By Electronic Submission **July 15 2026**

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

Re: Discussion Paper on Identifying Additional Flexibilities for Satisfying the Food Traceability Rule's Lot-Level Tracking Requirement, Docket No. FDA-2014-N-0053

Dear Sir or Madam:

FMI -The Food Industry Association appreciates the opportunity to provide comments on the U.S. Food and Drug Administration's (FDA's) Discussion Paper on Identifying Additional Flexibilities for Satisfying the Food Traceability Rule's Lot-Level Tracking Requirement (the "discussion paper"). 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 the wide variety of companies providing critical services—to amplify the collective work of the industry.

FMI's member companies receive and ship thousands of foods on FDA's Food Traceability List (FTL) each day and are thus uniquely affected by the traceability rule. In keeping with their strong commitment to food safety, our members have dedicated significant time and resources towards understanding the rule's requirements, enhancing their traceability programs, and coordinating with supply chain partners to ensure compliance. In parallel, FMI has invested substantial resources in supporting industry's implementation of the rule, including through developing compliance guides, conducting member trainings and webinars, and participating in cross-industry working groups.

Through these efforts, we have identified several components of the rule that continue to present fundamental barriers to effective implementation with minimal benefit to public health, including the de facto case level tracking requirement the rule will place on distributors and the redundant recordkeeping requirements the rule will create for intracompany shipments. Complying with these requirements will place immense burdens on companies, who will be forced to restructure their recordkeeping practices and invest in new technological solutions, while offering little public health benefit relative to current recordkeeping and business practices. The investments required to address these challenges will be cost-prohibitive for many—particularly small- and mid-sized firms—and could ultimately result in increased prices for consumers. This is particularly alarming given that many FTL foods are the types of whole, nutrient-dense foods that consumers are encouraged to prioritize under the recently revised

Dietary Guidelines for Americans.[1] These components of the rule also exceed FDA's statutory authority under the Food Safety Modernization Act (FSMA), which, among other restrictions, prohibits FDA from requiring "product tracking to the case level" or requiring "the creation and maintenance of duplicate records."[2]

We thus applaud FDA's efforts to work with stakeholders to identify and implement additional flexibilities for satisfying the rule's lot-level tracking requirements. As outlined below, we are confident that by adopting additional, targeted flexibilities—particularly the "reasonable range" flexibility for distributors and additional flexibilities regarding intracompany shipments—FDA can address the rule's core challenges and reduce undue regulatory burdens and costs, while still preserving the rule's core structure and intended food safety benefits.

I. FDA should adopt additional flexibilities to address the rule's de facto case level tracking requirement for distributors.

The rule requires shippers and receivers to maintain and pass forward shipping records that reflect only the specific TLCs included in each shipment.[3] Absent fundamental changes in business practices of the sort that Congress did not intend for the rule to require,[4] the only way for entities in distribution channels to fulfill this requirement will be to engage in case level tracking. Specifically, when receiving pallets with cases from multiple traceability lots, entities will need to determine the precise TLC associated with each case on the pallet. Then, when assembling orders, they will need to track which cases (and thus which TLCs) are pulled from each pallet or pick slot and included in an order. While this challenge is most likely to arise in the context of lower-volume specialty items where full-pallet quantities are less common, such as specialty cheeses, certain produce items, and seafood, there are various other circumstances under which distributors might receive mixed-lot pallets.

As noted above, this de facto case level tracking requirement not only exceeds FDA's authority under FSMA, but also would place immense, and often cost-prohibitive, burdens on distributors, who would have to completely restructure their recordkeeping and business

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[1] U.S. Dept. of Health and Human Services and U.S. Dept. of Agriculture, Dietary Guidelines for Americans 2025-2050, at 1, https://cdn.realfood.gov/DGA.pdf (stating that "American households must prioritize diets built on whole, nutrient-dense foods" including fruits and vegetables).

[2] FSMA § 204(d)(1).

[3] 21 C.F.R. § 1.1340(a) (requiring that entities maintain and pass forward shipping KDE records "for each traceability lot" of each FTL food they ship and that these records be linked to each product's TLC).

