CENTER FOR Science IN THE Public Interest
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Via Certified First Class Mail

Catherine Teti
Deputy Agency Chief FOIA Officer
U.S. Department of Health & Human Services
Office of the Assistant Secretary for Public Affairs
Room 729 H
200 Independence Avenue, S.W.
Washington, DC 20201

RE: Freedom of Information Act Appeal, Request No. 2017-7084

Dear Ms. Teti:

On behalf of Center for Science in the Public Interest (CSPI), I am writing to appeal in full the Food and Drug Administration's (FDA) denial of FOIA request number 2017-7084.

I. Background

A. Maradol papaya recall

The Centers for Disease Control (CDC) and FDA are currently tracking an ongoing outbreak of *Salmonella* illnesses linked to the consumption of Maradol papayas. FDA.gov, *FDA Investigates Multiple Salmonella Outbreak Strains Linked to Papayas* (Sept. 1, 2017), www.fda.gov/food/recallsoutbreaksemergencies/outbreaks/ucm568097.htm. As of September 1, 2017, over 200 people have been infected with *Salmonella*, from 23 states, with 65 hospitalizations and 1 death. CDC.gov, *2017 - Multistate Outbreak of Salmonella Infections Linked to Imported Maradol Papayas* (Sep. 1, 2017), www.cdc.gov/salmonella/kiambu-07-17/index.html. This outbreak is ongoing, with 28 more ill people from 12 states added to the investigation since the last case count update on August 18, 2017. *Id.*

On July 26, 2017 Grande Produce issued a press release to notify consumers that it had conducted a limited recall of Caribeña brand Maradol papayas distributed during the dates of July 10 to July 19, 2017. www.fda.gov/Safety/Recalls/ucm568780.htm. (Jul. 26, 2017). On August 4, 2017, Agroson's, LLC, issued a press release announcing the recall of certain Cavi brand Maradol papayas distributed on July 16-19, and available to consumers until July 31. www.fda.gov/Safety/Recalls/ucm570258.htm. (Aug. 4, 2017). On August 7, 2017, Freshtex Produce, LLC, issued a press release announcing the recall of Valery brand Maradol papayas that were distributed in the state of Illinois from July 10-13. These papayas may have been further distributed outside of Illinois. www.fda.gov/Safety/Recalls/ucm570424.htm. (Aug. 7, 2017)

Grande Produce, Agroson's, and Freshtex did not sell the recalled papayas directly to consumers. *FDA Investigates Multiple Salmonella Outbreak Strains Linked to Papayas* (Sept. 1, 2017), www.fda.gov/food/recallsoutbreaksemergencies/outbreaks/ucm568097.htm. Rather, these papayas were distributed under the brand names Caribeña, Cavi, and Valery to wholesalers in various states. *Id.* FDA traced back the papayas to three Mexican farms: Carica de Campeche in Tenabo, Campeche, Caraveo Produce in Tecomán, Colima, and El Zapotanito in La Huerta, Jalisco.

However, FDA did not identify the name or location of the retailers that sold the possibly tainted papaya products to consumers. *Id.* FDA merely instructed customers to "ask restaurants and retailers whether they use Caribeña, Valery or Cavi brands of Maradol papayas and/or whether their distributors receive product from Carica de Campeche in Mexico, Caraveo Produce in Tecomán, Mexico, and El Zapotanito in La Huerta, Mexico."

B. The FOIA request

On August 9, 2017, using FDA's online request portal, I submitted a FOIA request on behalf of CSPI. for:

> [T]he names and locations of all retailers known by the FDA to have received shipments of Caribeña, Cavi and Valery brands of Maradol papayas that have been recalled due to potential contamination with *Salmonella*.

By email sent on August 17, 2017, FDA confirmed receipt of my request and assigned the request reference number 2017-7084. By email dated September 5, 2017, FDA estimated the volume of records covered by the request at 451 pages, and denied CSPI's entire request.

