December 5, 2019

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

Re: A New Era of Smarter Food Safety; Public Meeting, Request for Comments; Docket No. FDA-2019-N-4187

Dear Sir or Madam:

The Food Marketing Institute (FMI) appreciates the opportunity to provide comments on the Food and Drug Administration's (FDA's) development of its *Blueprint for a New Era of Smarter Food Safety*.

FMI proudly advocates on behalf of the food retail industry, which employs nearly 5 million workers and represents a combined annual sales volume of almost $800 billion. FMI member companies operate nearly 33,000 retail food stores and 12,000 pharmacies. FMI membership includes the entire spectrum of food retail venues; single owner grocery stores, large multi-store supermarket chains, pharmacies, online and mixed retail stores. Through programs in public affairs, food safety, research, education, health and wellness industry relations, FMI offers resources and provides valuable benefits to almost 1,000 food retail and wholesale member companies and serves 85 international retail member companies. In addition, FMI has almost 500 associate member companies that provide products and services to the food retail industry. For more information, visit www.fmi.org and for information regarding the FMI Foundation, visit www.fmifoundation.org.

FMI appreciates FDA's efforts to modernize its approach to protecting public health as the food industry and the various technologies it employs continue to evolve. The agency's document entitled *Food for Thought: Ideas on How to Begin a New Era of Smarter Food Safety*, detailing its current ideas and questions, was a helpful tool to stimulate our thinking on these issues. We have organized our comments into the four categories reflected in the Food for Thought document. Before presenting our more detailed comments, however, there are several key principles to highlight that are reflected throughout our comments.

- **Focus on Outcomes:** FDA's efforts to modernize protection of public health should focus on desired outcomes, rather than prescribing particular technologies or standards. By focusing on outcomes, FDA will provide the flexibility for businesses to adopt methods of achieving those outcomes that are best suited to their organization. This approach also will

allow for further innovation and technological development and prevent the agency's efforts from becoming outdated.

- **Leverage Existing Tools:** While FMI supports exploring whether there are new tools that could be developed to facilitate prevention, we also encourage FDA to take stock of existing tools and resources. This review should consider how existing resources could be enhanced to address developing needs, as well as where gaps exist that may require new tools.

- **Increase Communications with Stakeholders:** FDA's *Blueprint for the New Era of Smarter Food Safety* presents numerous opportunities for FDA to invigorate its communication with stakeholders. We encourage FDA to consider the ways in which it can be more transparent in its actions, as well as how it can engage stakeholders to collaborate on addressing issues of public health concern. We commend FDA for its stakeholder outreach through the public meeting and docket on A New Era of Smarter Food Safety.

- **Account for the Food Industry's Variable Resources and Abilities:** The food industry is quite diverse, made up of companies of all sizes, resources, and abilities. As it considers how new and emerging technologies can be used to promote food safety, FDA should take into account the burden those technologies will place on individual businesses and ways to lessen this burden. FDA also should ensure any additional costs imposed on the industry are balanced across the food chain, rather than falling on any particular sector.

- **Uniformity Will Promote Success:** One of the primary ways of promoting food safety is through uniformity—for example, of agency communications, inspections, and state implementation of the FDA Food Code. By striving to enhance uniformity in these areas, FDA can mitigate confusion and allow greater focus on addressing food safety concerns.

Our more detailed comments follow.

Tech-enabled Traceability and Foodborne Outbreak Response

At the outset, we want to encourage FDA to carefully adhere to the statutory limitations regarding traceability that were established through Section 204 of the FDA Food Safety Modernization Act. Congress deliberately codified several meaningful restrictions on FDA's ability to mandate additional traceability requirements, and it is incumbent for the agency to follow the Congressional mandate. Among them, new requirements can only apply to high-risk foods (based on foodborne illness data, the likelihood that a particular food has a high potential risk for contamination, and steps taken during manufacturing to reduce the likelihood of contamination). Additionally, Section 204 provides that FDA shall not (1) prescribe specific technologies for the maintenance of records, (2) require a full pedigree, or record of the complete previous distribution history of the food from the point of origin of such food, (3) require records of recipients of a food beyond the immediate subsequent recipient of such food, or (4) require product tracking to the case level. We also think it would be premature for FDA to consider requiring additional traceability requirements beyond the scope of the statute given that Section 204 has not yet been implemented.

