PLASTICS
INDUSTRY ASSOCIATION

April 4, 2022

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Docket No. FDA-2021-N-0403-0001; Comments on the Proposed Rule Regarding Food Additives: Food Contact Substance Notification That is No Longer Effective

Dear Sir or Madam:

The Plastics Industry Association (PLASTICS), through its Food, Drug, and Cosmetic Packaging Materials Committee (FDCPMC),[1] is responding to the Food and Drug Administration's (FDA) request for comment on its proposed rule, "Food Additives: Food Contact Substance Notification That Is No Longer Effective."[2] PLASTICS' members are committed to providing consumers safe food packaging materials. Our members fully support effective, safety-based regulations that protect public health and the environment without unnecessary interference with the marketing of safe food packaging. Many members of PLASTICS' FDCPMC rely on the Food Contact Notification (FCN) program to market their food-contact substances (FCSs) in the United States and will be directly impacted should FDA finalize this proposal.

FDA has proposed amending 21 C.F.R. § 170.105 ("*The Food and Drug Administration's (FDA's) determination that a premarket notification for a food contact substance (FCN) is no longer effective*") to provide itself new authorities for determining when effective FCNs may be revoked

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[1] PLASTICS was founded in 1937, as the Society for the Plastics Industry (SPI) and is the trade association that represents one of the largest manufacturing industries in the United States. PLASTICS' members represent the entire plastics industry supply chain, including processors, machinery and equipment manufacturers, and raw material suppliers. The FDCPMC is composed of PLASTICS members with particular interest and expertise in packaging for food, drugs, cosmetics, and related products. The Committee has cooperated with government agencies on regulatory issues concerning packaging since its formation in 1957 and has provided meaningful input on every major regulatory action regarding food-contact substances since the Food Additive Amendments were enacted in 1958.

[2] *Food Additives: Food Contact Substance Notification That Is No Longer Effective*, 87 FR 3949 (Jan. 26, 2022).

based on reasons other than safety or public health. These new authorities include: (1) a determination that the FCN is no longer effective if FDA staff determine that the manufacturer is no longer marketing the FCS; (2) the authority to promulgate new Agency-initiated food additive regulations that would revoke and replace effective FCNs; (3) creating a process whereby manufacturers may provide input to such FDA revocation decisions; and (4) clarifying the public availability of information FDA relied on to make these decisions.

These new authorities are not necessary to the well-grounded aims of the proposal and unnecessarily complicate the matter. What should have been a simple amendment to add clarity to the regulations became a complicated proposal that muddled the original purpose of making the change. There has been a lack of clarity over the last 22 years of the FCN program regarding the status of an FCN after a manufacturer/supplier notifies FDA of its intent to withdraw products from the market that are the subject of such an FCN. PLASTICS members recognize that benefit may be obtained by amending Section 170.105 to clarify the status of an FCN following a manufacturer's notification to FDA of this intent to withdraw such products. FDA's proposal should simply make clear that manufacturers/notifiers control their own FCNs unless FDA identifies a safety concern. Such an amendment would protect the ability of the manufacturer/supplier of an FCN to remove products that are the subject of an effective FCN from the market for any reason while also providing FDA and the public with assurance that withdrawn products that are re-introduced to the market remain safe for the intended use. FDA's proposal, however, creates a process that would allow the Agency, at its own discretion, to collect information to support decisions to revoke FCNs without proposing specific criteria or standards that assure fair and consistent treatment for all manufacturers and suppliers with effective FCNs and without connecting this new proposed authority to an identifiable safety or public health benefit. The process proposed also requires expenditure of Agency time and resources on matters that pose no safety concerns. PLASTICS members are concerned that fair and unbiased administration of the regulations as proposed would be unlikely because the proposed actions are detached from a safety or public health reason.

