June 23, 2016

Electronic Submission
Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: 3M Corporation; Filing of Food Additive Petition. Docket No. FDA-2016-F-1153

Dear Sir or Madam:

Breast Cancer Fund, Center for Environmental Health, Center for Food Safety, Center for Science in the Public Interest, Children Environmental Health Network, Consumer Federation of America, and Environmental Defense Fund are pleased to submit these comments to FDA in support of the food additive petition submitted by Keller and Heckman LLP on behalf of 3M Corporation (Petitioner) and posted for public comment in Docket No. FDA-2016-F-1153. Petitioner has requested that Food and Drug Administration (FDA) amend its food additive regulations to no longer allow 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.

The two petitioned substances approved food additives at 21 CFR 176.170 are:

- Ammonium bis(N-ethyl-2-perfluoroalkylsulfonamido ethyl) phosphates, containing not more than 15% ammonium mono (N-ethyl-2-perfluoroalkylsulfonamido ethyl) phosphates, where the alkyl group is more than 95% C8 and the salts have a fluorine content of 50.2% to 52.8% as determined on a solids basis; and
- Perfluoroalkyl acrylate copolymer (CAS Reg. No. 92265-81-1) containing 35 to 40 weight percent fluorine, produced by the copolymerization of ethanaminium, N,N,Ntrimethyl-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.

We also take this opportunity to encourage FDA to revoke its approval of seven food contact notifications for long-chain perfluorinated compounds (PFCs) that industry has already voluntarily ceased using as grease-proofing agents.[1] The six PFCs with a chain length of at least eight carbons are described in Table 1.

According to FDA, manufacturers DuPont, BASF and Clariant voluntarily committed to stop distributing products containing the long-chain PFCs on or before October 1, 2011. In its website, FDA states that "[t]he industry's voluntary action to cease using grease-proofing agents containing C8 perfluorinated compounds means that these products will be out of the

[1] US Food and Drug Administration. Update on Perfluorinated Grease-proofing Agents. See http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/Notifications/ucm308462.htm. Accessed May 25, 2016.

marketplace in a relatively short period of time."[2] After five years, the precise status of these six food contact notifications remains uncertain.

The notation is helpful to readers but has no meaning under the Federal Food, Drug and Cosmetic Act, Section 309 of the Food and Drug Administration Modernization Act of 1997[3] that authorized the agency to create the food contact substances notification program, and the rules FDA promulgated in 2000 to implement the law. While the notation implies that the notices are somehow suspended, the FCNs remain fully effective. Rather than a status that exists outside the law, FDA should use the process laid out in its rules at 21 CFR 170.105 where the agency informs the notifier in writing and provides an opportunity for the firm to make its case. If after hearing from the notifier the agency has not changed its position, then it publishes a notice in the *Federal Register*. In 2011, FDA did not follow its rules and essentially left the last step undone.

The seven long-chain PFCs approved as FCNs and voluntarily removed from commerce by manufacturers belong to the same class of chemicals that also included the three food-contact substances FDA struck from 21 CFR 171.170 on January 4, 2016. FDA's decision was based on its finding that "new data are available as to the toxicity of substances structurally similar to these compounds that demonstrate there is no longer a reasonable certainty of no harm from the food-contact use of these FCSs."[4]

In 2011, in a letter to the manufacturer of FCN 628, FDA stated that "additional safety testing is required to support the continued effectiveness" of the FCN because data became available after the FCN became effective demonstrating "systemic toxicity for compounds similar in chemical structure to the low molecular weight constituents of the FCS, combined with data which demonstrates biopersistence of the starting monomer for the commercial FCS and a lack of information specific to the low molecular weight constituents of the FCS to address the additional toxic endpoints relevant to long-chain perfluorinated compounds discussed above."[5]

These are the same safety concerns FDA described as the rationale for prohibiting the three food-contact substances struck from 21 CFR 171.170. These three long-chain PFCs had also been approved for use as oil and water repellants for paper and paperboard for use in contact with aqueous and fatty foods. They are in the same class of chemically-similar substances and pose similar safety risks.

