

August 22, 2017

Scott Gottlieb, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
Department of Health and Human Services
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VIA EMAIL

Dear Dr. Gottlieb,

The undersigned organizations write to request that the Food and Drug Administration (FDA) change its policy regarding the disclosure of the names and locations of retailers that sold recalled FDA-regulated food products. Product recalls are the last line of defense for consumers who may have eaten potentially contaminated food that could make them sick. The names and locations of retail stores where recalled products were sold is critical information that is necessary to effectuate a recall, the goal of which is to prevent consumers from suffering illnesses that can lead to serious adverse health consequences or death. When consumers have access to this critical information, they can more readily determine whether they purchased potentially contaminated food, and can take steps to protect themselves and their families accordingly.

FDA sometimes provides this information, most recently with recalls involving products adulterated with Hepatitis A. On May 3, 2017, FDA announced that Tropic Fish Hawaii, LLC was recalling frozen raw tuna cubes imported from Indonesia that tested positive for Hepatitis A. The announcement included the names and locations of retailers and food service establishments that sold the recalled product.¹ The agency posted the names and addresses of more establishments as the scope of the recall expanded.² There is a short time window for people who may have consumed a contaminated food product to get a Hepatitis A vaccine that will protect them from illness, a fact that may have prompted FDA to release the names and addresses of retailers in this case. However, when FDA announced last year that the International Company for Agricultural Production and Processing (ICAPP) was recalling strawberries imported from Egypt that tested positive for Hepatitis A, it declined to publish any information regarding retail consignees.³ This inconsistency is perplexing and undermines public health. Failing to disclose the names and locations of retailers that sell recalled products may make it much harder for consumers to determine if they have purchased recalled items, and might prevent them from responding to recalls appropriately.

¹ FDA. "Imported Frozen Raw Tuna (Ahi) Cubes Distributed on Oahu Test Positive for Hepatitis A; Voluntary Product Recall Underway" (May 3, 2017), <https://www.fda.gov/Safety/Recalls/ucm556597.htm>.

² FDA. "FDA Investigates Findings of Hepatitis A Linked to Frozen Tuna" (June 8, 2017), <https://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm561199.htm>.

³ See Coral Beach. "Federal law gags FDA on recall as vaccination window closes" *Food Safety News*, Nov. 9, 2016, <http://www.foodsafetynews.com/2016/11/federal-law-gags-fda-on-recall-as-vaccination-window-closes/#.WVUHyojyuUm>.

The U.S. Department of Agriculture’s Food Safety and Inspection Service (FSIS) changed its policy on disclosing the names and locations of retailers that sold recalled products in 2008.⁴ Since then, FSIS has generally released this information when there is a recall.⁵ As the agency explained in its rulemaking finalizing the change, the information serves as “an additional mechanism for prompting consumers to examine products stored in their refrigerator, freezer, or cupboard when there is a reasonable probability that the product will cause adverse health consequences.”⁶ Consumers have expressed overwhelming support for this policy, with one poll finding that 95% of respondents approved of the statement: “In the event of recall, USDA should make public the names of stores/restaurants that sold contaminated meat.”⁷

FDA has not made clear why it chooses not to disclose the names and addresses of retailers that sold recalled products. A recent statement from FDA spokesman Peter Cassell suggests that the agency interprets Exemption 4 of the Freedom of Information Act (FOIA) as barring the release of retailer names and locations because they qualify as “confidential commercial information.” Specifically, a *Washington Post* article this past March quoted Mr. Cassell as saying that “raw material supplier lists, finished product customer lists, trace back information, etc.” qualify as “confidential commercial information,” which “is exempt from Freedom of Information Act requests, but can be shared through certain information sharing agreements (including with other Federal agencies).” Cassell went on to explain that “[i]n some cases, the FDA can release certain information that is otherwise exempt from disclosure if it is necessary to effectuate a recall.”⁸ Shortly after publication of the *Washington Post* article, however, the advocacy group Public Citizen filed FOIA requests for the names and locations of retailers that sold recalled frozen strawberry and soy nut butter products, and following an initial denial and appeal, FDA provided at least some of the requested information.⁹

FDA should always release the names and locations of retailers of recalled food products because this information does not fall under Exemption 4 of FOIA or FDA’s related regulations.¹⁰ According to federal case law, “commercial or financial matter is confidential if disclosure of the

⁴ FSIS “Availability of Lists of Retail Consignees During Meat or Poultry Product Recalls.” 73 *Federal Register* 40939-40948, (July 17, 2008), <https://www.gpo.gov/fdsys/pkg/FR-2008-07-17/html/E8-16221.htm>.

