U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

November 13, 2026

Sandra Eskin, J.D.
Chief Executive Officer
Stop Foodborne Illness
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Sent via email to: klombardo@stopfoodborneillness.org

Re: Docket Number FDA-2026-P-1448

Dear Chief Executive Officer Eskin:

This letter responds to your 2026 citizen petition regarding the disclosure of company names linked to a foodborne illness outbreak and the Food and Drug Administration's (FDA's) interpretation of what is confidential commercial information (CCI).[1] Your petition requests that FDA "change its position that a company name is CCI."[2] Alternatively, you ask that FDA "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 . . . , 21 U.S.C. §393(b)(2)(A), or by revising the language of 21 C.F.R. §20.91 . . . ."[3] Your petition also requests that FDA "adopt a policy of publicly disclosing the names of all companies associated with foodborne illness outbreaks, whether or not there is a related recall."[4]

Thank you for raising these issues. We have carefully considered your requests and arguments. In addition, consistent with our regulations on citizen petitions,[5] we have considered input from the U.S. Department of Justice's Office of Legal Counsel (OLC). For the reasons stated below and in the attached OLC opinion,[6] we are denying your petition insofar as it is premised on a misunderstanding of FDA's current position regarding CCI, requests FDA to take actions that would violate the Trade Secrets Act, or requests specific changes to 21 CFR 20.91.

However, FDA is committed to providing information relevant to helping consumers and others in identifying products that are part of a foodborne illness outbreak or a recall. Therefore, although FDA is denying your petition, we agree that actively exploring rulemaking is an

[1] Citizen Petition from Stop Foodborne Illness, submitted to the Division of Dockets Management, Food and Drug Administration, dated February 5, 2026 (Petition).
[2] Petition at 2.
[3] Petition at 2-3.
[4] Petition at 2.
[5] 21 CFR 10.30(h).
[6] Public Disclosure of Supply Chain Information in Foodborne Illness Outbreaks and Recalls, __ Op. O.L.C. __ (Oct. 26, 2026), https://www.justice.gov/olc/media/1468731/dl.

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important next step on this issue, and we welcome input from you and other stakeholders as we engage in this iterative process.

I. It Is Not FDA's Position That a Company Name Itself Is CCI; Rather It Is the Supply Chain Relationship That Is Potentially CCI

As an initial matter, we are clarifying our current position. In your petition, you state, "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."[7] This is not an accurate description of our position.

FDA does not consider a company's name itself, or the association of the company's name with a foodborne illness outbreak, to be CCI. Rather, it is the business relationship between firms in the supply chain that is generally considered CCI unless such a relationship is public. For example, a supply chain could include farms, manufacturers, distributors, and retailers. Because supply chain information may qualify as CCI, identifying a company as being part of the supply chain that is associated with an outbreak may disclose CCI if such identification also discloses otherwise non-public relationships in the supply chain.

Accordingly, we deny your petition's request that FDA "change its position that a company name is CCI," as this request is premised on a misunderstanding of FDA's position.

II. FDA Currently Does Name Companies Associated with a Foodborne Illness Outbreak

FDA's practice is to publicly disclose information related to an outbreak or recall that would best assist consumers in protecting themselves and ensure that entities in the food supply chain are removing contaminated food from the market. FDA publicly discloses as much information as possible given what information is available and is legally permissible to disclose. We may notify the public of the names of companies that sell products associated with outbreaks, even in the absence of a recall, and have done so in several circumstances.[8] FDA often publicizes the name of the firm that is most closely associated with a product (or products) impacted by an outbreak to ensure a consumer can take action. For example, FDA may publicize the brand name, provide photographs or descriptions of the product, and provide information about its retail or geographic distribution. In addition, for many outbreaks, there are associated recalls, and FDA regularly relies on its regulation under 21 CFR 20.91 to disclose supply chain information

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[7] Petition at 4.

[8] *See*, *e.g.*, "Outbreak Investigation of Shiga Toxin-producing E. coli & Salmonella: Sprouts," (Aug. 21, 2026), available at https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-shiga-toxin-producing-e-coli-salmonella-sprouts-august-2026 ("Epidemiologic and traceback data show that alfalfa sprouts distributed by Everything Sprouts, LLC of Minneapolis, MN may be contaminated with multiple pathogens and have been identified as a source of illnesses in this outbreak."); "Outbreak Investigation of E. coli O157:H7: Raw Cheddar Cheese," (March 15, 2026), available at https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-e-coli-o157h7-raw-cheddar-cheese-march-2026 ("State and local public health officials have interviewed 3 ill people about food exposures of interest in this outbreak. All 3 people (100%) reported eating RAW FARM- brand raw cheddar cheese. . . . Epidemiologic evidence indicates that RAW FARM-brand raw cheddar cheese products made by RAW FARM, LLC are the likely source of this outbreak.").

that is necessary to effectuate the recall.

