October 27, 2023

Submitted electronically via regulations.gov

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Modernizing Food and Drug Administration Recalls Listening Session (FDA-2023-N-2393)

Dear Sir or Madam:

FMI-The Food Industry Association (FMI) appreciates the opportunity to comment on recall modernization and U.S. Food and Drug Administration's (FDA) "Public Meeting: Modernizing Recalls of FDA-Regulated Commodities." We are pleased that FDA is seeking stakeholder input on the recall processes. We encourage the agency to continue to work with multiple stakeholders as you work through the process of updating systems, processes and policies related to recalls of FDA regulated products.

As the food industry association, FMI works with, and on behalf of, the entire industry to advance a safer, healthier, and more efficient consumer food supply chain. FMI brings together a wide range of members across the value chain — from retailers that sell to consumers, to producers that supply food and other products, as well as a wide variety of companies providing critical services — to amplify the collective work of the industry. Read more about us at www.FMI.org.

Three Common Factors are Necessary for an Efficient and Effective Recall System – Transparency, Collaboration, and Communication

- Transparency – information needs to be available, the policies known and consistently applied.
- Collaboration – collaboration between all stakeholder groups is necessary for effective recall execution.
- Communication – a high level of clear and accurate communication is needed for all stakeholder groups. Delays, confusing or ambiguous language hinder effective recall communication.

FMI comments will focus on two general categories –

1. **FDA Regulatory Processes, Procedures, Compliance and Administrative Issues Recommendations: Specifically, FDA should**
   - Align the FDA Reportable Food Registry (RFR) and FDA recall coordination process.
   - Utilize current mandatory recall authority as Congress intended.
   - Classify recalls quickly to prioritize class I recall execution.

2. **Industry and Consumer Processes and Communication**
   Business to business communications are efficient and often faster than regulatory communications. Consumer communications are highly variable and need to remain flexible to account for the multiple variabilities in recalls yet provide consumers with the information needed to protect public health.

FDA Regulatory Processes

We do not think that changes are needed to 21 CFR §7 unless it is determined that changes are needed to the classification system or methods of communication. Sections 21 CFR §7.45, §7.49 and §7.84 all reference telegrams and do not mention electronic communications.

For the most part, the regulatory text is general and the issues the industry has identified relate to the application of the regulation in written or unwritten policies. We think that FDA and stakeholder groups can modernize recalls by updating systems and policies without changing the regulatory language.

Integrate Reportable Food Registry and Recall Coordinators to Streamline Recall Management

FDA should start the process of modernizing recalls by updating FDA systems to allow for easy sharing of information. At the current time, the Reportable Food Registry (RFR) system is completely separate from the recall coordinators in the divisions. The RFR and recall systems present a clear example of an integration challenge that creates issues for FDA as well as the regulated industry. Integrating the RFR with the recall system would allow divisions to address recalls more consistently. There are multiple opportunities to include seamless communication tools between collaborating departments and agencies.

For industry to report a problem to the FDA, the establishment must enter information into the RFR and if the event turns into a recall, they must separately provide the same information to the recall coordinator. The industry is required to submit the same information multiple times to multiple different offices within FDA, as well as to other public health agencies such as state agencies. The agencies should be able to share information and access the same information submitted once by the industry to FDA. The initial RFR notification occurs before many details

are known. There should be a process to provide additional or updated information to the RFR portal which should then be available to all regulatory officials needing the information. The industry sees the RFR as the required step in notifying the agency of a public health issue. We do not see coordination between the RFR and the recall coordination teams. We strongly believe that FDA should coordinate and streamline that process inside the agency.

Information should also be shared with other public health agencies working to protect public health. Duplicate requests from multiple agencies take time away from executing the recall, results in delays and increases the chance of inaccurate information or mistakes in conveying information. Integrating these systems and facilitating information sharing would streamline the process and establish a more efficient and effective recall process.

Federal and State Agency Coordination

Many recalls involve multiple agencies at the state and federal levels. It is essential for all stakeholders to have a comprehensive understanding of what happened or is happening throughout the recall process. Establishments are required to provide the same information to multiple agencies because the agencies do not have the ability to share information with one another. We encourage seamless communication and coordination between public health agencies with authority over food recalls.

FDA should use Mandatory Recall Authority

Industry works diligently to comply with all local, state and federal regulations. When the Food Safety Modernization Act (FSMA) was working its way through the legislative process, there was broad support for providing FDA with mandatory recall authority to remove products that could be harmful to consumers. We encourage FDA to use the authority Congress granted the agency and work to remove adulterated products. In over a decade, FDA has only used mandatory recall authority on rare occasions (we found three examples).