Therefore, we respectfully ask FDA to remove the effectiveness approvals of FCNs 59, 206, 255, 311, 338, 628 and 648 consistent with the agency's January 4, 2016 rule banning long-chain PFCs in which it stated that "data for subsets of long-chain PFCs (demonstrating biopersistence and reproductive and developmental toxicity) are applicable to long-chain PFCs on a general basis."

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[2] US Food and Drug Administration. Update on Perfluorinated Grease-proofing Agents.
[3] Public Law 105-115, 1997.
[4] 81 *Federal Register* 5. "Indirect Food Additives: Paper and Paperboard Components." Food and Drug Administration. Jan. 4, 2016 (Amending 21 CFR 176.170).
[5] US Food and Drug Administration. Letter to Clariant Corporation Acknowledging Receipt of Voluntary Commitment for Food contact substance (FCS). June 25, 2012.

The agency should have removed the effectiveness of the seven FCNs based on abandonment in 2011 and should do it now based on its decision on January 4, 2016 decision.

For more information, contact Tom Neltner at tneltner@edf.org and Maricel Maffini at drmvma@gmail.com.

Sincerely,

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Table 1: Long-Chain Perfluorinated Compounds Removed from Commerce in 2011. Effective Food Contact Substance Notifications for Long-Chain Perfluorinated Compounds for which the manufacturer voluntarily ceased introduction into interstate commerce in 2011 in response to FDA's 2010 request.

FCN No.	Manufacturer	Description of Food Contact Substance (FCS) covered by the effective FCS Notification (FCN)	Intended Use	Effective Date (before cessation)
59	BASF Corp.	Glycine, N,N-bis[2-hydroxy-3-(2-propenyloxy)propyl]-, monosodium salt, reaction products with ammonium hydroxide and pentafluoroiodoethane-tetrafluoroethylene telomer (CAS Reg. No. 220459-70-1).	As a component of paper and paperboard in contact with nonalcoholic food.	August 16, 2000
206	DuPont Chemical Solutions Enterprise	Copolymer of 2-perfluoroalkylethyl acrylate, 2-N,N-diethylaminoethyl methacrylate, and glycidyl methacrylate.	As an oil and grease-resistant treatment for paper and paperboard intended for food-contact use.	June 12, 2002
255	BASF Corp.	3-cyclohexane-1-carboxylic acid, 6-((di-2-propenylamino)carbonyl)-,(1R,6R), reaction products with pentafluoroiodoethane-tetrafluoroethylene telomer, ammonium salts.	As an oil repellent sizing agent in the production of paper and paperboard.	September 5, 2002
311	DuPont Chemical Solutions Enterprise	Copolymers of 2-perfluoroalkylethyl acrylate, 2-N,N-diethylaminoethyl methacrylate, and glycidyl methacrylate.	As an oil or grease resistant treatment for paper and paperboard intended for single service use in microwave heat-susceptor packaging; the food-contact substance is intended to contact all food types.	April 15, 2003
338	DuPont Chemical Solutions Enterprise	Copolymers of 2-perfluoroalkylethyl acrylate, 2-N,N-diethylaminoethyl methacrylate, and glycidyl methacrylate.	As an oil or grease resistant treatment for paper and paperboard intended for food-contact use.	August 19, 2003
628	Clariant Corp.	Copolymer of 2-perfluoroalkylethyl acrylate, 2-(dimethylamino)ethyl methacrylate, and oxidized 2-(dimethylamino)ethyl methacrylate (CAS Reg. No. 479029-28-2).	As an oil and grease repellent in the manufacture of paper and paperboard.	October 10, 2006
646	DuPont Chemical Solutions Enterprise	Copolymers of 2-perfluoroalkylethyl acrylate, 2-N,N-diethylaminoethyl methacrylate, glycidyl methacrylate, acrylic acid, and methacrylic acid (CAS Reg. No. 870465-08-0).	As an oil and grease resistant treatment for paper and paperboard employed either prior to the sheet forming operation or at the size press.	September 30, 2006
See http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/Notifications/ucm308462.htm.				