PLASTICS members provide below a very simple proposal that clarifies the status of an FCN following a manufacturer's notification to FDA of their intent to withdraw products from the market that are the subject of effective FCNs. Specifically, it is proposed that re-introduction of the FCS into the market for the same use would require submission of a new FCN. A new FCN is needed under these circumstances to evaluate the safety of the proposed use considering possible new dietary exposures and/or safety data that may have become available during the market withdrawal. Such a requirement would involve no action or resource expenditure on the part of the Agency consistent with Congress' intent for the FCN program that the Agency not devote time and resources to matters that present little opportunity for safety concerns.[3]

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[3] *See, e.g.,* S. Rep No. 105-43, at 48 (1997), "*A premarket notification system for food contact substances would improve allocation of scare agency resources by allowing the agency to reduce the resources spent on reviewing low-risk food additives, including most food contact substances. This most efficient use of resources will allow the Agency to focus on premarket review of those additives with the greatest potential for risk to consumers*."

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Background

Congress amended the Federal Food, Drug, and Cosmetic Act (FFDCA) in 1958 to require premarket approval of food additives (sections 201(s), 402(a)(2)(C), and 409 (21 U.S.C. 321(s), 342(a)(2)(C), and 348)). The new Section 409 defined a safety standard for food additives and a food additive petition process by which food additives may be shown to be safe. The food additive petition process requires the petitioner to show that the intended use of the food-contact substance is safe within the meaning of section 409(c)(3)(A) of the FFDCA. The Agency was required to review the petition and publish an order in the Federal Register either including a regulation that lists the conditions of safe use for the food additive or denying the petition and providing the reasons for the Agency's denial.

The Food and Drug Administration Modernization Act (FDAMA, 1997) added paragraphs (h) and (i) to Section 409 of the FFDCA, thereby creating the FCN program. Paragraph 409(h) now requires manufacturers or suppliers of FCSs to notify FDA at least 120 days before placing their products on the market. This notification includes the manufacturer's safety assessment. FDA is now required to review the notification within 120 days and to notify the petitioner in writing if it concludes that the information in the notification does not support the manufacturer's determination of safety by the standard provided in Section 409(c)(3)(A). Nothing is required of FDA if they do not object to the notification. The notification is said to become effective if FDA does not object within the 120-day period and manufacturers may lawfully begin marketing their products on that basis.

Although any person may legally manufacture and market food additives in compliance with food additive regulations, a notification for an FCS is not effective for a similar or identical substance manufactured or prepared by anyone other than the manufacturer identified in the notification. Thus, additional manufacturers who wish to market the same FCS for the same use must independently notify FDA by filing their own FCNs.

Congress intended, with this amendment via FDAMA, to create a simple notification process for food-contact substances as an alternative to the food additive petition process *that requires no action by FDA to authorize the use of new food additives except in the case of an objection to the manufacturer's safety determination*. The proposal for FDA's implementing regulations for the FCN program states that this notification process "is to be the preferred process."[4] In fact, FFDCA Section 409(h)(3)(A) states that the petition process is available under only two circumstances: 1) the Secretary of Health and Human Services determines that the submission and review of a petition are necessary to provide adequate assurance of *safety* and 2) the Agency and the manufacturer or supplier agree that a petition may be submitted. These narrow bases for obtaining a regulatory clearance for an FCS demonstrate that Congress intended to create, and for FDA to use, a simplified notification

[4] *See* 65 Fed. Reg. 43270 (2000).

program that eliminated FDA's need to act, except in case of an objection to the manufacturer's safety determination, and not just to put a new time limit on FDA's review of food additives.

Title 21 C.F.R. § 170.105 implements Congress' intent in Section 409(i) of the FFDCA by providing a process by which FDA may determine that an FCN is no longer effective because it has demonstrated that new information indicates that the intended use of the FCS is not safe. This authority granted to FDA by Congress contrasts with the broad market control afforded to a manufacturer/supplier of an FCN, which may withdraw products that are the subject of an effective FCN from the market for any reason. FDA's January 26, 2022 proposal recommends amendment of 21 C.F.R. § 170.105 in two significant ways. Specifically, FDA is proposing to grant itself the following two new authorities for revoking effective FCNs:

1. FDA proposes to determine that an FCN is no longer be effective because FDA staff have determined that production, supply, or use of the FCS has ceased or will cease; and,

2. FDA proposes to determine that an FCN is no longer effective because the use of an FCS identified in an FCN is authorized by a food additive regulation or a threshold of regulation exemption.