On August 16, 2023, FDA issued an advisory for pet food products because certain lots tested positive for *Salmonella.* On October 12, 2023, FDA expanded the advisory to include an additional lot that tested positive for *Salmonella*. FDA has recommended the manufacturer recall the products and notify the public.[1] To date, the firm has not recalled any of the affected product lots of product manufactured in 2023 despite product testing positive for *Salmonella*. With mandatory recall authority provided by Congress in 2011, we expect FDA to use the authority to remove adulterated products from the market.

[1] https://www.fda.gov/animal-veterinary/outbreaks-and-advisories/fda-advisory-do-not-feed-certain-lots-darwins-natural-pet-products-dogs-cats-due-salmonella

Timely Recall Classifications are Essential
The regulatory process should not slow down the removal of products from sale, nor prevent consumer communication of recalls. The classification of a recall is critical to determining how that recall will be communicated internally and externally. Industry recall procedures are dependent on the recall classification. Classifications are also important and determine the speed at which products will be removed from commerce. Slow or delayed recall classification can lead to further delays in recalling food and removing the recalled food from commerce. There are multiple examples of recall classifications taking over a month.

The industry responds to recalls based on the classification or expected classification. In general, class I recalls are acted upon immediately, within a few hours. Most FMI members report that in the case of class I recalls, product is removed from sale within two hours of notification from the supplier. Class II recalls are typically prioritized but in general, the timelines are not as urgent for product removal. Due to consistent delays in classifying recalls, the industry has resorted to predicting the class of the recall. There are also examples of classifications being changed after initial classification, which causes additional confusion in the industry and for consumers. We encourage swift and predictable recall classifications for all FDA regulated product recalls.

We are also concerned about exceptions relating to classifications. We have been seeing more class II recalls that are required by the recall coordinators to provide public notification. If a recall needs to be communicated to the public, we believe that it should be a class I recall. We are also concerned about recalls in which the division has asked for notification in a specific manner or on a particular social media platform.

Opportunity to Utilize Technology to Assist with Classification
Given the volume of data available and the tools used to classify recalls, we think this is an area that would be appropriate for FDA to use predictive analytics or even machine learning to assist in recall classification. Technology tools could standardize decisions as well as reduce the time necessary to classify recalls.

Effectiveness Checks
Effectiveness checks vary across divisions and agencies (federal, state or contractors) and are often burdensome to industry from a labor, time and administrative point of view.

A recent example of a recall with multiple challenges was during the 2022 infant formula recall and outbreak. Effectiveness checks began almost immediately and were performed by multiple agencies. Some establishments were contacted by multiple different agencies with requests for the same information while the industry was working to accurately execute a large and

challenging recall. With limited resources, these duplicative requests are very burdensome to the industry.

The FDA Regulatory Procedures Manual (chapter 7)[2] is one resource intended for FDA staff but is available for the industry to utilize in the planning process and the manual provides flexibility on effectiveness checks and recall audit checks. There are also multiple other resources from the agency on recalls and some are regulatory, and some are guidance or other documents. Overwhelmingly, the issues the industry encounters are with the interpretation of the procedures and inconsistent requests from FDA divisions.

Delayed effectiveness checks are also problematic because stores are approached and asked for records months after a recall was initiated and acted upon. The FDA Regulatory Procedures Manual (chapter 7), cites several factors for not doing a retail audit check (RAC), including factors such as "all the recalled product is expired or past shelf life" and "the recall was completed before the FDA was made aware of it, and due to the length of time since products were available, RACs are not likely to be beneficial." Despite these factors, members state receiving requests for RACs months after a recall has been completed or months after the expiration of a product shelf life.

FMI urges FDA to provide clarity to the industry on what to expect when third party contractors are used for effectiveness checks as well as share information about the third-party contract company who will be collecting the data. With concerns about security, the industry is very hesitant to provide information to unconfirmed organizations and unfortunately, there have been incidents with individuals pretending to represent government officials. Clarity to the industry in advance would be helpful.

Due to changing practices of businesses, a wide range of communication tools could be effective including phone and electronic communications. Not all retail stores have phones and not all retail stores have email. Often, stores are not permitted to communicate or share information over the phone. It is important to note that there is not a one size fits approach to conducting an effective audit check. The regulatory procedures manual is vague on what method should be used when for conducting effectiveness check and the tools used for communication should be consistent with common communication tools with some level of flexibility to accommodate different types of establishments and different resources available.