[4] For example, section 204 of FSMA expressly provides that the rule shall "relate only to information that is reasonably available and appropriate" and that "to the extent practicable, [the rule shall] not require a facility to change business systems to comply with such requirements." FSMA §§ 204(d)(1)(A), 204(d)(1)(G).

practices and invest in new technological solutions. This, in turn, will drive up compliance costs and increase prices for consumers, all while offering few, if any, public health benefits compared to current practice. There are multiple flexibilities FDA should adopt to address the rule's de facto case level tracking requirement while preserving the rule's public health benefits.

A. FDA should allow distributors to pass forward a reasonable range of TLC records when necessary to avoid case level tracking.

FMI strongly supports the "reasonable range" solution identified in the first section of FDA's discussion paper. This solution would provide that, when distributors cannot pass forward precise TLC records without engaging in case level tracking, they have the flexibility to instead "maintain and share records that reflect a range of all possible TLCs that could reasonably be associated with a shipping event."[5] This solution would eliminate the rule's de facto case level tracking requirement since, when receiving and assembling orders from pallets that contain multiple TLCs, warehouses and distributors would no longer be required to determine the precise combination of TLCs contained in each shipment from that pallet. Instead, they would be allowed to identify the limited range of TLCs that could be in each shipment. At the same time, these flexibilities would not undercut the rule's public health objectives, since these entities would still need to maintain and pass forward records tied to only a limited set of TLCs and would still need to maintain and pass forward KDE records tied to each Critical Tracking Event (CTE). Put otherwise, distributors would still maintain and pass forward, and FDA would still be able to access, a detailed set of KDE records. If anything, this approach would streamline the rule's requirements such that distributors would have the capacity to develop, maintain, and quickly pass forward accurate records, thereby improving the overall efficiency of investigations.

While FMI strongly supports this proposal, we also appreciate the importance of establishing clear parameters around how entities implement this flexibility, including the means by which they determine what constitutes a "reasonable" range. We address these parameters in the sections below.

1. Definition of "Reasonable" Range

The appropriate range of TLCs in a shipment will depend on the FTL item, product volume and shelf-life, as well as each company's unique operational factors, including the number of TLCs included in a pallet or pick slot, how lots are defined, and each entity's inventory management and pick slot replenishment practices. Thus, while our members estimate that, in most cases, the range of TLCs on a single pallet or in a pick slot generally will be quite low (i.e., low single digits), there are circumstances under which there could be greater. This could occur, for example, when dealing with variety packs (e.g., bags of Halloween candy that contain multiple types of peanut-butter containing candies), commingled products, or products from operations that define lots by production shift or product line, operations that use

[5] *See* Discussion Paper at 3.

broker or selection based pallet building (i.e., where a pallet is assembled from many different lots), and or other unconventional distribution processes. Similarly, while it is typically the case that mixed-lot pallets will contain only TLCs from the same TLC source, there are circumstances under which a mixed-lot pallet may contain TLCs from different TLC sources. For example, pallets of eggs or seafood may contain TLCs from different TLC sources, depending on how products are consolidated before shipping. The likelihood of this occurring varies based on the commodity, the production environment, and the handling model.

Given this variation, and to maximize the effectiveness of this flexibility, a "reasonable" range of TLCs should not be defined by a universal numerical threshold, nor should it be limited to only TLCs from the same TLC source. Instead, a "reasonable" range should be defined as "the narrowest range of potential TLCs in a shipment that an entity can feasibly provide under the specific circumstances of their operations without engaging in case level tracking." In this context, a "reasonable" range should encompass only the quantity and range of TLCs associated with a specific product description within a shipping event, rather than a broader range of unrelated products within the same shipment. For example, a firm would provide records for 10 cases of romaine shipped with lot codes TLC A, TLC B, and TLC C. This definition will require that distributors pass forward the narrowest range of records possible, while accounting for the fact that various operational factors can affect the exact number of TLCs an entity might need to include in any given product shipment. As an added guardrail, and as discussed in more detail below, distributors should be expected to describe their procedures for using this flexibility and determining the "reasonable range" of TLCs for shipping events in the traceability plan, thereby ensuring standardized application of this flexibility and availability of the necessary information for understanding the records.