With that framework in mind, below we respond to FDA's ideas related to technology-enabled traceability, as well as the agency's thoughts on enhancing responses to foodborne illness outbreaks.

- **Traceability Should Be Simple:** We urge FDA to keep traceability simple so as to facilitate broad adoption and compliance. When implementing FSMA section 204, we recommend that FDA identify just the key data elements that are critical to tracking food, and then focus on ensuring these elements are captured throughout the food supply chain and for all types of food covered by the new regulation. Focusing on a discrete number of data elements will help ensure technologies are able to communicate with one another and facilitate higher rates of adoption. On the other hand, maintaining too many data elements can be overly complicated, cause confusion and decrease compliance, and risk detracting from the ability to trace quickly to protect public health.

  FMI has compared the key data elements in several leading traceability systems and identified the following commonalities, which could be a basis for deriving the key data elements:
  - GTIN or unique company identifier and unique product identifier;
  - Lot/batch identifier;
  - Origin location and trackable date, if not in lot/batch;
  - Date and time stamps of key events (i.e., shipping, receiving, transforming); and
  - Quantities of product shipped/received.

  FDA could consider engaging in a similar comparison exercise, which we expect would likely net out on the same elements.

- **Traceability Should Be Flexible:** Consistent with FSMA section 204, FDA should not prescribe use of a particular technology. Instead, FDA should articulate what needs currently are not being met by industry, as well as its desired outcomes and goals. From there, FDA should provide entities covered by the new rule with the flexibility to adopt whatever technologies are needed to achieve those outcomes. By focusing on outcomes and not specific technology, FDA will avoid creating requirements or expectations that quickly become outdated as technology continues to evolve at a fast pace. This approach also will enable covered industry members to choose the best methods for their business for achieving the desired outcomes.

- **Interoperability**: The FDA should plan for interoperability of systems and communication between different systems that exist now and in the future. Interoperable systems have the ability to exchange and interpret shared data.

- **FDA Should Consider Firms' Varying Resources:** We encourage FDA to remain mindful that businesses have significantly varying resources available to adopt new technologies. FDA should take into account the burden that adopting traceability would have, for example, on an entity that sells many different SKUs (e.g., a grocery store) compared to a company with operations only in one product category. Additionally, FDA also should consider who will be responsible for maintaining traceability data, the costs associated with storing that information, and how the cost of generating and storing this data can be balanced across the supply chain.

- **FDA Should Enhance its Outbreak-Related Communications with Industry:** We appreciate that FDA is considering how to leverage industry insights to enhance foodborne outbreak response. To that end, we urge FDA to communicate earlier and more frequently with industry when it is conducting an outbreak investigation. Industry often has insights into what is happening in the supply chain, buying and selling patterns, and food chain distribution that can be helpful to FDA as it conducts its investigation. We encourage FDA to engage in open and transparent communications with industry as soon as it begins an investigation to

help identify and address the root cause more quickly. At the same time, however, we urge the agency to be careful to avoid causing public concern about a particular food, commodity, supplier, or region until the agency has completed its outbreak investigation.

Once there is a known outbreak, however, it is helpful for retailers to become aware of the issue before FDA distributes the information more broadly, when possible. The earlier retailers have the information, the sooner they can pull affected product from store shelves. We therefore suggest that FDA notify retailers once it has made a decision to communicate with the public and is in the process of finalizing the public communication. FMI would be pleased to work with FDA to help facilitate broad, swift communication within our sector.

FDA Should Handle Recalls More Consistently: FMI encourages FDA to use a combination of technology and internal policies to make the agency's handling of recalls more consistent. Presently, different Districts may handle a virtually identical recall differently, which is confusing to industry and makes it difficult for companies to understand FDA's risk assessment. FDA is inconsistent with recall classifications. Recalls involving the same hazard (e.g., undeclared soy allergen) may be classified as a Class I recall but other times may be classified as a Class II recall. FDA is also inconsistent in the time it takes to classify a recall across divisions and from recall to recall. Obtaining recall classification is essential for determining disposition of recalled product.

