4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 176

[Docket No. FDA-2016-F-1153]

3M Corporation; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by Keller and Heckman LLP on behalf of 3M Corporation (Petitioner), requesting that we amend our food additive regulations to no longer provide for the use of two different perfluoroalkyl containing substances as water and oil repellents for paper and paperboard in contact with aqueous and fatty foods because these uses have been abandoned.

DATES: Submit either electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://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 http://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): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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-2016-F-1153 for "Filing of Food Additive Petition: 3M Corporation." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management 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 http://www.regulations.gov. Submit both copies to the Division of Dockets Management. 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: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vanee Komolprasert, Center for Food Safety and Applied Nutrition (HFS-275), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-1217.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 409(b)(5) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348(b)(5)), we are giving notice that we have filed a food additive petition (FAP 6B4814) submitted on behalf of 3M Corporation (Petitioner) by Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, DC 20001. The petition proposes that we amend 21 CFR 176.170 to no longer provide for the use of two different perfluoroalkyl containing substances as components of paper and paperboard in contact with aqueous and fatty foods because these uses have been intentionally and permanently abandoned. The two petitioned substances are as follows:

1. Ammonium bis (N-ethyl-2-perfluoroalkylsulfonamido ethyl) phosphates, containing not more than 15 percent ammonium mono (N-ethyl-2-perfluoroalkylsulfonamido ethyl) phosphates, where the alkyl group is more than 95 percent C8 and the salts have a fluorine content of 50.2 percent to 52.8 percent as determined on a solids basis; and
2. Perfluoroalkyl acrylate copolymer (CAS Reg. No. 92265-81-1) containing 35 to 40 weight percent fluorine, produced by the copolymerization of ethanaminium, N,N,N-trimethyl-2-[(2-methyl-1-oxo-2-propenyl)-oxy]-, chloride; 2-propenoic acid, 2-methyl-, oxiranylmethyl ester; 2-propenoic acid, 2-ethoxyethyl ester; and 2-propenoic acid, 2[[(heptadecafluoro-octyl)sulfonyl]methyl amino]ethyl ester.

FDA authorized use of these two substances under 21 CFR 176.170 in response to food

additive petitions submitted by the Petitioner (33 FR 14544, September 27, 1968; 35 FR 14840, September 24, 1970; 37 FR 9762, May 17, 1972; and 52 FR 3603, February 5, 1987).

II. Abandonment

Under section 409(i) of the FD&C Act, we "shall by regulation prescribe the procedure by which regulations under the foregoing provisions of this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of such regulations." Our regulations specific to administrative actions for food additives provide that the Commissioner, on his own initiative or on the petition of any interested person, under 21 CFR part 10, may propose the issuance of a regulation amending or repealing a regulation pertaining to a food additive or granting or repealing an exception for such additive (§ 171.130(a) (21 CFR 171.130(a))). These regulations further provide that any such petition shall include an assertion of facts, supported by data, showing that new information exists with respect to the food additive or that new uses have been developed or old uses abandoned, that new data are available as to toxicity of the chemical, or that experience with the existing regulation or exemption may justify its amendment or appeal. New data shall be furnished in the form specified in 21 CFR 171.1 and 171.100 for submitting petitions (21 CFR 171.130(b)). Under these regulations, a petitioner may propose that we amend a food additive regulation if the petitioner can demonstrate that there are "old uses abandoned" for the relevant food additive. Such abandonment must be complete for any intended uses in the U.S. market. While section 409 of the FD&C Act and § 171.130 also provide for amending or revoking a food additive regulation based on safety, an amendment or revocation based on abandonment is not based on safety, but is based on the fact that regulatory authorization is no longer necessary because the use of the food additive has been abandoned.

Abandonment may be based on the abandonment of certain authorized food additive uses for a substance (e.g., if a substance is no longer used in certain product categories), or on the abandonment of all authorized food additive uses of a substance (e.g., if a substance is no longer being manufactured). If a petition seeks an amendment to a food additive regulation based on the abandonment of certain uses of the food additive, such uses must be adequately defined so that both the scope of the abandonment and any amendment to the food additive regulation are clear.

The petition submitted on behalf of 3M Corporation includes the following information to support the claim that the uses of the two respective substances are no longer being introduced into the U.S. market. The Petitioner provides a statement that, to the best of the Petitioner's knowledge, the Petitioner was the sole and exclusive domestic and international manufacturer of the two respective substances for the abandoned uses and that the Petitioner does not currently manufacture them for food contact use in the U. S. In addition, the Petitioner submitted information on its May 2000 agreement with the U.S. Environmental Protection Agency (EPA) to voluntarily phase out production of perfluorooctane sulfonate (PFOS), which is used to produce the two petitioned substances (https://www.epa.gov/sites/production/files/2014-04/documents/factsheet_contaminant_pfos_pfoa_march2014.pdf). According to the petition, the Petitioner completed a voluntary phase-out of PFOS production in 2002. The Petitioner states that it does not intend to manufacture or import, nor does it maintain an inventory for sale or distribution, of the two respective substances for use in food-contact applications in the U.S. in the future.

We expressly request comments on the Petitioner's request to amend 21 CFR 176.170 of the food additive regulations to no longer permit the use of the two respective perfluoroalkyl

containing substances as water and oil repellants for paper and paperboard in contact with aqueous and fatty foods. More specifically, these two petitioned substances as identified in this section may currently be used as components of the uncoated or coated food-contact surface of paper and paperboard for use in contact with aqueous and fatty foods, subject to the provisions of 21 CFR 176.170. As noted, the basis for the proposed amendment is that the uses of the respective substances have been permanently and completely abandoned. Accordingly, we request comments that address whether these uses of the respective substances have been completely abandoned, such as information on whether food-contact paper and paperboard containing the two respective substances are currently being introduced or delivered for introduction into the U.S. market. Furthermore, we request comments on whether the uses that are the subject of the petition have been adequately defined. We are not aware of information that suggests continued use of the respective substances as water and oil repellents for paper and paperboard in contact with aqueous and fatty foods. We are providing the public with 60 days to submit comments. We anticipate that some interested persons may wish to provide FDA with certain information they consider to be trade secret or confidential commercial information (CCI) that would be exempt under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552). Interested persons may claim information that is submitted to FDA as CCI or trade secret by clearly marking both the document and the specific information as "confidential." Information so marked will not be disclosed except in accordance with the Freedom of Information Act (5 U.S.C. 552) and the FDA's disclosure regulations (21 CFR Part 20). For electronic submissions to http://www.regulations.gov, indicate in the "comments" box of the appropriate docket that your submission contains confidential information. Interested persons must also submit a copy of the comment that does not contain the information claimed as confidential for inclusion in the

public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice.

We are not requesting comments on the safety of the uses of these two perfluoroalkyl containing substances because, as discussed previously in this document, such information is not relevant to abandonment, which is the basis of the proposed action. Any comments addressing the safety of the two perfluoroalkyl containing substances or containing safety information on these substances will not be considered in our evaluation of this petition.

We have determined under 21 CFR 25.32(m) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: April 22, 2016.

Dennis M. Keefe,

Director,

Office of Food Additive Safety,

Center for Food Additive Safety and Applied Nutrition.

[FR Doc. 2016-09932 Filed: 4/28/2016 8:45 am; Publication Date: 4/29/2016]