However, as addressed in Section III, we acknowledge that we are limited in our ability to publicly identify additional firms in the supply chain when such information is CCI.

III. For the Reasons Described in the Attached OLC Memo, FDA's Ability to Publicly Disclose Supply Chain Information Is Limited Under Our Current Legal Authorities

In your petition, you ask in the alternative that FDA "more broadly disclose the name of a company linked to an outbreak" based on current statutory authority, including Section 1003(b)(2)(A) of the FD&C Act (21 U.S.C. § 393(b)(2)(A)).[9] FDA shares your interest in publicly disclosing as much relevant supply chain information related to an outbreak or recall as possible. Providing such information can, among other things, assist consumers in protecting themselves and ensure that entities in the food supply chain are removing contaminated food from the marketplace and are able to address problems in their supply chain. To that end, after receiving your petition, the Office of General Counsel in the Department of Health and Human Services asked OLC to opine on whether FDA may disclose additional supply chain information under our current statutory and regulatory authorities. As the OLC opinion explains, FDA's disclosure authority is limited under current regulations. We have attached OLC's opinion, which we incorporate by reference, to this response.

IV. FDA Is Committed to Exploring Rulemaking to Address This Issue

As another alternative to your request that FDA change its interpretation regarding what qualifies as CCI, your petition requests that FDA revise the language of 21 CFR 20.91 and suggests specific regulatory text.[10] FDA is denying your specific requested revision to 21 CFR 20.91 because it finds the suggested language to be unclear. For example, it is unclear what the phrase "when the brand name is known" means or whose knowledge it is referring to.

However, we recognize the importance of the issues that you raise and are committed to exploring regulatory solutions to address these concerns. As noted above, FDA agrees that actively exploring rulemaking is an important next step on this issue. As FDA engages in this process, we welcome input and engagement from you and other stakeholders as we work towards a long-term regulatory solution.

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[9] Petition at 2.

[10] Petition at 2-3, 6-7. Specifically, the Petition requests that the last sentence of 21 CFR 20.91 be revised as follows: "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.** . .~~– effectuate such actions, e.g., the brand name, code designation, and distribution information are released when a product is recalled.~~"

V. Conclusion

For the reasons stated above, in accordance with 21 CFR 10.30(e)(3), your petition is denied.

Sincerely,

DONALD A. PRATER -S
Digitally signed by DONALD A. PRATER -S
Date: 2026.11.13 11:16:54 -05'00'

Donald Prater, DVM
Acting Deputy Commissioner for Food
Human Foods Program

Attachment: Public Disclosure of Supply Chain Information in Foodborne Illness Outbreaks and Recalls, Op. O.L.C. (Oct. 26, 2026), https://www.justice.gov/olc/media/1468731/dl.

(Slip Opinion)

Public Disclosure of Supply Chain Information in Foodborne Illness Outbreaks and Recalls

Current FDA regulations generally do not authorize government disclosure of supply chain information for purposes of the Trade Secrets Act.

FDA has authority pursuant to 21 U.S.C. § 375(b) to amend its regulations to permit disclosure of supply chain information in situations involving imminent danger to health or gross deception of the consumer. Such regulations would constitute legal authorization such that disclosure would not create liability under the Trade Secrets Act.

October 26, 2026

MEMORANDUM OPINION FOR THE ACTING GENERAL COUNSEL
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Self-government requires an informed citizenry. As James Madison put it, "'[a] popular Government, without popular information . . . is but a Prologue to a Farce or a Tragedy.'" *Bd. of Educ., Island Trees Union Free Sch. Dist. No. 26 v. Pico*, 457 U.S. 853, 867 (1982) (quoting 9 Writings of James Madison 103 (G. Hunt ed. 1910)). And "those who execute the laws" must also have the means of "securing the information and data necessary for the most effective and intelligent conduct of Government." *Shapiro v. United States*, 335 U.S. 1, 53 (1948) (Frankfurter, J., dissenting). With increased regulation, "federal agencies' demands for information about the activities of private individuals and corporations" have also increased. *Chrysler Corp. v. Brown*, 441 U.S. 281, 285 (1979). This accumulation of proprietary information in the files of the federal government requires compromise between the rightful confidentiality of such information and the needful transparency in government decision-making. *See Critical Mass Energy v. NRC*, 975 F.2d 871, 872 (D.C. Cir. 1992). Congress struck such a compromise in the Trade Secrets Act. 18 U.S.C. § 1905. Dating to 1864, *see* Revenue Act of 1864, § 38, 13 Stat. 238, the Act prohibits government officers and employees from "publish[ing], divulg[ing], disclos[ing], or mak[ing] known in any manner or to any extent not authorized by law any information" obtained by the federal government and relating to "the trade secrets, processes, operations, style of work, or apparatus" of business actors. 18 U.S.C. § 1905. But the Act permits disclosure of such information if "authorized by law." *Id.*