We suggest that FDA could ensure the Districts address recalls more consistently by aligning its technology (e.g., aligning the Reportable Food Registry (RFR) with the recall system). For a recalling firm, information is entered into the RFR and if the event turns into a recall, the division recall coordinator then asks for the same information again. It would be helpful if FDA's systems talked to each other and were integrated. We find that the more frequently data is entered, the more mistakes are made. FDA also could review its internal policies to ensure that recall procedures are standardized across Districts. Finally, we agree with the Association of Food and Drug Officials' public comments that there needs to be greater alignment among state and federal regulators during recalls, so as to expedite market actions and reduce confusion. Similarly, we also encourage FDA to share and make RFR information available to state and local regulatory agencies to streamline the process and avoid entering information into multiple systems.

- **FDA Should More Clearly Define its Food Safety Communication Tools:** We encourage FDA to define what constitutes a consumer advisory or a public health alert, as well as the actions FDA takes when issuing a consumer advisory or public health alert in the absence of a recall. Having a better understanding of these types of communications and when they are used will help industry work with supply chain partners to develop a process for responding in order to protect public health.

- **FDA Should Improve the Quality of Recall Information Shared:**
  FDA recently started sharing retail consignee information for recalls. That information is typically shared via pdf that is linked to the recall notice. The pdf does not typically contain any identifying information about the recall or the date the information was updated. This has been confusing for some when the information was used out of context. We ask that the FDA use standard document management tools when creating the pdf documents so that the recall is identified, and a date is on the document so the industry will know if they are looking at the most recent version of the retail consignee list.

- **FDA Should Ensure Recall and Outbreak Communications Are Accurate and Provide Meaningful Information:** We also encourage FDA to ensure that any recall or outbreak communications issued to the public are accurate and complete. A public notification is more useful if it is accurate and complete than if it is issued faster and then must subsequently be corrected. We also encourage FDA to consider how these communications can provide more consumer-relevant information, such as conveying to the public the level of risk associated with an event. By putting the public health risk into context, the agency can help assure that consumers have access to safe food.

Smarter Tools and Approaches for Prevention

FMI supports FDA's focus on new tools and platforms to inform the agency's prevention efforts. Just as FSMA is focused on preventing food safety outbreaks, so too should FDA's *Blueprint for the New Era of Smarter Food Safety* focus on modernizing FDA's approach to preventing outbreaks.

- **Prevention Tools Should Be Flexible:** In considering how FDA can foster the adoption of smarter tools for prevention, the agency should begin by focusing on its desired outcomes. FDA should articulate its goals and then allow industry the flexibility to choose the tools it needs to satisfy those goals. Specific technologies should not be mandated. As is also the case with traceability technology, this flexibility will accommodate future technological developments.

- **FDA Should Consider the End User:** When considering the tools it can invest in to promote prevention, including existing tools, FDA should collaborate with stakeholders on the types of information that would be helpful to the stakeholders and then consider how stakeholders will use the information. For instance, FDA's new Data Dashboard is a terrific resource and provides helpful information for industry but could be improved to be more user friendly. The Data Dashboard groups food and cosmetics together and requires users to go line-by-line to separate food from cosmetics. Additionally, it would be more helpful for data to be grouped by event, rather than by product. Finally, the Data Dashboard could be made even more useful if it aggregated information on recalls, rather than providing links to the FDA website. FDA also could consider conducting pilot projects when it rolls out new programs, similar to FDA's roll out of the Food Defense Plan Builder 2.0, so that the tool reflects input from potential users.

- **FDA Should Use Predictive Tools to Target Inspections:** We agree with FDA that the use of predictive tools and data can be used to promote prevention. In particular, we suggest that FDA could use predictive data to tailor its inspection efforts and focus on the highest risk operations.

- **FDA Should Communicate Conclusions of its Root Cause Analyses:** FMI supports FDA's consideration of methods to enhance how the findings of root cause analyses are reported and communicated. While we think there would be benefit to FDA sharing more information with industry throughout the entire investigation process, we encourage FDA to focus on ensuring that root cause analysis findings are routinely communicated to industry. This information is important so that industry can focus on addressing the identified risks in the future. When appropriate, FDA also should provide targeted advice to industry, such as

recommendations of potential Food Safety Plan lapses that could warrant reanalysis across a particular product sector (e.g., informing industry that they should be sure to consider a specific hazards in their hazard analysis, which may not previously have been known to be of concern). Sharing such information could help prevent similar events from reoccurring in the future.