It is also important that, when implementing this flexibility, FDA affords entities subject to the rule, the discretion to select the best means of communicating a range of TLCs to their customers. While advanced shipping notices (ASNs) are one method for providing traceability information, and may be used in many situations, they are not the only method by which distributors can communicate this information, and they may not be sufficient in all circumstances. For example, small suppliers and retailers do not have the technology in place to receive and process traceability data electronically, and thus may not be positioned to receive this information via ASNs. Thus, consistent with the traceability rule's broader structure, FDA should permit entities shipping items on the FTL to determine the appropriate means through which they will communicate with customers regarding the reasonable range of TLCs in a shipment.

2. Additional Guardrails

Defining "reasonable range" to encompass only the "narrowest range" of TLCs a distributor can provide without engaging in case level tracking will, by itself, impose important guardrails on this flexibility, as it will obligate distributors to limit the TLCs they pass forward to the narrowest possible range based on actual operational constraints and shipment-specific

factors. Consistent with this, and as an added guardrail, FDA should expect distributors to outline their approach to implementing this flexibility in their traceability plans. In doing so, distributors should specifically address the following, for example:

- How lot codes of FTL items are identified, maintained, and assigned within the operation;
- The circumstances under which the company will utilize the reasonable range flexibility;
- How a company determines what constitutes a reasonable range in the context of a specific shipment, including the operational factors that influence that decision;

Requiring that documentation of this information in their traceability plans will ensure that distributors implement this flexibility in a standardized and structured manner that reflects existing operational practices, and not result in the transmission of overly broad records. Documenting this information in traceability plans will also facilitate FDA's ability to assess and understand the specific means by which individual distributors apply these flexibilities.

B. Inferred TLC Proposal

The inferred TLC proposal discussed in the second section of FDA's discussion paper could offer helpful flexibilities under certain circumstances. We note, however, that unlike the reasonable range solution discussed above, not all distributors will be able to readily implement the inferred TLC solution. Specifically, while some warehouse management systems are capable of providing data on the inferred TLCs likely included in a shipment, many are not. Thus, to access this flexibility, many distributors would need to supplement or replace their existing systems. This would require significant additional investments that would not be feasible for many distributors, particularly small- and mid-sized distributors. In contrast, the reasonable range proposal would allow distributors to readily leverage existing systems without significant additional investments, thereby benefitting a broader range of stakeholders. Thus, while we encourage FDA to allow for use of this flexibility where appropriate, it should only be offered *in addition to*, not in place of, the reasonable range flexibility.

II. FDA should adopt additional flexibilities to address the rule's duplicative recordkeeping requirements for intracompany shipments.

The rule currently requires that covered entities maintain and provide KDE records at each CTE for all product movement including intracompany shipments. In practice, this means that companies will need to capture, maintain and pass forward shipping and receiving records each time a covered food is moved from one location owned by a firm to any other location owned by the same firm. Due to the frequency of these intracompany shipments, capturing, maintaining and sharing these records would be incredibly burdensome and, in many cases, would result in the creation of a large volume of redundant records. This requirement would be particularly burdensome for distributors, most of whom receive and ship thousands of covered

foods on a daily basis and have existing inventory and shipment records documenting product movement between locations under the ownership and operational control of the same firm.

FMI appreciates FDA's clarification that entities may be able to rely on certain provisions of the rule, including 21 C.F.R. § 1.1455(f) (which allows entities to rely on existing records that contain information required under the rule) and 21 C.F.R. § 1.1455(g) (which provides that the information required under the rule need not be maintained in a single set of records), to avoid maintaining duplicative records for intracompany shipments. We remain concerned, however, that, in order to rely on current recordkeeping systems, many companies will still need to produce additional, redundant records in order to capture the precise KDE records required for intracompany shipments. Specifically, our members have indicated that, while current systems can often track product movement at a general level, thus allowing companies to quickly track the location and movement of products within their internal network, the ability to accurately preserve and communicate KDEs such as the TLC and TLC source across intracompany transfers varies significantly depending on system design and the extent to which lot-level information is native to a company's specific warehouse management system. This poses particular challenges when products move between company locations and where systems were not designed to maintain KDEs transactionally at every CTE. In this case, inventory is under the control of one company. These burdens of redundant recordkeeping offer minimal public health benefit since, using existing systems, companies can already identify and provide the required information for foods within their internal networks.