You have asked if the Food and Drug Administration ("FDA") is authorized by law to disclose supply chain information in foodborne illness outbreak and recall scenarios. Under current regulations, FDA's disclosure authority is limited, as described below. But under 21 U.S.C. § 375(b), the Secretary of Health and Human Services and his delegees may amend those regulations to allow further disclosure.

I.

FDA—under the purview of the Department of Health and Human Services ("HHS")—is charged with "protect[ing] the public health by ensuring," among other things, that "foods are safe, wholesome, sanitary, and properly labeled" and that "drugs are safe and effective." 21 U.S.C. § 393(b). To fulfill its statutory duties, FDA wields authority delegated from the Secretary of HHS to gather relevant information from interstate and foreign commercial actors, including through review of business records. *See id.* §§ 373(a), 374(a), 381(a), 384a(d); 2 *FDA Staff Manual Guides: Delegations of Authority*, No. 1410.10, at 1 (2023), https://perma.cc/DH7T-4YMV (delegating authorities granted by the Federal Food, Drug, and Cosmetic Act to the FDA Commissioner). Pursuant to the same delegation, the FDA Commissioner may also promulgate regulations governing the collection and disclosure of needed business information. *See* 21 U.S.C. § 371(a). In addition, FDA has delegated authority to issue regulations "necessary to prevent the introduction, transmission, or spread of communicable diseases." 42 U.S.C. § 264(a).

During its investigation of a foodborne illness outbreak, FDA often obtains proprietary information, including the names and locations of various entities in a supply chain. FDA considers supply chain information to be confidential commercial information because it is "valuable data or information which is used in one's business and is of a type customarily held in strict confidence." 21 C.F.R. § 20.61(b). As a general matter under current regulations, such information is "not available for public disclosure." *Id.* § 20.61(c); *see also id.* § 20.82(b)(1) ("The Commissioner shall not make available for public disclosure any record that is . . . [e]xempt from public disclosure pursuant to § 20.61."); *id.* § 20.111(d)(3) ("Production, sales, distribution, and similar data and information" "are not available for public disclosure . . . ."). There are limited exceptions to this ban on disclosure, such as when nonpublic information has "previously

been disclosed in a lawful manner to any member of the public," *id.* § 20.81(a), or when disclosure is required for "compliance with a final court order," *id.* § 20.83(a). And because the owner of nonpublic proprietary information "can waive his right" to confidentiality, FDA may also disclose such information with the consent of the proprietors. *Release to a Court of Trade Secret Information Protected Under the Federal Food, Drug, and Cosmetic Act*, 2 Op. O.L.C. 193, 194 (1978).

Under 21 C.F.R. § 20.91, FDA may also disclose supply chain information when "necessary to effectuate" an administrative or court enforcement action such as a recall. Determining whether disclosure is authorized under this regulatory exception requires a case-by-case analysis that includes consideration of several factors, such as whether the food is likely to be available for consumption, whether the food is easily identified as being subject to the recall from its retail packaging (or lack thereof), whether consumers are likely to have discarded the food labeling, and whether the food distribution was confined to a specific region. *See* FDA, *Public Availability of Lists of Retail Consignees to Effectuate Certain Human and Animal Food Recalls: Guidance for Industry and FDA Staff* at 4–5 (Nov. 2020), https://perma.cc/YB52-VJXM.

The Federal Food, Drug, and Cosmetic Act nowhere requires this arduous analysis. And in practice, the exercise apparently proves onerous. We understand that supply chain information often does not qualify for disclosure under section 20.91 for a variety of reasons, including because there has been no official administrative action to effectuate, or because the action is completed before FDA can collect the information.

II.

