral estoppel, can be validly applied to the administrative process (see *Pac. Seafarers, Inc.* v. *Pac. Far East Line, Inc.*, 404 F.2d 804, 809 (D.C. Cir. 1968)). In explaining why these principles ought to apply to an agency proceeding, the U.S. Court of Appeals for the District of Columbia Circuit wrote: "The underlying concept is as simple as this: justice requires that a party have a fair chance to present his position. But overall interests of administration do not require or generally contemplate that he will be given more than a fair opportunity" (*Retail*

Clerks Union, Local 1401 v. *NLRB*, 463 F.2d 316, 322 (D.C. Cir. 1972); see also *Costle* v. *Pac. Legal Found*., 445 U.S. at 215-17).

IV. Analysis of Objections and Response to Hearing Requests

As explained in the 2017 denial (82 FR 20847 at 20849), 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 (see section 409(b)(1) and (i) of the FD&C Act). The petitioners' requests to revoke TOR exemption No. 2005-006 and issue a regulation under part 189 prohibiting the use of perchlorate in the manufacture of antistatic agents to be used in food-contact articles do not propose the issuance of a new food additive regulation or the amendment or repeal of an existing food additive regulation (82 FR 20847 at 20849). As the 2017denial states, the petitioners' TOR exemption revocation request and part 189 regulation request are not within the scope of a food additive petition and FDA's denial of these requests is not an order under section 409(c)(1)(B) of the FD&C Act (82 FR 20847 at 20858). Therefore, the provision for objections and public hearing under section 409(f) of the FD&C Act does not apply to the requests to revoke TOR exemption No. 2005-006 and issue a regulation under part 189.

A. Objections 1 and 2

The submission's first two "objections" are 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 those objections and we do not consider the related requests for a hearing.

The submission's first "objection" asserts that we improperly dismissed its request to revoke TOR exemption No. 2005-006 because, it claims, we relied on a flawed interpretation of the definition of a food additive in the TOR regulation. The submission additionally asserts that

the use of sodium perchlorate monohydrate allowed under TOR exemption No. 2005-006 is not eligible for a TOR exemption and that we made "myriad errors" in determining that it was eligible for a TOR exemption. Because TOR exemption No. 2005-006 is not subject to the objections and hearing procedure in section 409(f) of the FD&C Act, we will not address the arguments detailed in "objection" 1.

To the extent that any of the arguments made in "objection" 1 may be construed as also pertaining to the petitioners' request to amend § 177.1210 to remove potassium perchlorate as an allowed additive in closure-sealing gaskets for food containers, a request that is subject to section 409(f) of the FD&C Act, this request became moot when we amended § 177.1210 to no longer authorize this use of potassium perchlorate because it had been abandoned (see 82 FR 20847 at 20849). A hearing will not be granted on factual issues that are not determinative with respect to the action requested (see § 12.24(b)(4)). Therefore, to the extent that "objection" 1 pertains to the petitioners' request to amend § 177.1210, we are overruling the submission's objection and denying the submission's request for a hearing on this point.

The submission's second "objection" challenges as "contrary to law" FDA's determination that the petition's requests to revoke TOR exemption No. 2005-006 and issue a regulation under part 189 are not within the scope of a food additive petition. Section 409(f)(1) of the FD&C Act permits objections and requests for a hearing only to orders made under section 409(c) and (d) of the FD&C Act. Because FDA's denial of the petitioners' TOR revocation request and part 189 request was not an order under section 409(c)(1)(B) of the FD&C Act (see 82 FR 20847 at 20850), the submission's second "objection" is not an objection to an order under section 409(c)(1)(B) of the FD&C Act and 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 presented in "objection" 2.

B. Objection 3

Objection 3 challenges FDA's determination that the petitioners' request to amend § 177.1210 was moot when we issued a final rule in response to the abandonment petition that removed potassium perchlorate as an allowed additive in closure-sealing gaskets for food containers. Specifically, the submission alleges that FDA's mootness determination was "poor public policy" because it discourages industry to file abandonment petitions except in the face of a petition that may find the use no longer safe, and unfair to the petitioners, whose petition was filed before the abandonment petition.

In presenting objection 3, the submission fails to identify any specific factual dispute that could be resolved by a hearing. Accordingly, we are denying the submission's hearing request on objection 3 because a hearing will not be granted on issues of policy (§ 12.24(b)(1)). We also note that, in granting the abandonment petition and removing potassium perchlorate as an allowed additive in closure-sealing gaskets for food containers, we took the third action requested in the petition. As stated in response to a similar comment from the petitioners to the filing notice for the abandonment petition, FDA has numerous responsibilities related to food additives, and we receive and respond to hundreds of submissions annually under the various petition and notification programs that we administer. Accordingly, if a use of a food additive is no longer authorized in response to an abandonment petition, we may determine that it is neither necessary nor an efficient use of our limited resources to address safety arguments related to an abandoned use (see 82 FR 20829 at 20831).

V. Summary and Conclusion

After evaluating the objections from the submitters, we have concluded that "objections" 1 and 2 are 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 these "objections" and we do not address the related requests for a hearing. To the extent that "objection" 1 pertains to the petitioners' request to amend § 177.1210, this request became moot when we amended § 177.1210 to no longer authorize this use of potassium perchlorate, and therefore we are overruling the submission's objection and denying the request for a hearing on this point. Objection 3 does not provide any basis to reconsider our decision to deny the petition. We also have determined that objection 3 does not raise any genuine and substantial issue of fact that would justify an evidentiary hearing. Therefore, we are overruling this objection and are denying the related request for a hearing.

Dated: April 17, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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