FDA stated in its denial that the requested customer information was exempt from disclosure under FOIA, 5 U.S.C. 552, under the following exemptions:

- (As to all records) Exemption (b)(4) - Trade secret and confidential commercial information.
- (As to portions of approximately 445 pages) Exemption (b)(6) - Information involving matters of personal privacy.
- (As to approximately 5 pages) Exemption (b)(5) - Inter-agency or intra-agency communications that are protected by legal privileges.
- (As to approximately 5 pages) Exemption (b)(7)(A) – Records or information compiled for law enforcement purposes, to the extent that the production of those records could reasonably be expected to interfere with enforcement proceedings.

I appeal in full the agency's denial of CSPI's FOIA request.

II. Exemption 4 Does Not Apply to the Names and Locations of Retailers that Received the Recalled Products.

FDA cites FOIA exemption (b)(4) for its denial of all 451 pages of records. The names of the retailers that received possibly contaminated papaya products are not exempt from disclosure. Exemption 4 applies to "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). The names of the retailers that received the recalled food products are not confidential commercial or financial information.

A. The customer information is required to be submitted to the government.

Whether information is confidential under Exemption 4 depends on whether it was voluntarily submitted to the Government or whether it was required to be submitted to the Government. *Critical Mass Energy Project v. Nuclear Regulatory Comm'n*, 975 F.2d 871, 879 (D.C. Cir. 1992) (*en banc*). FDA requires the submission of the customer information, both through the Reportable Food Registry and as part of carrying out a recall.

First, FDA, at the direction of Congress, established a Reportable Food Registry, an electronic portal for industry to report when there is a "reasonable probability" that an "article of food will cause serious adverse health consequences or death to humans or animals." 21 U.S.C. § 350f(a)(2), (b). Food facilities subject to FDA regulation must report to FDA any food products suspected of contamination within 24 hours of learning of the suspected adulteration. *Id.* § 350f(d). The food facility must submit to the database certain information, including "contact information for parties directly linked in the supply chain[.]" *Id.* § 350f(e)(9). For the three papaya recalls covered under this request, FDA-regulated food facilities are required to report that they received the adulterated product and must submit information about the entities above and below them in the supply chain, meaning that retail consignee information must be submitted to the database. Therefore, customer information is a mandatory submission to FDA.

Second, the retail consignee information is also a required submission in the food recall process, whether voluntarily initiated or initiated by FDA. FDA monitors the effectiveness of recalls and verifies that customers in the supply chain receive notice of the recall. *See* GAO, *Food Safety: FDA's Food Advisory and Recall Process* 5 (July 2012), www.gao.gov/assets/600/593031.pdf. Firms initiating recalls should provide "a consignee list (names/address/city/state/contact name/phone number) to the local District Recall Coordinator." FDA, *Guidance for Industry: Product Recalls, Including Removals and Corrections* (issued Nov. 3, 2003), www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm. If a regulated food facility fails to conduct a voluntary recall "within the time and in the manner" prescribed by FDA, FDA has the authority to order a mandatory recall, and thus, order the submission of necessary information. 21 U.S.C. § 350l(b)(1). Accordingly, customer information submitted as part of a food product recall is a compelled submission. Finally, FDA may access and copy records from entities that distribute food if FDA reasonably believes that the food is adulterated and presents a threat of serious adverse health consequences, 21 U.S.C. § 350c(a), including customer distribution lists. FDA, *Guidance for Industry: FDA Records Access Authority* (Apr. 2014), www.fda.gov/downloads/Food/GuidanceRegulation/UCM292797.pdf.

B. The requested customer information is not confidential.

The question of whether information that is required to be submitted to the government is considered confidential is governed by the three-part test laid out in *National Parks & Conservation Ass'n v. Morton*, 498 F.2d 765 (D.C. Cir. 1974).

