Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Element Building, Rm. 4141, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Peter Fox, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Element Building, Rm. 4146, Rockville, MD 20857, 240–402–1857.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and FDA staff entitled ''Initiation of Voluntary Recalls Under 21 CFR part 7, subpart C.'' The draft guidance, if finalized, would establish guidance for industry and FDA staff regarding timely initiation of voluntary recalls of FDA-regulated products under 21 CFR part 7, subpart C. The draft guidance is part of a larger effort FDA is undertaking to give additional guidance to industry and FDA staff regarding the execution and oversight of voluntary recalls under part 7, subpart C.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, if finalized, would represent the current thinking of FDA on ''Initiation of Voluntary Recalls Under 21 CFR part 7, subpart C.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 7.45(c), 7.46(a), and 7.59 have been approved under OMB control number 0910–0249.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/FoodGuidances* or *https://www.regulations.gov.*

Dated: April 18, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–08198 Filed 4–23–19; 8:45 am]

BILLING CODE 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: April 24, 2019.

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.

[FR Doc. 2019–08262 Filed 4–23–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2019–N–1250]

General and Plastic Surgery Devices; Reclassification of Certain Surgical Staplers

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is proposing to reclassify surgical staplers for internal use (currently regulated under the classification for ''manual surgical instrument for general use'' and assigned the product code GAG) from class I (general controls) into class II (special controls) and subject to premarket review. FDA is identifying the proposed special controls for surgical staplers for internal use that the Agency believes are necessary to provide a reasonable assurance of the safety and effectiveness of the device. FDA is proposing this reclassification on its own initiative based on new information. As part of this reclassification, FDA is also proposing to amend the existing classification for ''manual surgical instrument for general use'' to remove staplers and to create a separate classification regulation for surgical staplers that distinguishes between surgical staplers for internal use and external use.

DATES: Submit either electronic or written comments on the proposed order by June 24, 2019. Please see section XI of this document for the proposed effective date of any final order that may publish based on this proposed order.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 24, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 24, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal Rulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–N–1250 for ''General and Plastic Surgery Devices; Reclassification of Certain Surgical Staplers.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, 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: R. Dale Rimmer, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G425, Silver Spring, MD 20993, 240–402–4828, *ralph.rimmer@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to