U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Petition to Request that FDA Change its Interpretation that a Company Name is Confidential Commercial Information or Allow Disclosure of the Name of a Company Linked to a Foodborne Illness Outbreak Even When There is no Related Recall.	)	Docket No. ___

Citizen Petition
Submitted by:

Stop Foodborne Illness
February 5, 2026

The undersigned submits this petition under 21 C.F.R. §10.30 on behalf of Stop Foodborne Illness to request that the Commissioner of Food and Drugs change the Agency's interpretation that a company name is confidential commercial information or disclose the name of a company linked to a foodborne illness outbreak even when there is no related recall, by relying on the relevant section of the Federal Food Drug and Cosmetic Act or by revising 21 C.F.R. §20.91.

Introduction

This petition urges the U.S. Food and Drug Administration (FDA) to adopt a policy of publicly disclosing the names of all companies associated with foodborne outbreaks, whether or not there is a related recall. Currently, the agency protects the identity of these companies from disclosure because it believes a company name is "confidential commercial information" (CCI). This interpretation is inconsistent with applicable statutory language and case law. However, if the agency decides to continue to treat a company name as CCI, then we ask that it still disclose the names of all companies linked to an outbreak based either on its responsibility to ensure safe food under the Federal Food Drug and Cosmetic Act (FDCA) or by revising the language of 21 C.F.R. §20.91 to allow broader disclosure of the brand name of any company linked to the outbreak. Such action is consistent with FDA's mission to protect public health, and with this Administration's commitment to "radical transparency."

Petitioners

Stop Foodborne Illness (STOP) is a non-profit organization that for over 30 years has worked with "constituents" – foodborne illness survivors and victims' families to advocate for and support improved government policy and industry best practices to ensure continuous improvement in food safety. STOP called for changes in how the U.S. Department of Agriculture oversees the safety of meat following the Jack in the Box *E. coli* outbreak in 1992-93 and was part of the consumer-industry coalition that supported enactment of the FDA Food Safety Modernization Act in 2011. In addition to constituent support and policy advocacy, STOP collaborates with food companies to address issues such as food safety culture and recall modernization.

A. Action Requested

STOP urges FDA to change its position that a company name is CCI. This action can be easily achieved through an agency statement or memorandum announcing a change in its interpretation of the Trade Secrets Act.[1] If the agency chooses not to change its position regarding CCI, we ask, in the alternative, that the agency more broadly disclose the name of a company linked to an outbreak based either on its statutory responsibility to ensure safe food under the Federal Food Drug and Cosmetic Act (FDCA), 21 U.S.C. §393(b)(2)(A), or by revising the language of 21 C.F.R. §20.91, as follows:

[1] 18 U.S.C. §1905

> Nothing in this part or this chapter shall prevent the Food and Drug Administration from using any data or information, whether obtained voluntarily or involuntarily and whether or not it is available for public disclosure, as the basis for taking any administrative or court enforcement action within its jurisdiction. Data and information**, including the brand name of a food product identified in an outbreak,** otherwise exempt from public disclosure are nevertheless available for public disclosure when the brand name is known. ~~or.. effectuate such actions, e.g., the brand name, code designation, and distribution information are released when a product is recalled~~.

B. Statement of Grounds

a. Factual Grounds

Each year, an estimated 48 million people in the U.S. – one in six Americans – get sick with a foodborne illness, 128,000 are hospitalized, and 3,000 die.[2] Otherwise healthy adults usually experience mild symptoms when they contract a foodborne infection and the illness resolves itself after a few days of gastrointestinal discomfort. However, older people, young children, pregnant women, and anyone with a compromised immune system can suffer severe symptoms and long-term health effects. They may require hospitalization and are at higher risk of death from the infection.

As an example, in one multistate foodborne illness outbreak that occurred at the end of 2024, romaine lettuce contaminated with *E. coli* O157:H7 sickened 89 people across 15 states and resulted in one reported death.[3] The contaminated romaine lettuce was served at schools, restaurants, catered events, or purchased at retail. The resulting illnesses were severe, prolonged, and in many cases, life threatening, requiring lengthy hospitalization, intensive medical interventions, and ongoing recovery.