National Parks Test – Impairment. Turning to the first prong of the *National Parks* test, disclosure of the names of customers of the recalled food products is not likely to impair the Government's ability to obtain this information in the future, because FDA can require the companies to submit this information, as discussed above. Where the submitter is required to provide the information to the Government, "there is presumably no danger that public disclosure will impair the ability of the Government to obtain this information in the future." *Nat'l Parks & Conservation Ass'n*, 498 F.2d at 770. Moreover, disclosure of the names would not impair the quality of the submitted information about customers, because the information is merely names and locations, which is not the type of information that the submitter can disclose to a greater or lesser extent.

National Parks Test – Substantial Harm. Under the second prong of *National Parks*, disclosure of the retail customers is not likely to cause substantial harm to the competitive positions of the submitters of that information. In some cases, Exemption 4 protects a complete list of a company's customers because disclosure of that information would enable a different company to "contact those customers and attempt to lure them away," harming the company's competitive position. *Judicial Watch, Inc. v. Exp.-Imp. Bank*, 108 F. Supp. 2d 19, 32 (D.D.C. 2000). However, the names of customers are not categorically exempt, and in this instance, FDA cannot justify withholding the names of retail consignees of the recalled papaya products as "customer lists." The requested information is merely a snapshot of *some* of the retailers selling *some* of a company's products, and even under circumstances where the entire customer list is disclosed, it will not be identified as such. Furthermore, the requested information does not disclose for which companies the retailers are customers, because there are often intermediary entities in the supply chain between the recalling company and the retail consignees.

Significantly, the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS), which regulates the safety of meat and poultry and egg products, has already determined that the identities of the retail outlets that received recalled food are not customer lists protected by Exemption 4. Availability of Lists of Retail Consignees During Meat or Poultry Product Recalls, 73 Fed. Reg. 40939, 40943 (July 17, 2008) (codified at 9 C.F.R. 390), *available at* www.federalregister.gov/documents/2008/07/17/E8-16221/availability-of-lists-of-retail-consignees-during-meat-or-poultry-product-recalls. For Class I recalled products, FSIS releases a list of the retailers' names and locations. *See* FSIS.usda.gov, *Current Recalls and Alerts*, www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts/current-recalls-and-alerts/. FDA cannot justify withholding the names of customers as confidential commercial information in the face of FSIS's determination that the requested customer information is *not* confidential commercial information. The only distinction between FSIS-recalled foods and FDA-recalled foods is the type of food product involved, which has no bearing on whether customer information is confidential.

One of the reasons FSIS releases this information is because disclosure of the names of customers that received, for example, papayas, is unlikely to amount to disclosure of complete

distribution lists for any single company. Availability of Lists of Retail Consignees During Meat or Poultry Product Recalls, 73 Fed. Reg. 40939, 40943. Nor is a list of certain customers a list of "any of the intermediate consignees that received recalled product or that routinely receive product from that firm." *Id.* As aptly explained by FSIS in its final rule announcing that it would make available the names and locations of retail consignees of recalled products:

> Because of the complex food distribution system in the United States, which can include multiple wholesalers or other intermediate distributors, it is quite possible, and perhaps likely, that the retail consignees that ultimately sell the product to the consumer are not customers of the federal establishment that produced the product. Therefore, only very rarely, if ever, will the names and locations of retail consignees expose a recalling establishment's entire customer or distribution list. Even in such circumstances, the establishment's customer list will not be identified as such. As a result, members of the public and industry will not be able to determine what significance the list has for the recalling establishment.

Id. FDA would not be releasing the names of the companies for whom the retail consignees are customers, just the ultimate retail consignee of the recalled papaya products.

To the extent FDA is withholding the requested information on the grounds that disclosure of the names of the grocery stores and other retailers would cause those entities to suffer competitive harm, that position is unsupported by law. Reputational harm from selling products that may have been contaminated with *Salmonella* is not a recognized competitive injury for purposes of Exemption 4. "Exemption 4 does not guard against mere embarrassment in the marketplace or reputational injury." *United Techs. Corp. v. U.S. Dep't of Def.*, 601 F.3d 557, 564 (D.C. Cir. 2010).