In light of the above, FMI requests that FDA offer companies the flexibility to use existing systems to track intracompany shipments, even if those systems do not strictly comply with the rule's recordkeeping requirements. This would allow companies to efficiently leverage existing business systems, thereby minimizing compliance costs and mitigating the risk of recordkeeping errors associated with maintaining duplicative records, while still preserving FDA's ability to quickly identify which TLCs were originally received by a company, which TLCs were ultimately shipped to another company, and how specific TLCs moved through different locations within the same company.

III. FDA should adopt additional flexibilities to address the other challenges identified in the discussion paper.

A. Flexibilities for Eaches

"Eaches" refers to individual units within a case which are packaged either individually or grouped as an inner pack.[6] Eaches can be removed from the case and shipped separately (e.g., 10 nut butter candy bars in a wrapped unit are pulled from a case and shipped from the DC to a retail store). While cases may be broken down into eaches at various points in the supply chain, this most commonly occurs at distribution centers before products are sent to restaurants and retail food establishments. The use of individual units ("eaches") varies across sectors but is

[6] GS1, Packaging Level Definitions, https://www.help.gs1us.org/packaging-level.

observed throughout the food supply chain across numerous commodities and distribution formats. Eaches are most commonly associated with low-volume specialty products and smaller retail package sizes; however, distributors frequently ship individual units to a broad range of customer types, extending beyond traditional retail establishments.

The traceability challenges presented by eaches largely mirror those presented by mixed-lot pallets, and thus the most practical way to address these challenges would be to adopt the reasonable range flexibilities discussed above. Namely, once a case is broken and product is handled at the each level, the lot-level linkage becomes far more difficult to maintain. As a result, most companies do not track lot information at the each level, but can still identify key information associated with an each, such as when a given product was sent to a store, the number of cases shipped, the number of units picked, and how product flowed through the order process. Thus, while it would generally not be feasible for distributors to identify the precise TLC associated with every individual each in a shipment, they should be able to identify a reasonable range of TLCs associated with the eaches in a shipment. Adopting the reasonable range flexibilities will thus prove helpful in addressing the unique traceability challenges associated with eaches.

While FMI recognizes that including additional labeling information on the outside containers in which eaches are shipped could also help address the challenges associated with eaches, we do not support proposals to *mandate* such labeling. Though helpful for some stakeholders, these additional labeling requirements would be cost-prohibitive for many others and, for some manufacturers and distributors, would not be logistically viable absent significant operational changes and investments. Further, many products on the Food Traceability List are fresh or produce items that are not typically shipped or sold with outer packaging at the "each" level and therefore would not be able to implement this flexibility. Thus, while entities should have the flexibility to apply additional labeling when feasible according to their business needs, FDA should not mandate such labeling, and should instead focus on advancing widely-accessible flexibilities, such as the reasonable range proposal.

B. Flexibilities for Reverse Logistics

Reverse logistics describes the backward flow of products through the supply chain. Reverse logistics encompasses a number of processes, including returns, reclamation, and backhauls. These processes often pose unique traceability challenges given that, once a product leaves a company's possession, forward-chain traceability information may no longer be consistently preserved. This makes it challenging to maintain reliable TLC and KDE information for returned items, particularly since these items are typically accompanied by missing or incomplete labeling information. We note, however, that the volume of products that are moving backwards in the supply chain is exceedingly small and is primarily shelf stable, packaged product (not perishable). Given this, we urge FDA to recognize that companies are not able to maintain complete KDE records for all returned products, and to afford companies the flexibility to maintain existing records for these products which typically include product identification, volume of product and date. The records for these operational practices differ

from the majority of outbound shipping records. For this reason, and given the fractional volume of product, we propose that this practice be eligible for an ad hoc partial exemption with reliance on existing records, should traceability records be needed.