We encourage FDA to consider what information is needed for effectiveness checks and how best to collect that information. Streamlining requests and procedures and making that

[2] FDA Regulatory Procedures Manual, Version 10 https://www.fda.gov/media/71814/download

information known will facilitate information collection from retail establishments executing the recall. The disposition of the product should also be considered for the recall audit check. Consumers are often told to throw away the recalled product. When discarding product is in the instructions to a consumer, obtaining a count of product is irrelevant. We encourage FDA to consider appropriate disposition instructions given the type of recall and to make sure the audit checks are realistic and capture valuable information.

We should rethink effectiveness checks in light of information FDA needs to confirm or verify, and changes in industry practices in consolidation of records at a central or corporate office. Consider using a standard form, template, portal or other tool to facilitate information collection as well as simplify the process and eliminate duplicate requests.

Need for Consistency Across FDA Divisions and Offices

FMI urges FDA to implement consistent policies across divisions to make the agency's handling of recalls more consistent. Presently, different FDA Divisions may handle identical recalls differently, which is confusing to industry and makes it difficult for companies to understand FDA's risk assessment. Similar recalls have been classified differently, divisions have asked for specific information on products, and divisions have required different communications methods for notifications. The food industry reports different procedures as well as different policy interpretations in the FDA divisions.

We strongly recommend that FDA provide consistent policies to the divisions and calibrate training and enforcement actions. FDA should establish a process to monitor whether the agency is following the recall procedures and meeting the goals established. The Agency should develop performance goals and measures to assess the effectiveness of its recall process. We also strongly believe that there should be an oversight office with the authority to answer questions in a timely manner and establish an appeal process when there are inconsistencies in actions. There are many examples of differences between FDA divisions related to timing of response, classifications, recall audit checks and notification requirements.

Public Health Alerts are Confusing to Consumers

FMI supports efforts to help consumers access information about potentially unsafe, recalled food. We encourage FDA to initiate consumer research on the messaging used with Public Health Alerts and whether they achieve the desired outcome. When public health alerts are issued, the industry receives many questions from consumers seeking clarity on how they should respond to the alert. Given the number of inquiries received, the term is confusing to consumers who do not associate it with product recalls. Industry also sees recalls and public health alerts differently.

When the FDA issues a public warning without identifying the establishment associated with the incident, the industry as found that consumers will stop purchasing the entire product category as well as related product categories. These warnings also stoke fear in consumers that extends beyond the affected product and can last for a significant amount of time.

To ensure public warnings are meaningful to consumers and provide them with information that will equip them to avoid potentially unsafe products, FMI urges FDA to provide as much detail regarding the food's source and specific distribution as possible. FDA also should identify the specific impacted retailers in these warnings, whenever possible, to limit the scope of public concern. In addition, when possible while still protecting public health, FMI suggests that FDA avoid issuing public warnings/alerts that do not identify the supplier or source of the food in question. Adopting these guardrails will both improve the efficacy of public warnings and ensure that safe food is not wasted.

Published Retail Consignee Lists should be Dated and Properly Labeled

In the case of some recalls, retail consignee lists are published. The industry welcomes the opportunity to work with the FDA to ensure the information shared is accurate. The list does not typically contain any identifying information about the recall or the date the information was updated. This has been confusing to the industry and consumers when information is published without information and has resulted in information being used out of context. We ask that the FDA use standard document management tools when creating the documents. Retail consignee lists from FDA need to include a description or reference to the specific recall and a date should be on each page so the industry will know if they are referencing the most recent version of the retail consignee list. Additionally, we also recommend a process for correcting the information should it be published with inaccurate information.