- **FDA Should Facilitate Information Sharing by Industry**: We encourage FDA to consider the ways in which the agency and industry can share environmental assessments and root cause analyses with each another in a non-regulatory setting. In other words, industry should be encouraged to participate in environmental assessments and root cause analysis investigations and share their findings with FDA without the fear of penalization. Findings of outbreaks should be published so that the industry can use the information to improve hazard-based food safety plans and prevent future contamination events.

- **FDA Should Hold Monthly Meetings with Industry Stakeholders:** FMI encourages FDA to establish a forum for more regular communication with industry, similar to the U.S. Department of Agriculture (USDA) Food Safety and Inspection Service's (FSIS's) monthly industry stakeholder meeting/call. At these meetings, FSIS discusses issues such as ongoing foodborne illness outbreaks, forthcoming regulatory actions, laboratory method changes and includes an opportunity for stakeholders to ask FSIS leadership questions. FDA could meet with stakeholders monthly to provide continuous updates on outbreak signals, ongoing outbreaks, and any other information that industry could implement into its own prevention approaches.

- **FDA Should Leverage Existing Communication Tools**: FDA states it is considering an app for alerting consumers of recalls and outbreaks. We encourage the agency to use its existing tools, rather than developing new ones that may not be as effective. For example, emails from Food Track generally are issued more quickly than an FDA recall or other notification and may be faster than an app that would require considerable stakeholder adoption to be effective.

- **FDA Should Consider the Costs of New Technologies on Industry:** The *Ideas* document discusses development of scannable labels and associated apps to give product information through the supply chain and information on recalls/outbreaks. We question whether the benefits of this technology would counterbalance the considerable costs it would impose for many companies.

New Business Models and Retail Modernization

FMI supports FDA's evaluation of new and emerging business models and the potential need to address new risks associated with these models. We encourage FDA to apply existing regulatory tools to these models, where possible, and focus any new efforts on just those areas where there are gaps in oversight or proven risks in new business models.

- **Regulation of New Business Models Should Be Risk Based:** We appreciate FDA's foresight in considering how the agency should adapt its regulatory approach in light of new and emerging business models. We strongly encourage FDA to take a risk- and data-driven approach to the regulation of new business models. FDA should focus its resources on areas where there are data supporting the presence of a public health risk, and it should evaluate new business models to determine whether existing regulatory controls are adequate. Where

no risk exists, we discourage FDA from imposing additional regulation that could hinder innovation and will not add benefits for public health.

- **Regulation of New Business Models Should Be Flexible:** Where data indicate there is a need for agency regulation, we encourage FDA to adopt commonsense regulatory frameworks that are flexible and will accommodate future innovation. To the extent FDA considers it necessary to regulate the cold chain for e-commerce, we suggest that FDA do so by focusing on the facility where the food originated (e.g., the entity subject to existing FDA or FSIS regulations, as applicable) and applying the existing regulations in place.

  Business models are rapidly changing and any regulatory framework should be broad in nature or have the ability to be flexible to adapt with business practices. For example, there are business models today in which a delivery service is arranged by the consumer and the service provider has no contact with the food establishment from which they obtain the food. In these cases, the commercial entity should be responsible for maintaining the safety of the product through temperature control or other means necessary. Food establishments do not have the ability to control which entities shop their stores and resell product. Responsibility for the safety of the product should remain with the commercial entity responsible for maintaining the safety and integrity of the product at each point in the supply chain and business partners should not be responsible for each other's business practices.

- **FDA Should Collaborate with Stakeholders:** Where there is a need to address potential risks, FDA should utilize existing organizations and forums such as the Conference for Food Protection (CFP) to bring together all stakeholders to collaboratively develop food safety solutions to protect public health. FDA also could support efforts to ensure that the CFP is an effective, collaborative forum for this purpose.

  FMI strongly supports prevention of contamination from foodborne pathogens and strongly believes that everyone plays a role in the prevention of illnesses from farm to fork. We encourage FDA to partner with a variety of stakeholders to extend the reach of programs and messaging. This extends to consumer food safety education and FMI supports the efforts of the Partnership for Food Safety Education (PFSE). We encourage FDA to work with organizations such as PFSE to help educate consumers on how they can reduce their risk of foodborne illness. Smarter food safety also applies to smarter food safety education and we look forward to working with the FDA on new tools and messages.