Moreover, as part of the Food Safety and Modernization Act of 2011, Congress requires grocery store chains to notify consumers if the grocery store sells a food that is suspected of contamination. 21 U.S.C. § 350f(h). The statutory requirement for a retail consignee to affirmatively disclose that it is a customer of a company that has recalled a food product further demonstrates that disclosure of customer information is not confidential.

Finally, FDA has already acknowledged that the names and locations of retail consignees that received recalled products are not categorically covered under Exemption 4. On March 17, 2017, Public Citizen submitted a FOIA request for the names of retail consignees that received I.M. Healthy Soynut Butters, I.M. Healthy Granola products, and frozen strawberries associated with prior recalls (FOIA reference No. 2017-2571). FDA initially denied the request in full under Exemption 4. However, following an appeal by Public Citizen, the agency granted the request in part, delivering records that included the names and locations of retail consignees, but redacting the names of individual sales representatives under FOIA Exemption (b)(6). This release of records indicates an acknowledgment on the part of FDA that lists of retail consignees that received recalled products, including company names and locations, are not covered under Exemption 4.

III. Exemption 6 Does Not Apply to the Names and Locations of Retailers that Received the Recalled Products.

FDA cites exemption (b)(6), information involving matters of personal privacy, for its denial of portions of approximately 445 pages. Exemption 6 does not apply to corporations, which lack individual privacy rights under FOIA, *FCC v. AT & T Inc.*, 562 U.S. 397, 398 (2011) (distinguishing Exemptions 6 and 7C, which apply to individual persons, from exemption 4, which applies to corporations). Therefore Exemption 6 cannot serve as a basis for redacting the company names and addresses of retailers that received recalled products. To the extent that any of the material covered by this request *does* fall under Exemption 6 (*e.g.*, names and contact information of individual persons who serve as agents/representatives of different retailers), FDA has a duty to provide any reasonably segregable portion of the record not falling under the exemption. 5 U.S.C. § 552(b). In this case, names, phone numbers, and other individual personal information were not requested, and any incidental references contained in the requested records could easily be redacted prior to release.

IV. Exemptions 5 and 7A Do Not Apply to the Names and Locations of Retailers that Received the Recalled Products.

FDA cites exemption (b)(5), Inter-agency or intra-agency communications that are protected by legal privileges, as well as Exemption (b)(7)(A), records or information compiled for law enforcement purposes, for its denial of approximately five of the 451 pages covered by the request.

The burden is on the agency to show that the information being withheld falls under a privilege covered by Exemption 5. *Coastal States Gas Corp v. DOE*, 617 F.2d 854, 868 (D.C. Cir. 1980) (emphasizing the narrow scope of Exemption 5). In this case the agency has not met that burden because it has not identified the deliberative process involved or the role played by the documents in that process.

Similarly, to establish that information is exempt under 7A, the agency must demonstrate both that a law enforcement proceeding is pending or prospective, and that release of the information might reasonably be expected to cause some articulable harm. *See, e.g., Sussman v. U.S. Marshals Serv.*, 494 F.3d 1106, 1114 (D.C. Cir. 2007) (stressing need for "specific information about the impact of the disclosures"). Here again, that burden has not been met because FDA has not explained how the disclosure might reasonably be expected negatively impact a pending or prospective law enforcement proceeding.

Moreover, even assuming these five pages are exempt from FOIA release, the agency has a duty to segregate and release the remaining 446 pages requested, marking the amount and location of deleted information. 5 U.S.C. § 552(b).

V. Conclusion

For all of these reasons, CSPI is entitled to the requested records.

Thank you for your attention to this matter. If you have any questions, please contact me at ssorscher@cspinet.org or 202-777-8397.

Sincerely,

Sarah Sorscher
Chief Regulatory Affairs Counsel
Center for Science in the Public Interest