FDA's January 26, 2022 proposal also intends to amend 21 C.F.R. § 170.105 to provide the manufacturer or supplier of an FCS that is the subject of an effective FCN an opportunity to provide input before FDA makes its determination that an FCN is no longer effective based on these two proposed new authorities. This opportunity to provide input is already codified in Section 170.105 in the case where the Agency determines that the authorizing FCN is no longer effective because new safety data demonstrate that the intended use of the food-contact substance is not safe.

Finally, the proposal aims to amend 21 C.F.R. § 170.102 ("Confidentiality of information in a premarket notification for a food contact substance (FCN)") to include information related to FDA's determination that an FCN is no longer effective based on these two new proposed authorities.

We provide our comments regarding these proposed amendments to the FCN regulations below.

1. FDA may not determine an FCN is no longer effective because production, supply, or use of the FCS has ceased or will cease.

This proposal explicitly states that its purpose is to grant FDA new authority to revoke effective FCNs for reasons other than safety. Specifically, the proposal aims to provide FDA with new authority to determine that an FCN is no longer effective because FDA staff have determined that production, supply, or use of the FCS has ceased or will cease. This proposed new authority reflects an FDA interest in regulating markets for food-contact substances for reasons distinctly different from assuring public safety.

Section 409(h)(2)(a) of the FFDCA explicitly limits the basis of any FDA objection to an FCN within the initial review period to a determination that the use of the food-contact substance has not been shown to be safe under the standard described in subsection (c)(3)(A).[5] Congress did not explicitly provide FDA with broader authority for revoking FCNs once they have become effective. Importantly, paragraph 409(i) states that food additive *regulations* promulgated under the provisions of Section 409 may be amended or repealed only by procedures that conform to the procedure provided in Section 409 for the promulgation of such regulations. This has long been understood to include conformance or non-conformance with the safety standard identified in Section 409(c)(3)(A). Consistent with that provision of law, 21 C.F.R. § 170.105 now provides that FDA must have data and/or other information available that demonstrates that the intended use of the FCS is not safe before it may determine that an FCN is no longer effective.

Any reasonable reading of the statute indicates that FDA's discretion to revoke already-effective FCNs is limited to the same safety standard applied to objecting to FCNs within the 120-day review period. This limitation on FDA's food additive review is consistent with the purpose of the FCN program, and the entirety of Section 409, generally – i.e., assuring the safe use of food additives.

Section 409(i) of the FFDCA does not provide FDA authority to publish regulations allowing Federal interference in markets for reasons that are outside of the scope of Section 409 itself. This inability for government agencies to promulgate regulations beyond the scope of the statute that the regulations are implementing is made clear in 5 U.S.C. § 706(2)(C), which governs judicial review of agency actions.[6] FDA's proposal has provided no explanation of a legal basis that would support such an expansion of authority via Agency regulation thereby not allowing the public to provide meaningful comment on the legal basis for this point.

Explicit, manufacturer-specific authorizations, such as effective FCNs, can have commercial value with potential to impact business acquisitions even when the production of the FCS may have been temporarily suspended. The proposal has not discussed the potential harm that a business unit may suffer as a result of FDA concluding that an FCS is no longer being marketed, nor has the proposal identified any public health benefits to justify such potential destruction of value or the expenditure of Agency time and resources on such matters.

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[5] The statute provides that an FCN shall become effective 120 days after receipt, "[…] unless the Secretary makes a determination within the 120-day period that, based on the data and information before the Secretary, such use of the food contact substance has not been shown to be safe under the standard described in subsection (c)(3)(A)[…]." 21 U.S.C. §348(h)(2)(a)(2020).

[6] The statute provides that the reviewing court should hold unlawful any agency action "in excess of statutory discretion, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C)(2020).

Importantly, this proposal describes no criteria by which FDA would apply the provisions proposed. Without proposing criteria to mark the limits of FDA's new proposed authority to revoke an effective FCN on these new bases, FDA staff will have no guiding principles that assure that all notifiers are treated in an equitable and fair manner and that Agency decisions are consistent. There is also no standard that a judicial review could apply in case of an appeal. Congress has provided an explicit safety standard in FFDCA Sec. 409(c)(3)(A) that a judicial review can apply in the case of a disagreement regarding safety.