⁵ See, e.g., FSIS, Current Recalls and Alerts, <https://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts/current-recalls-and-alerts> (FSIS’s practice of publishing retail consignee lists in a static PDF file is less than ideal in that it does not accommodate searches by retailer and location).

⁶ FSIS, *supra* note 4, at 40940.

⁷ See Consumers Union Comments to United States Department of Agriculture’s Food Safety Inspection Service on Docket No. 04-006P, Availability of Lists of Retail Consignees During Meat or Poultry Product Recalls, <http://consumersunion.org/news/cu-comments-on-usdas-proposal-to-disclose-the-names-and-locations-of-supermarkets-involved-in-meat-recalls/>.

⁸ Caitlin Dewey. “Why the FDA hides the names of grocery stores that sell contaminated food.” *The Washington Post* (March 13, 2017), https://www.washingtonpost.com/news/wonk/wp/2017/03/13/fda-says-soynut-butter-could-make-your-child-sick-who-sold-it-thats-a-trade-secret/?utm_term=.bc80ed3769b4 (emphasis added).

⁹ See FOIA request #2017-2571 filed March 17 and subsequent July 21 partial response.

¹⁰ 5 U.S.C.A. § 552(b)(4); 21 C.F.R. 20.61 (“Data and information submitted or divulged to the Food and Drug Administration which fall within the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure.”).

information is likely either (1) to impair the Government's ability to obtain necessary information in the future; or (2) to cause substantial harm to the competitive position of the person from whom the information was obtained.”¹¹ For example, FSIS recognizes product formulas and processing procedures as potentially confidential information, as the disclosure of such information could place a company at a competitive disadvantage.¹² However, as FSIS explained in its 2008 rulemaking, disclosing the names and locations of retailers of recalled food products would neither harm the competitive position of businesses nor hinder the government from obtaining essential information in the future.¹³

First, disclosing this information will not “impair the Government's ability to obtain necessary information in the future” because the Federal Food, Drug, and Cosmetic Act authorizes FDA to require submission of the information.¹⁴ Since the information is required to be submitted, “there is presumably no danger that public disclosure will impair the ability of the Government to obtain this information in the future.”¹⁵

Second, publishing the names and locations of retailers of recalled products is not likely to “cause substantial harm to the competitive position” of food companies. As FSIS explained in its rulemaking, “the names and locations of retail consignees” are different from “distribution lists” or “customer lists” and therefore “do not constitute confidential commercial information.” As FSIS has explained:

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

¹¹ *Critical Mass Energy Project v. Nuclear Reg. Commn.*, 975 F.2d 871, 873 (D.C. Cir. 1992) citing *National Parks and Conservation Ass'n v. Morton*, 498 F.2d 765 (D.C.Cir.1974) (internal quotations omitted).

¹² FSIS, “Safeguarding Confidential Industry Information,” Directive 4735.6 (March 25, 1985), <https://www.fsis.usda.gov/wps/wcm/connect/5747ed9d-5262-4d32-9fc3-40841d8f7d93/4735.6.pdf?MOD=AJPERES>.

¹³ FSIS, *supra* note 4, at 40942-43 (“FSIS, however, in considering the application of Exemption 4, has determined that the names and locations of retail consignees of recalled meat and poultry products compiled by the Agency do not constitute confidential commercial information because the disclosure of this information will not impair the Agency's ability to obtain necessary information in the future and will not cause substantial harm to the competitive position of any business.”).

¹⁴ See, e.g., 21 U.S.C. §350f(d), (e)(9) (requiring food companies to submit a report to FDA on recalled foods that includes “[t]he contact information for parties directly linked in the supply chain”; 21 U.S.C. §350f(f) (“the Secretary may require a responsible party to submit to the Secretary consumer-oriented information regarding a reportable food, which shall include . . . any other information the Secretary determines is necessary to enable a consumer to accurately identify whether such consumer is in possession of the reportable food.”); 21 U.S.C. § 350l(b)(1) (describing FDA's authority to order a mandatory recall).

¹⁵ *Nat'l Parks & Conservation Ass'n*, 498 F.2d at 770.