One of the 89 people sickened in this outbreak was nine-year-old Colton George, an energetic and athletic boy from Indiana who became seriously ill shortly after consuming the tainted lettuce. His symptoms escalated quickly and he was hospitalized for 18 days. Colton was one of seven people in this outbreak who developed hemolytic uremic syndrome (HUS), a serious and potentially fatal complication that can result in kidney failure, neurological injury, and death. During his hospitalization, Colton underwent nine days of continuous renal replacement therapy (hemodialysis) followed by five more days of intermittent hemodialysis. He also received five blood transfusions. While Colton eventually recovered from the acute phase of his infection, he now takes daily medications and requires regular nephrology appointments to monitor his kidney function.

Colton's dad, Chris, was determined to uncover how his son had contracted such a devastating illness; he wanted to know the name of the company that sold the contaminated food item. He eventually learned that the bacteria that caused Colton's illness shared the exact same genetic fingerprint of *E. coli* O157 as other

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[2] https://www.cdc.gov/food-safety/data-research/facts-stats/index.html. The U.S. Department of Agriculture estimates the deaths, chronic illness, medical treatment, and lost productivity from food-related illnesses amounted to $75 billion in 2023: Economic Burden of Foodborne Illnesses Acquired in the United States - PubMed.

[3] https://www.fda.gov/food/outbreaks-foodborne-illness/investigations-foodborne-illness-outbreaks,

cases in the romaine outbreak. FDA had posted the case count and the likely source of the outbreak on its outbreak table on December 4, 2024, but did not include the name of the company that sold the lettuce to consumers, even though it was known to the agency.[4] FDA's current policy reveals the company name only if there is a related, on-going recall or the product is still being sold. Since neither was the case for this outbreak, FDA did not disclose the name of the implicated company, leaving Chris and other parents and families at risk of illness if the contaminated product was still in their refrigerators.

b. Legal Grounds

FDA maintains that the name of a company that sells a contaminated food product linked to a foodborne illness is CCI under the Trade Secrets Act, and, as such, can be disclosed only in limited situations. The Trade Secrets Act allows disclosure of CCI if disclosure is "provided by law."[5] FDA satisfies this requirement through a regulation – 21 C.F.R. §20.91 – which specifically allows disclosure of CCI only when it is necessary to effectuate a recall.[6] As discussed below, the plain language of the Trade Secrets Act, as well as the relevant case law, do not support FDA's interpretation that a company name is CCI.

i. FDA incorrectly treats a food company's name as "confidential commercial information" under the Trade Secrets Act.

An examination of the relevant language in the Trade Secrets Act reveals that it does not include a company's name in its description of what constitutes CCI. Section 1905 of Title 18 characterizes confidential information as:

> Any information . . . which concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or association; or permits any income return or copy thereof or any book containing any abstract or particulars thereof.

1. A company name is not "commercial" information.

While the case law related to the Trade Secrets Act does not address the issue of what constitutes CCI, courts have considered the meaning of nearly identical language in Exemption 4 of the Freedom of Information Act (FOIA)[7], and those decisions are instructive here.

The D.C. Circuit has held that under Exemption 4, an agency must first demonstrate that the withheld information is "commercial or financial" in nature to be considered CCI. In a recent decision, *Citizens for*

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[4] Coordinated Outbreak Response & Evaluation (CORE) "*E. coli* O157:H7/Romaine Lettuce/Nov 2024 Executive Incident Summary CARA #1280.

[5] 18 USC §1905.

[6] The regulation states in relevant part: "Data and information otherwise exempt from public disclosure are nevertheless available for public disclosure to the extent necessary to effectuate such action, e.g., the brand name, code designation, and distribution information are released when a product is recalled."

[7] "The FOIA exempts from disclosure trade secrets as well as commercial or financial information that is obtained from a person that is either privileged or confidential." 32 U.S.C. §1662.21.