Nevertheless, it is true that several manufacturers have notified FDA in the past of their intent to withdraw their food-contact substances from the market. Several of these withdrawals from the market were due to the availability of new safety data that was not considered during the initial FCN review. Although the manufacturer's market withdrawal eliminated any potential safety concerns by eliminating potential exposures, the FCNs authorizing the uses of these products nevertheless remained effective as long as FDA did not follow the process in 21 C.F.R. § 170.105 for determining that the FCN is no longer effective. There is little utility in FDA invoking the process now described in Section 170.105 for products that are no longer on the market and therefore can present no safety concerns.

Consequently, the status of an FCN after a manufacturer has notified the Agency of its intent to withdraw the FCS from the market might be clarified by amending 21 C.F.R. § 170.105. Such proposal would simply clarify that re-introduction to the market of the FCS for the same use would require submission of a new FCN. In keeping with Congress' intent to rely on the safety standard described in FFDCA Section 409, a new FCN is needed under these circumstances to evaluate the safety of the proposed use considering possible new dietary exposures and/or safety data that may have become available during the market withdrawal. We have proposed a simple amendment in Section 6 below that accomplishes this goal with no investment of time of resources by the Agency.

2. FDA may not determine an FCN is no longer effective because the use of an FCS identified in an FCN is authorized by a food additive regulation or a threshold of regulation exemption.

FDA is also proposing to give itself authority to determine that an FCN is no longer effective because it has determined that the use of an FCS identified in an FCN is authorized by a food additive regulation or threshold of regulation exemption. The proposal does not clearly state or explain that the agency has, for the duration of the FCN program, not accepted FCNs for review when the proposed use of the substance was the subject of a food additive regulation or threshold of regulation exemption [*see* 21 C.F.R. §170.100(b)(1) and (2)]. This proposal therefore would have no effect unless FDA were planning to conduct agency-initiated rulemaking for the purpose of making already-effective FCNs no longer effective. This aspect of the proposal was not made clear, so FDA cannot receive meaningful comment from the public on this point.

Certainly, there can be no safety-based reason for FDA to codify the safe use of an FCS in a food additive regulation that is already the subject of an effective FCN and then to initiate a process of revoking the FCN because it is now the subject of the newly promulgated agency-initiated rule. This

process runs counter to Congressional intent when FFDCA Section 409(h) and (i) were made law. Specifically, Congress recognized that the FCN process would provide the Agency with more information on the use of all food-contact substances in the food supply than the petition process and that these additional data would provide a benefit to public health. The Senate Report on Amendments to the FFDCA states:

> *FDA also is likely to receive more information on the use of all food contact substances in the American food supply since more manufacturers and suppliers are likely to submit PMN's than currently submit food additive petitions. In addition, the increased predictability will increase the incentive for companies to make FDA aware of new uses of food contact substances. As a result, the agency should have an improved data base to assess total exposure to food contact materials. These additional data will ultimately benefit the public health by providing FDA with more information on the identity and levels of food contact substances in use. FDA will then be able to more effectively monitor these substances and respond to any public health problems that may arise.*

Should FDA promulgate food additive regulations or issue threshold exemptions to replace effective FCNs, the additional manufacturer-specific information Congress considered to be important for FDA to collect would be lost to the Agency. New manufacturers would come to market without any notification to the Agency because any manufacturer may comply with a food additive regulation or threshold of regulation exemption without notifying the Agency whereas FCNs are effective only for the manufacturer identified in an FCN. Current manufacturers would be able to make significant changes to their manufacturing processes without notifying FDA of such changes.