Industry and Consumer Notification Processes and Communication

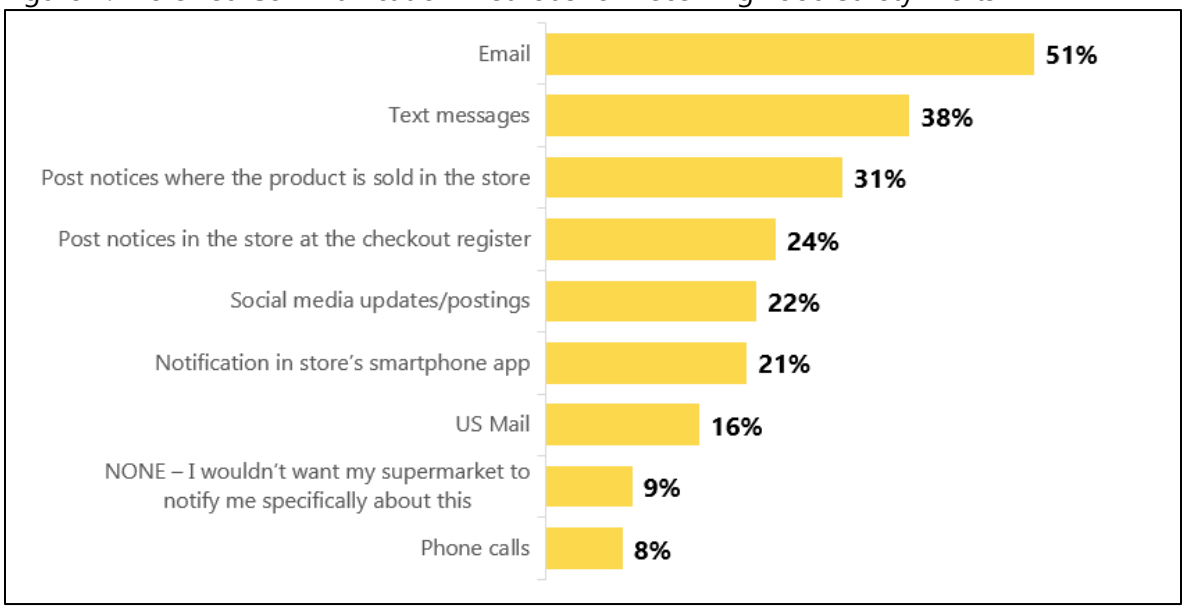
Consumer Notifications

Flexibility is necessary to permit the food industry to use the most effective approach(es) to communicate recall information as quickly and effectively as possible to consumers. To maximize the number of consumers reached, the appropriate communication method is dependent on multiple factors including, but not limited to, the following:

- Online vs brick and mortar store
- Use of technology in store and by customers
- Urgency of recall
- Control over product – is it still in distribution, can customers be contacted?
- Shelf life of product

Providing consumer notification without delay is imperative. Retailers often are able to alert consumers about a recalled product before FDA has posted the information on their website, Consumers rely on a variety of methods to learn about food recalls. Each year, FMI surveys consumers about many different issues applicable to the food industry. In this year's survey (2023), we included questions about recall notifications to obtain information regarding consumer preferences on how they want to receive information about recalls.

Figure 1. Preferred Communication Methods for Receiving Food Safety Alerts



Source: FMI U.S. Grocery Shopper Trends, 2023. n=2,105

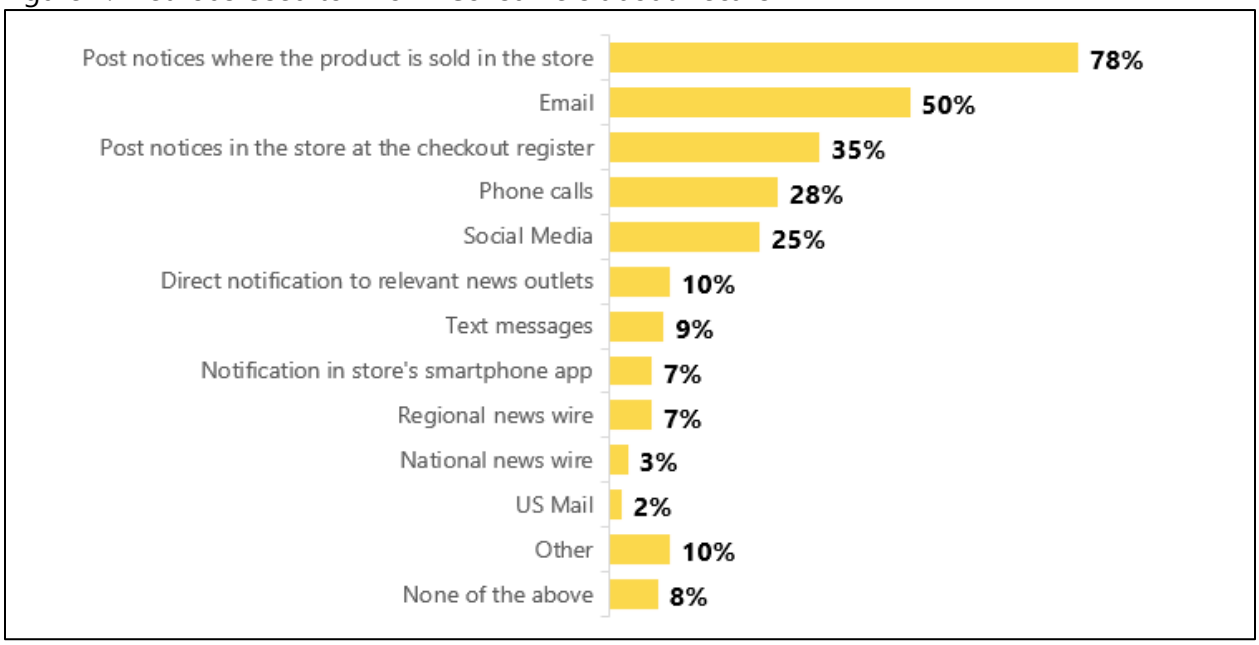
As visible in figure 1, the preferred communication method is email. However, with rapidly changing technology, email may not be the preferred communication method in five or ten years. A variety of methods are preferred by consumers. Flexibility in posting is needed to reach consumers depending on the type of recall, the scope, the type of store and the customers.