C. Flexibilities for Retailers Transforming Food and Sending to Other Retailers

FMI agrees that it may be impractical for certain restaurants and retail food establishments to maintain transformation KDEs for foods they manufacture and ship to offsite retail locations. Many of these entities do not operate systems that are designed to support comprehensive lot-level traceability across products, nor are they equipped to distinguish between foods intended for sale at the originating location or for distribution to another retail location. The production environments are highly organized and operate at a rapid pace to ensure the efficient production of safe food. Requiring documentation of each incoming ingredient and the assignment of batch or lot numbers at every transformation event would necessitate significant changes to existing operational practices and workflows. These operations are designed around established food safety protocols, standardized production processes, and tightly managed operations, leaving limited flexibility to incorporate additional recordkeeping activities without disrupting efficiency and increasing operational burden. Given these challenges and the relatively small scale with which such production occurs, we agree that such transformation events at retail should be exempt from the rule's transformation KDE requirements.

D. Flexibilities to Support Food Waste Recovery

The rule currently excludes the donation of surplus food from the definition of "shipping," thus exempting such donations from the rule's recordkeeping requirements.[7] FMI supports this exemption and encourages FDA to extend it to an analogous scenario: situations in which retailers sell surplus foods to charitable organizations at a significant discount. While these discounted sales are technically commercial transactions, rather than outright donations, they are an important avenue through which many retailers, particularly small- and mid-sized retailers, can sustainably advance their food waste recovery objectives. Moreover, the practical and public health distinction between a deeply discounted charitable sale and a donation is minimal: in both cases, the food leaves the retail supply chain and enters a charitable distribution network. Requiring full shipping KDE compliance for these discounted sales would thus create unnecessary administrative burdens and discourage participation in food waste recovery efforts. We therefore encourage FDA to either expand the existing food waste recovery exemption to cover discounted sales to charitable organizations or provide clear guidance that such transactions may be treated equivalently to donations for traceability purposes.

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[7] 21 C.F.R. § 1.1310.

IV. FDA should take additional actions to facilitate compliance with the traceability rule.

In addition to adopting the specific flexibilities discussed above, there are additional actions FDA can take to facilitate compliance with the rule. In particular, and as outlined below, we request that FDA take steps to encourage adoption of the GS1US data standard throughout the supply chain, which will play a central role in ensuring interoperability between stakeholders. We also request that, when conducting traceback investigations, FDA take steps to refine the scope of its information requests, such that stakeholders are only required to provide the narrowest range of records relevant to an investigation.

A. FDA should encourage adoption of GS1 US data standards across the supply chain.

FMI supports industry-wide adoption of GS1 US data standards to identify, capture and share traceability information across the food supply chain. A standardized approach to data sharing will promote interoperability among trading partners regardless of the technology platforms or software solutions they utilize. Because the Food Traceability Rule requires the exchange of significant volumes of traceability data between shipping and receiving partners, interoperability is critical to achieving efficient, accurate, and scalable compliance. Broad adoption of a common data standard will help reduce complexity, minimize the need for customized data exchanges, and facilitate the seamless flow of traceability information throughout the supply chain. Notably, GS1 US standards have already been widely implemented by stakeholders across the food industry, providing an established framework that can support traceability objectives while minimizing disruption and promoting consistency across supply chain operations.

There are several steps FDA can take to encourage adoption of the GS1 US standards. These include, for example, revising FDA's draft guidance on the rule, or amending the FAQ section of FDA's website, to expressly recommend adoption of the GS1 US standards, and to provide recommendations on how entities might integrate the GS1 US standard into their traceability programs. FDA could also issue additional template documents and other educational materials or host additional public meetings and webinars specifically focused on how entities might integrate the GS1 US standard. These actions would meaningfully facilitate voluntary adoption of the GS1 US standard and would mirror steps FDA has taken to encourage adoption of specific data standards in other contexts.[8]

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[8] *See, e.g.*, FDA, Guidance for Industry on DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs, at 9 (Sept. 2023), https://www.fda.gov/media/171796/download (recommending that entities subject to the Drug Supply Chain Security Act adopt the Gs1 Electronic Product Code Information Services (EPCIS) standard).