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.¹⁶

This rationale similarly applies to FDA-regulated food products. Indeed, when a recall notice has applied to both FDA and FSIS regulated products, FSIS has sometimes published the names and locations of retailers of recalled products while FDA has not. For example, during a recent recall of frozen waffle products, some of which contained meat, FSIS posted a notice of the recall on its website that included a list of “retail consignees” that sold the recalled products, while the notice on the FDA website included no such information.¹⁷

Even if FDA rejects FSIS’s interpretation and believes that the information about where recalled product was sold is “confidential commercial information,” the agency may still release the information if otherwise authorized by law. “The mere fact that information falls within a FOIA exemption does not of itself bar an agency from disclosing the information.”¹⁸

The FDA Food Safety Modernization Act authorizes the FDA to release information about where a recalled product is sold by directing the agency to determine what information is “necessary to enable a consumer to accurately identify whether such consumer is in possession of the reportable food,” and to publish that information “on the Internet website of the Food and Drug Administration.”¹⁹ The names and locations of retailers of recalled products are absolutely “necessary to enable a consumer” to take action that would protect themselves and their families in response to a recall, as consumers may lack information about a product beyond knowing the store at which the product was purchased. This information can serve to prevent illness long after a recall is announced in the case of foods that may be held in freezers or pantries for months or even years after purchase. Additionally, the information may prompt a consumer to seek medical attention for a serious foodborne illness, rather than take a “wait-and-see” approach.

For these reasons, publishing the names and addresses of retailers that sold recall product is “necessary to effectuate a recall.” Moreover, in the aggregate, publishing this information will

¹⁶ FSIS, *supra* note 4, at 40943.

¹⁷ Compare FDA. “Pinnacle Foods Inc. Voluntarily Recalls Aunt Jemima Frozen Pancakes, Frozen Waffles & Frozen French Toast Slices Due to Possible Listeria Contamination” (May 5, 2017), <https://www.fda.gov/safety/recalls/ucm557098.htm> with FSIS. “Valley Innovative Services Recalls Meat and Poultry Frozen Entrée Products Due to Possible Listeria Contamination” (May 12, 2017), <https://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts/recall-case-archive/archive/2017/recall-049-2017-release>. See also, News Desk. *Food Safety News*. “Waffles with Listeria contamination requires a meat recall.” (May 12, 2017), <http://www.foodsafetynews.com/2017/05/waffles-with-listeria-contamination-requires-a-meat-recall/#.WYHpHogrKUK>. Other regulatory agencies have also published retail consignee information that FDA has declined to divulge. In connection with the aforementioned Egyptian strawberry recall, for example, the California Department of Public Health released a 178-page list of establishments that served or sold products containing the recalled strawberries. See, e.g. California Department of Public Health, *California Retail Distribution List, Recall: ICAPP Frozen Strawberries* (Oct. 30, 2016), <http://www.cdph.ca.gov/pubsforms/Documents/fdbFriCAPP1d.pdf>.

¹⁸ *Bartholdi Cable Co., Inc. v. F.C.C.*, 114 F.3d 274, 281 (D.C. Cir. 1997) (holding that challenged Federal Communications Commission regulation could provide for disclosure of materials exempt under FOIA Exemption 4 to the extent that policy considerations favoring non-disclosure were outweighed by factors favoring disclosure.)

¹⁹ 21 U.S.C. §350f(g)-(h).

generate public health benefits by raising consumers' awareness of FDA-regulated food recalls in general. By offering more actionable information about recalled products, FDA will attract more consumers and members of the news media to its website. More informed consumers may even push their local stores to adopt other best practices too, such as using data from loyalty or membership programs to contact purchasers of recalled foods.

We urge FDA to begin disclosing on its website as soon as possible lists of retailers that sold recalled products. To a large extent, the manner in which the agency publishes this information will determine its usefulness to consumers, and by extension, the degree to which it helps to "effectuate a recall." Currently, FDA publicizes a subset of recalls by posting companies' announcements and alerts on its website. The agency also discloses details of these and other food recalls in its weekly enforcement report.²⁰ The agency's website already includes a search function to navigate the weekly enforcement report archives, and FDA should consider adding fields that allow consumers to search recalls by retail establishment and to view all of the recalls associated with a given retail consignee.

Alternatively, FDA might take an approach similar to that of FSIS, which posts lists of retail consignees alongside recall notices. FSIS's practice of publishing retail consignee lists in a static PDF unfortunately does not allow for searches by retailer and location. FDA could improve on this practice by displaying the lists in a different format and enabling searches. Whatever the case, the agency should strive to make the information as easily accessible and helpful as possible to consumers.

We would appreciate the opportunity to discuss this request with you and your staff. By including the requested information in its recall announcements, FDA will improve public health and enable consumers to better protect themselves.

Thank you for your consideration.

Sincerely,

Center for Science in the Public Interest
Center for Food Safety
Center for Foodborne Illness Research & Prevention
Consumer Federation of America
Consumers Union
Food & Water Watch
National Consumers League
Public Citizen
STOP Foodborne Illness
The Pew Charitable Trusts
Trust for America's Health

²⁰ FDA, "FDA 101: Product Recalls" (Updated: May 18, 2010), <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm049070.htm> ("Not all recalls are announced in the media. But all recalls go into FDA's weekly Enforcement Report.").