Retailers primarily receive product recall notification requests from their suppliers or manufacturers, usually before the information is provided by FDA or via the reportable food registry (RFR). In these situations, retailers take action within hours of initial notification to remove recalled products from store shelves, stop sales and hold products either at store level or at the distribution center or warehouse. Furthermore, retailers subsequently implement actions to notify consumers while preventing the sale of recalled products.

To reach the broadest audience, the food industry uses various methods to inform consumers about food safety recalls. These tools include electronic, in-store communication, and news

outlets, among others. According to FMI's *The Food Retailing Industry Speaks 2023*[3] report, retailers reported the use of shelf notices where product is sold in the store (78%) as their top in-store communication method, followed by checkout register notices (35%). Retailers using technology-driven forms of communication reported using email (50%) as the top method followed by phone calls (28%), social media (25%), text messages (9%) and store smartphone notifications (7%) (Figure 2).

Figure 2. Methods Used to Inform Consumers about Recalls



Source: The Food Retailing Industry Speaks, 2023.

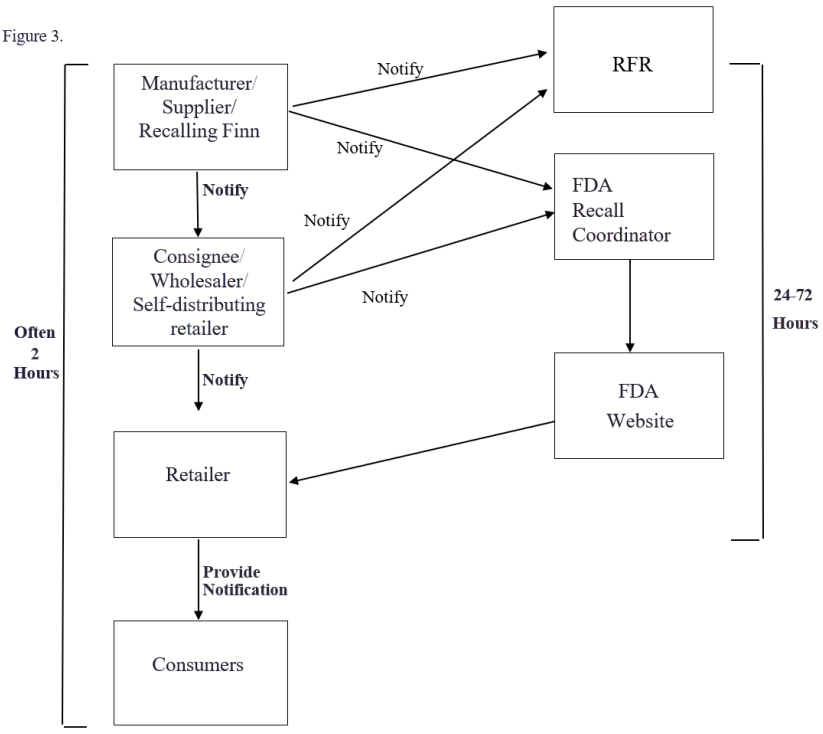
Depending on the circumstances, retailers will utilize multiple methods or use a different method of notification for different recalls. FMI members have used certain notification methods in circumstances where they were clearly advantageous over more traditional techniques such as posting a notice in a store. For instance, electronically contacting consumers who have purchased food via the Internet is often the best communication method choice because the retailer knows exactly what the consumer purchased and has reliable information to contact them, and because those consumers may never see a posting in a store location. Loyalty card programs may also provide retailers with a highly effective tool in notifying consumers.