Resp. & Ethics in Wash. v. United States DOJ,[8] the Court determined that a company name is not "commercial or financial" "in and of itself." The D.C. Circuit made clear in this case that Exemption 4 protects only information that private entities typically keep confidential because it reveals "basic commercial operations, such as sales statistics, profits and losses, and inventories, or relate[s] to the income-producing aspects of a business."[9]

The Court in this case also rejected the argument that a contractor's name could be withheld merely because disclosure might result in reputational damage or economic consequences. The Court explained that while the government rested its claim of exemption exclusively on the potential commercial consequences of disclosure, "[these consequences] are not on their own sufficient to bring confidential information within the protection of Exemption 4 as 'commercial.'"[10]

This decision makes clear that the name of a company that sells a product linked to a foodborne illness outbreak is not "commercial or financial" information under any reasonable reading of FOIA (and therefore, arguably, similar language in the Trade Secrets Act); it is not like confidential business strategies, proprietary processes, financial data, or any other competitively sensitive material. Rather, it is a factual identifier of an entity that sells food products to consumers and markets its food products based on its name.

2. A company name is not "confidential."

To qualify as "confidential" under Exemption 4, information must meet at least one of the two conditions described by the Supreme Court in *Food Mktg. Inst. v. Argus Leader Media*.[11] First, the information must be "customarily kept private, or at least closely held, by the person imparting it."[12] Second, the party receiving the information must provide "some assurance that it will remain secret."[13] Neither condition is satisfied here.

First, the identity of a company that sells a food product to consumers is not the type of information that is customarily kept private. A company that is linked to an outbreak operates in public-facing, highly regulated sectors – agriculture, food distribution, and retail sales – where its role in the supply chain is widely known and often promoted through advertising or readily discoverable through public sources. Unlike trade secrets, pricing models, or proprietary formulas, the basic fact of who sells a food product is not "known only to a limited few" or "intended to be held in confidence or kept secret."[14]

Second, there is no indication that the FDA gives any assurance – formal or informal – that the identity of a company linked to an outbreak would be kept confidential. On the contrary, disclosure is standard practice when, under the current regulation, a recall occurs. Without any assurance of confidentiality and no

[8] 58 F.4th 1255 (D.C. Cir. 2023).
[9] *Id.* at 1263.
[10] *Id.* at 1267.
[11] 588 U.S. 427 (2019).
[12] *Id.* at 428.
[13] *Id.*
[14] *Id.* at 434 (citations omitted)

consistent, established practice of secrecy by the entities themselves, the withheld information simply does not meet the definition of "confidential" under Exemption 4 (or the Trade Secrets Act).

ii. If FDA decides to continue to treat a company name as CCI, then it can allow broader disclosure of the name by relying either on its general statutory authority under the FDCA or by revising the language in 21 C.F.R. §20.91.

If FDA chooses to continue to treat a company name as CCI, then STOP believes there are at least two options for allowing broader release of the name of a company linked to an outbreak.

1. The FDCA provides FDA with the legal basis for allowing broader release of the name of a company linked to an outbreak.

As noted above, the Trade Secrets Act allows disclosure of CCI if it is "provided by law." Rather than relying on 21 C.F.R. §20.91, FDA could simply rely on an FDCA provision, 21 U.S.C. §393(b)(2)(A). This section directs FDA to protect the public health by ensuring that foods are "safe, wholesome, sanitary, and properly labeled."

FDA may, in fact, have relied on this provision of the FDCA when it disclosed the names of companies implicated in a 2022 outbreak traced to pre-packaged "Power Greens" salads. FDA's outbreak communications disclosed the brand names of two companies – "Nature's Basket" and "Simple Truth"[15] – that sold the implicated products even though there was no recall, and the product, which was past its expiration date, was no longer available to consumers.

There are several ways that release of the name of a company linked to an outbreak – even when there is no recall – protects public health and prevents foodborne illness. First, publicizing the name of a company that produced contaminated food could prompt some consumers who ate the product but did not seek medical attention – or did not report their illnesses to the health department – to do so. Second, while the agency may believe there is no more contaminated product in commerce or consumers' kitchens, disclosing the company name in this situation could alert people who may still have the food product in their homes not to eat it and thereby prevent additional illnesses. Third, making public the name of a company responsible for an outbreak may incentivize that company to redouble its efforts related to food safety.