- **FDA Should Use Data to Change Practices in the Retail Industry that Present Risks to Public Health:** As FDA evaluates the new era of smarter food safety, we welcome opportunities to advance retail food safety to place more focus on public health protection. FMI was pleased to see that FDA is considering the ways in which the agency and its state partners can enhance their oversight of existing retail business models. We believe one of the greatest areas for improvement would be to achieve greater consistency in food retailer inspections and more consistent adoption of the FDA Food Code. Presently, our members are reporting significant inconsistencies in inspections across jurisdictions, in part because many jurisdictions' Food Codes differ from one another. For example, some states automatically adopt the newest version of the Food Code, and at least one state still implements the 1995 version. These variations lead to many different interpretations and detract from the focus on important food safety issues.

The regulatory framework of retail food safety is complex and due to state, local and tribal jurisdiction there are many differences in regulations across regional boundaries. This causes retail food establishments operating in multiple jurisdictions to have multiple or different training programs to meet the different requirements. Many of these differences are not critical to public health and are administrative in nature. These jurisdictional differences detract focus from issues related to food safety and protecting public health.

FMI supports uniform adoption of the FDA Model Food Code and encourages the use of the most recent Food Code published by the FDA. We rely on the consensus process through the Conference for Food Protection for recommending changes to the Food Code and we are confident in the scientific integrity of the practices set forth in the Food Code.

We encourage FDA to evaluate the retail food safety program and focus on recommendations and outcomes based on research, science, behavioral science and public health protection. We welcome alignment on inspections to provide consistency and reliable results and information to retail food establishments. Consistent training is essential and new methods for training and for inspections are needed to meet demands on a system under pressure. A system is also needed for quickly answering interpretation questions and for assistance from FDA to help train and implement the Food Code in jurisdictions.

The Retail Food Risk Factor study is a useful data collection but does not meet the rigors of academic research and, therefore, the data is not as usable or reliable. With a few modifications to the study design, data collection and analysis (statistics) the data would be publishable outside the agency and usable to a larger group of scientists. We encourage FDA to evaluate the data collected and utilized to solve problems instead of just providing a snapshot of the industry.

The goal of retail regulatory programs should be public health protection. Some regulatory programs are so complex and administratively burdensome, that it is questionable if the focus is still on food safety or meeting administrative goals. The program standards is one such example.

We welcome the evaluation of this issue and FMI welcomes the opportunity to advance the retail industry to help protect our customer's health. Due to the nature of the retail industry, simple is best and training is essential.

Food Safety Culture

FMI supports FDA's approach to promoting food safety not just within industry, but among regulators and consumers as well. Because a food safety culture can look different from business to business, we encourage FDA to explore the ways in which the agency can act as a resource in this area to help companies enhance their food safety culture, without setting prescribed metrics or standards.

- **Food Safety Culture Should Be Fostered, Not Regulated:** FMI and our members acknowledge that an appreciation for food safety that is pervasive throughout an organization is central to preventing foodborne illness. However, food safety culture is subjective and looks

different in different organizations. It cannot be measured quantitatively, compared qualitatively, or regulated through inclusion in inspections. For this reason, we encourage FDA to support the development of food safety cultures by providing resources to industry about ways in which companies can foster a food safety culture. Sharing success stories will be more effective than creating a new regulatory scheme or component of inspections, as food safety culture must be authentic to be effective.

- **Consumer Education Can Help Foster Food Safety:** We support FDA's inclusion of consumers in its efforts to help promote food safety culture throughout the supply chain. Potential avenues for reaching consumers include partnering with organizations such as the Partnership for Food Safety Education and the Cooperative Extension, which already have an established network and resources to amplify the work that is being done, as well as with education leaders to incorporate food safety into school competencies and curricula. FDA also can partner with stakeholders to develop educational materials to give consumers confidence in the food supply based on the proactive activities that FDA and industry are undertaking. Finally, we urge FDA to encourage stakeholders to provide accurate and science-based consumer food safety information that is not misleading. As previously discussed, providing consumers with accurate and meaningful information is of top importance in maintaining public confidence in the food supply.

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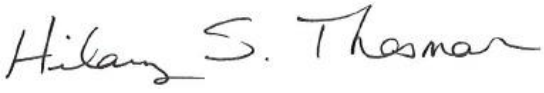
If you have questions about these comments or would like additional information, please feel free to contact Stephanie Harris at sbharris@fmi.org or Hilary Thesmar at hthesmar@fmi.org.

Sincerely,

Stephanie K. Harris
Chief Regulatory Officer & Legal Counsel



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