[3] FMI, The Food Retailing Industry Speaks 2023 https://www.fmi.org/our-research/research-reports/food-retailing-industry-speaks

Industry Communications and Business to Business Communications

An overview of typical recall communication channels is below in figure 3. While retailers report learning about a food recall from their suppliers, increasingly, retailers report first learning about a recall from FDA or through a notification service, such as FoodTrack, rather than from the recalling firm. Consequently, the consignee must reach out to the recalling firm to make the determination of whether they are impacted. Even then, obtaining additional information is a challenge due to the timing of the recall (i.e., 5 p.m. on a Friday) or the corporate clearance process of the recalling firm. Consignees are responsible for carrying out the instructions set forth by the recalling firm (21 CFR 7.49 (d)) therefore receiving information is necessary to finalize the customer notification process. The lack of information often leads to confusion and retail consignees are often forced to take action based on their knowledge and experience in order to quickly remove recalled product from commerce. We recommend FDA clarify expectations with regard to timing of recall communication to consignees for consistency and to assure recalls are executed without delay.

Figure 3. Recall Communication – Information Flow



Press Release Language
Flexibility is needed when communicating recalls to customers to ensure the language in the press release doesn't minimize the gravity of a recall. We urge FDA to limit or prohibit the use of terminology that could misconstrue the importance of the recall notice and the necessity of the actions that should be taken with the recalled product to protect the consumer. Such terms include "out of an abundance of caution," "precautionary recall" or "this is a *voluntary* recall" and should not be permitted in recall communications.

FDA Should Alter Notification Requirements Depending on Control of Product in Supply Chain at Time of Recall
The location of the product should be considered in recall execution as well as recall communications. Has the product been distributed? Is shelf life over? In many instances, products are still in the supply chain and under the control of FDA regulated facilities. In these instances, control over the product should be considered by the FDA in the response and notification as well as communicated by the recalling establishment to supply chain partners and consumers (when necessary).

Recall Readiness
When planning recall preparation practices and evaluations such as mock recalls, consideration should be taken for the type of facility and the frequency with which they handle recalls. For example, retailers and wholesalers have weekly and even daily experience with executing recalls. With hundreds of recalls each year from both FDA and USDA regulated products, retailers and wholesalers have become experts in recall procedures and communications. We welcome the opportunity to work with the FDA to provide best practices in recall execution and recall communication.

Consolidation of Resources on FDA Recall Regulatory Policies and Documents Would Assist the Industry
The food industry would benefit from clarity from FDA on recall policies and having all relevant documents in one place. We can read the regulation and the Regulatory Procedures Manual, but each recall seems to be a case-by-case situation and the expectations and proper procedures vary significantly. If FDA could share the training for FDA staff and clarify the regulatory requirements for industry, that could improve the process significantly. Many requests the industry receives go beyond what is in the regulation and the foundation of the request is unclear. It would help the food industry if FDA organized its resources in one location. Knowing what to expect is a huge challenge.

Summary and Recommendations to FDA to Modernize Recalls and Act Quickly

1. Update and integrate FDA systems to capture RFR information and share with recall staff.
2. Provide a recall resource portal with all related recall regulations, guidance and documents.
3. Modify effectiveness checks to make them practical and also useful to drive improvement – it is not just a number.

Additional Documents and Resources on Recall Modernization

1. AFDO Recall Modernization: Accelerated Partnering for Effective Recalls (2022)[4]
2. STOP Foodborne Illness Alliance - Collaborative Plan to Achieve Consumer-Focused Recall Modernization (2022) [5]

We look forward to working with FDA on recall modernization efforts in order to ensure effective and efficient recalls. We appreciate your consideration in these comments and welcome any questions you may have.

Sincerely,

Hilary S. Thesmar

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[4] https://www.afdo.org/wp-content/uploads/2022/04/AFDO-Recall-Whitepaper-Executive-Report-4.22.pdf
[5] https://stopfoodborneillness.org/plan-to-improve-and-modernize-consumer-food-recalls/