When FDA first proposed regulations implementing the FCN program in July of 2000, the Agency recognized Congress' intent to differentiate it from the already-existing Food Additive Petition (FAP) program:

> *[U]nder the petition process, once FDA publishes an authorizing regulation for a specific use of a food additive, any person may legally manufacture and market the food additive for the approved use. In contrast, under section 409(h)(6) of the act, a notification for an FCS is not effective for a similar or identical substance manufactured or prepared by anyone other than the manufacturer identified in the notification. Thus, additional manufacturers who wish to market the same FCS for the same use must also submit a notification to FDA.*[7]

This was included at the very beginning of FDA's original proposal for the FCN program. The FCN process created benefits for industry and the Agency alike, as it provided a means for manufacturer/supplier-specific review of FCSs and gave the Agency knowledge of which food-contact

[7] 65 FR 43269, 42370-1 (July 13, 2000).

substances have entered the market, who manufactured such substances, and in what amount. These public safety benefits will be lost if this proposal becomes final as it is now contemplated.

This proposed provision also contravenes Congress' explicit requirement that the FCN process shall be used for authorizing the marketing of a food-contact substance except where the Secretary determines that submission and review of a petition under subsection (b) is necessary *to provide adequate assurance of safety*, or where the Secretary and any manufacturer or supplier agree that such manufacturer or supplier may submit a petition.[8]

Most importantly, this proposal describes no criteria by which FDA would apply the provisions proposed. Without proposing criteria to mark the limits of FDA's new proposed authority to revoke an effective FCN on these new bases, FDA staff will have no guiding principles that assure that all notifiers are treated in an equitable and fair manner and that Agency decisions are consistent. There is also no standard that a judicial review could apply in case of an appeal. Congress has provided an explicit safety standard in FFDCA Sec. 409(c)(3)(A) that a judicial review can apply in the case of a disagreement regarding safety.

Not only would this proposal unlawfully expand FDA's statutory authority and contravene Congress' purpose in creating the FCN program, it would also create undue burdens for industry. Supply chain assurance statements, safety assessments, and other compliance documentation commonly include references to FCNs by number. If FDA retroactively deems an FCN no longer effective on the non-safety-related bases proposed by FDA, the manufacturer/supplier will be forced to shoulder the consequences by changing compliance documentation, creating a great deal of confusion in the marketplace about the FDA status of a product and, perhaps, inadvertently calling into question the safety of the substance for no reason.

We recommend that the Agency re-publish the proposal removing the proposed new provision to determine an FCN no longer effective because it is the subject of a food additive regulation or threshold of regulation exemption. This provision contravenes Congress' purpose in having FDA collect manufacturer-specific information on FCSs. Should the Agency disagree, we recommend that the Agency re-publish the proposal providing clarity on the Agency's intended use of this provision and describing the limits and criteria that FDA would use when applying this self-granted authority so that the public can have opportunity to comment on these important aspects of this proposed FDA rulemaking.

3. Manufacturers/suppliers may withdraw products covered by FCNs from the market for any reason

By contrast to the restraints placed upon the Agency's authority (*i.e.*, review on safety grounds only), because an FCN is unique to the manufacturer/supplier, it is entirely appropriate for a manufacturer/supplier to withdraw a food-contact substance from the market at its sole discretion for

[8] *See* FFDCA Section 409(h)(3)(A).

any reason. FCNs confer rights and responsibilities solely to the manufacturer/supplier, and it is the manufacturer/supplier's obligation to market the FCS according to the conditions of use described in the FCN and all applicable regulations. Since this individual clearance is voluntarily sought by the manufacturer/supplier, it is entirely appropriate for the manufacturer/supplier to voluntarily withdraw the FCN and dispose of the clearance if it so desires.[9] It is not appropriate for FDA to make such determination absent a safety concern.

Other unique notifications or government programs that permit a certain material or activity explicitly acknowledge the notifier's right to withdraw a previously reviewed product from the market. One example of a government program that permits an applicant to voluntarily cancel its registration for a product or a use of a product is the pesticide registration program under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Cancellation of a FIFRA registration may be initiated by the applicant at any time under Section 6(f) of FIFRA. Section 6(f) does not provide specific bases for voluntary cancelation of a FIFRA registration, so it follows that a FIFRA registration may be canceled by the applicant for any reason. It is not appropriate for manufacturers/suppliers of FCSs covered by effective FCNs to be constrained by FDA in their business decisions.