B. FDA should ensure that its information requests are appropriately tailored to encompass only necessary records.

FDA can facilitate foodborne illness investigations by ensuring that the information requests it issues when conducting traceback investigations are narrowly tailored, and by ensuring that these requests provide companies with adequate context to identify relevant records. Overly broad information requests pose disproportionate burdens on retailers and restaurants, who often serve as FDA's first point of contact in traceback investigations. These overly broad requests include, for example, requests that span multiple months or several product categories, or that otherwise fail to specify the types of products that could be implicated in an investigation (e.g., imported vs. domestic products) and result in very large sets of data. These burdens will be exacerbated by the traceability rule, which will require that entities provide FDA with large volumes of detailed traceability records, often on a short turnaround. By appropriately tailoring its information requests, FDA can help reduce regulatory burdens and ensure that retailers, restaurants, and other stakeholders are able to provide prompt and accurate responses.[9]

Further, there is an opportunity for collaboration between industry and public health officials to identify essential details related to industry production and supply chain practices that can best be shared through conversations rather than complex data requests. Additional context from industry can help public health officials develop narrow and specific records requests, which in turn helps industry respond quickly and provide more appropriate information during investigations. The industry stands ready to work with public health agencies to simplify and support epidemiological investigations and traceback records requests.

C. FDA should continue to educate the regulated community about the rule and the requirements.

Awareness of the Food Traceability Rule remains low across the entire industry, especially among foreign suppliers. Significant outreach and education efforts are needed to reach covered entities, both domestic and international, including small suppliers. Because supply chain partners must rely on each other to maintain and share the required KDEs,

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[9] "Leafy Greens Action Plan Tech Enabled Traceability," December 2020, https://www.ift.org/siteassets/1-page-sections-media-blocks/4-policy-and-advocacy/docs/gftc/fda-leafy-greens-pilot-final-report.pdf

widespread awareness and compliance is needed at all points in the supply chain for food and ingredients on the FTL.

V. FDA should adopt these flexibilities as soon as possible before the rule's compliance date.

FMI encourages FDA to adopt the flexibilities outlined above as soon as possible. Stakeholders throughout the supply chain have already dedicated significant time and resources towards compliance efforts, and will continue to do so ahead of the July 20, 2028, compliance date. To ensure these resources are used efficiently, and to ensure stakeholders are prepared to come into full compliance, it is vital that FDA clearly communicate the flexibilities it intends to afford, and that it do so as soon as possible. While we encourage FDA to continue engaging with stakeholders on these flexibilities, including through its Congressionally-mandated quarterly meetings, the agency need not wait until these meetings are complete before announcing additional flexibilities.

FMI also encourages FDA to adopt these flexibilities permanently, rather than treating them as temporary or transitional policies. As outlined above, these flexibilities account for the fact that, as written, components of the rule would place immense burdens on industry—burdens that would require fundamental changes to existing business systems, increase costs for companies and consumers, and, in some cases, exceed FDA's statutory authority. Adopting permanent flexibilities to address these challenges will thus facilitate long-term compliance and provide stakeholders with the certainty they need to continue developing their traceability programs. While FMI recognizes that adopting some of these flexibilities may ultimately require additional rulemaking, and while we support additional rulemaking where needed to make certain flexibilities permanent, we encourage FDA to issue interim policies implementing those flexibilities pending further rulemaking, as the agency has done in the context of other FSMA requirements.[10]

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For the reasons outlined above, FMI encourages FDA to adopt additional flexibilities for satisfying the traceability rule's lot-level tracking requirements as soon as possible. By adopting these flexibilities, FDA will further facilitate compliance with the rule, increase the availability and accessibility of traceability records for illness investigations, while reducing undue regulatory burdens and preventing cost increases for businesses and consumers.

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[10] *See, e.g.*, FDA, Guidance for Industry on Current Good Manufacturing Practice and Preventive Controls, Foreign Supplier Verification Programs, Intentional Adulteration, and Produce Safety Regulations: Enforcement Policy Regarding Certain Provisions (March 2022), https://www.fda.gov/media/156729/download (outlining several FSMA requirements for which FDA plans to exercise enforcement discretion pending consideration of further rulemaking).

Sincerely,

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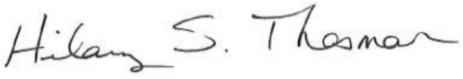

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