FDA's policy of limiting disclosure of company names results in the unintended consequence of keeping consumers who are sickened by fresh produce in the dark more often than those who consumed contaminated, non-perishable products. Given the perishable nature of produce, recalls often occur less frequently for fresh fruits and vegetables than for processed foods, which have longer shelf lives. Under FDA's current policy of releasing company names only when there is a recall, it is likely that consumers more

[15] "Outbreak Investigation of E. coli O157:H7: Power Greens Packaged Salad (January 2022)". https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-e-coli-o157h7-power-greens-packaged-salad-january-2022. Accessed: January 21, 2026.

often learn the names of companies that make processed foods that are linked to an outbreak than those that sell fresh fruits and vegetables.

By limiting the release of company names, FDA undermines public health more broadly. Consumers are encouraged to eat more fresh produce, through this Administration's Make America Healthy initiative and the recently released Dietary Guidelines for America, both of which recognize the vital role that "whole, healthy" foods like fresh produce play in improving health outcomes and reducing healthcare costs. At the same time, fresh produce is responsible for a significant percentage of foodborne illness outbreaks.[16] If consumers hear again and again about outbreaks linked to fresh produce – but they are not provided all the key information about these outbreaks, including the name of the company that produced or grew the contaminated product – then their confidence in the safety of fresh fruits and vegetables will likely decline and, as a result, they may decide not to increase their consumption of produce.

2. Alternatively, FDA could allow for broader release of a company name by revising the language in 21 C.F.R. §20.91.

Another option would be for the agency to revise its regulation, 21 C.F.R. §20.91, to broaden the circumstances under which disclosure is allowed. We suggested some revised language above. This option, however, is not our preferred course of action because it would require the agency to undertake a rulemaking proceeding, which can often take years to complete. We believe that other options suggested in this petition can be implemented quickly, which is appropriate, as in this situation, when public health is impacted.

Conclusion

Granting this petition would be consistent with this Administration's commitment to "radical transparency" related to food.

Moreover, as discussed above, it is also consistent with FDA's responsibility to ensure public health. As a 2024 Viewpoint piece in the *Journal of the American Medical Association* (JAMA) maintains, the relevant principles covering disclosure of CCI encompassed in FOIA and the Trade Secrets Act appear to give FDA broad authority to share information – if it so chooses.[17] The authors of this piece align with the position taken in this petition: "FDA can take steps to allow itself more flexibility to share information in the interest of public health."[18]

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[16] *See* Interagency Food Safety Analytics Collaboration. Foodborne illness source attribution estimates for *Salmonella*, *Escherichia coli* O157, and *Listeria monocytogenes* – United States, 2022. GA and D.C.: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Food and Drug Administration, U.S. Department of Agriculture's Food Safety and Inspection Service. December 13, 2024.

[17] C. Joseph Ross Daval, JD, A. Kesselheim MD, JD, MPH, Viewpoint: The Origins of "Confidential Commercial Information" at the FDA" JAMA p 533 (August 20, 2024).

[18] *Id.*

STOP urges FDA to disclose the name of the consumer-facing company linked to a foodborne illness outbreak even when there is no recall. It could take the requested action by deciding that a company name should not be treated as CCI. If the agency chooses to continue treating a company name as CCU, it can allow broader release by relying on its authority under the FDCA or by revising the regulation it relies on currently to allow only limited disclosure.

We wholeheartedly endorse the authors of the Viewpoint piece when they say, "a more balanced approach to public disclosure of company information is long overdue at the FDA, where careful sharing of information could save lives, advance research, and promote accountability.[19]

C. Environmental Impact

The action requested is subject to a categorical exclusion under 21 C.F.R. §§ 25.30 and 25.32 and, therefore, does not require the preparation of an environmental assessment.

D. Certification

The undersigned certifies that, to the best of her knowledge and belief, this petition includes all information and views on which the petition relies, and it includes representative data and information known to the petitioner that are unfavorable to the petition.

Respectfully submitted,

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[19] *Id.* at 534 (citation omitted).