4. FDA already offers an opportunity to provide input before FDA makes its determination that an FCN is no longer effective based on safety.

The opportunity for a manufacturer to provide input prior to an FDA determination that an FCN is no longer effective is already codified in § 170.105 where the Agency determines that the authorizing FCN is no longer effective because new safety data demonstrate that the intended use of the food-contact substance is not safe. The problem intended to be solved by the amendment to Section 170.105 is the uncertainty in FCN status that arises when a manufacturer/supplier withdraws products subject to an effective FCN from the market. This uncertainty may be resolved very simply without relying on new authorities, or any specific action by the Agency, as described above. In the absence of FDA granting itself additional authority, the additional opportunities for providing input proposed by FDA are unnecessary because Agency action would be unnecessary.

5. No changes are required to information related to FDA's determination that an FCN is no longer effective as releasable in § 170.102.

PLASTICS does not object to the information that is releasable under the Freedom of Information Act listed in 21 C.F.R. § 170.102(e) ("Confidentiality of information in a premarket notification for a food contact substance (FCN)"), provided that FDA's authority to determine that an FCN is no longer effective is limited to the safety basis provided to it by Congress. The uncertainty in FCN status following a manufacturer's notification to FDA of their intent to withdraw from the market

[9] Legal authority supporting the manufacturer/supplier's ability to withdraw an FCN may arise from FFDCA §348(h)(1), stating that such companies "may" file an FCN if they so choose. Since the filing is voluntary from the outset, withdrawal should be permitted.

may be resolved very simply without relying on new authorities, or any specific action by the Agency as we have proposed with new item (e), below. No new information would be provided to the FCN file beyond the manufacturer's notice to FDA of market withdraw because no action by the FDA is required. Therefore, no new amendments 21 C.F.R. § 170.102 ("Confidentiality of information in a premarket notification for a food contact substance (FCN)") are warranted.

6. Proposed new item (e) to 21 C.F.R. § 170.105

PLASTICS members recognize that benefit may be obtained by amending Section 170.105 to clarify the status of an FCN following a manufacturer's notification to FDA of their intent to withdraw products from the market that are the subject of effective FCNs. We propose here a very simple amendment that provides such clarity.

Specifically, it is proposed here that re-introduction of the FCS into the market for the same use would require submission of a new FCN. A new FCN is needed under these circumstances to evaluate the safety of the proposed use considering possible new dietary exposures and/or safety data that may have become available during the market withdrawal.

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER B - FOOD FOR HUMAN CONSUMPTION (CONTINUED)

PART 170 -- FOOD ADDITIVES
Subpart D - Premarket Notifications

Sec. 170.105 The Food and Drug Administration's (FDA's) determination that a premarket notification for a food contact substance (FCN) is no longer effective.

(a) …

(e) If, for any reason, a manufacturer or supplier of a food-contact substance notifies the FDA in writing of its intent to cease introduction into interstate commerce and delivery for introduction into interstate commerce of any food-contact substance that is subject of an effective FCN, a new FCN will be required before the FCS may be re-introduced into interstate commerce.

Such amendment clarifies the present uncertainty regarding the status of an FCN for which FDA has received a notice of market withdraw without attempting to use authority that is more expansive than the safety standard in FFDCA Section 409 itself. Importantly, this simple proposed item (e) would clarify the status of the FCN with no action or resource expenditure on the part of the Agency consistent with Congress' intent for the FCN program that the Agency not devote time and

resources to matters that present little opportunity for safety concerns.[10] New item (e), as proposed here, is far more efficient with respect to FDA time and resource expenditure than the process proposed by the Agency and is therefore also more in line with FDA's authority under section 21 USC 371(a), which provides the Secretary authority to promulgate regulations for the *efficient* enforcement of Title 21 USC Chapter 9.

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We appreciate this opportunity to comment on this proposed rule and wish to continue to work with FDA to ensure that food packaging is safe. If you have any questions or concerns regarding this letter, or if we can provide additional information regarding any of our comments provided above, please do not hesitate to contact us.

Cordially yours,

Devon Wm. Hill

Brennan Nesvacil

[10] *See* FN 3 above.