Liability under the Trade Secrets Act does not attach for the disclosure of protected information when the disclosure is "authorized by law." 18 U.S.C. § 1905.[1] The Supreme Court has held that "properly promulgated,

[1] We assume for purposes of analysis that supply chain information falls within the categories of information protected by the Trade Secrets Act. For our part, we question whether that assumption is grounded in the best reading of the law, since the identity of partners in the supply chain is different in kind from the types of information listed in the Act, which all relate to internal business processes. *See McLaughlin Chiropractic Assocs., Inc. v. McKesson Corp.*, 606 U.S. 146, 160 (2025) ("[T]he *noscitur a sociis* canon coun-

substantive agency regulations" can serve as the requisite authorization. *Chrysler Corp.*, 441 U.S. at 295–96. Thus, the permissibility of FDA disclosing confidential commercial information under the Act turns on relevant statutes and FDA's substantive regulations issued pursuant to statutory authority. If the regulations do not authorize or otherwise limit disclosure, then the Act's general bar on disclosure applies. But if the regulations affirmatively permit disclosure, then disclosure is "authorized by law," and there can be no liability under the Act. As noted above, FDA's regulations prohibit the public disclosure of confidential commercial information except under limited circumstances.

Given FDA's current regulations, the Trade Secrets Act largely prevents FDA from disclosing supply chain information. But FDA has authority to amend its regulations to allow broader disclosure, should it choose to do so in the future.

A.

From the above description of FDA's current regulations on confidential commercial information, *supra* Part I, it follows that disclosure of supply chain information is not authorized in the mine run of cases. The regulations dictate that such information is "not available for public disclosure" except under very limited circumstances. 21 C.F.R § 20.61(c). Confidential commercial information, including supply chain information, is expressly exempted from regulations allowing "[d]iscretionary disclosure by the Commissioner." *Id.* § 20.82(b)(1). And even when supply chain information is voluntarily submitted to FDA, regulations generally prevent its disclosure. *Id.* § 20.111(d)(3). Exceptions are narrow, though they constitute authorization for disclosure for purposes of the Trade Secrets Act where they apply. *See id.* §§ 20.81(a), 20.83(a).

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sels against reading [a] term . . . to be different in kind and broader than the other[s]" in a statute.). But some federal appellate courts have held that "[the Trade Secrets Act] and [FOIA] exemption (b)(4) cover basically the same material." *Gen. Motors Corp. v. Marshall*, 654 F.2d 294, 297 n.9 (4th Cir. 1981); *McDonnell Douglas Corp. v. U.S. Dep't of the Air Force*, 375 F.3d 1182, 1185 (D.C. Cir. 2004). Because that exemption covers "commercial or financial information obtained from a person and privileged or confidential," 5 U.S.C. § 552(b)(4), there is a substantial likelihood that these courts and perhaps others will view confidential commercial information as subject to the Trade Secrets Act.

True, current regulations allow FDA to disclose supply chain information when "necessary to effectuate" administrative or court enforcement actions such as recalls. *Id.* § 20.91. This, too, is authorization precluding liability under the Trade Secrets Act. But based on our understanding of how FDA implements section 20.91, this authorization is exceedingly narrow in practice. To start, it is limited to instances where there is an actual administrative or court enforcement action to effectuate. For example, FDA's hands are tied before a recall is officially initiated. More complicated still is the reality that collecting certain confidential commercial information may be time-consuming such that, by the time it is collected, it is no longer necessary. Thus, section 20.91 only seldom authorizes disclosure of supply chain information. Consequently, under regulations currently in force, the Trade Secrets Act prevents FDA from publishing supply chain information in many cases.

B.

Notwithstanding limits imposed by FDA's current regulations, FDA has statutory authority to amend those regulations to authorize disclosure of supply chain information more broadly. As noted above, the Federal Food, Drug, and Cosmetic Act nowhere mandates FDA's current context-limited, case-by-case approach to authorizing disclosure of confidential commercial information. Instead, it grants the Commissioner broad discretion to "cause to be disseminated information regarding food, drugs, devices, tobacco products, or cosmetics in situations involving, in the opinion of the [Commissioner], imminent danger to health or gross deception of the consumer." 21 U.S.C. § 375(b). That provision, combined with the authority to issue regulations to enforce it, *id.* § 371(a), enables the Commissioner to authorize by law the disclosure of confidential commercial information—including supply chain information—thereby foreclosing liability under the Trade Secrets Act for its disclosure.

The Federal Food, Drug, and Cosmetic Act authorizes the Secretary of HHS, and the Commissioner as his delegee, to issue regulations that are "substantive," such that they constitute legal authorization for purposes of the Trade Secrets Act. *Chrysler Corp.*, 441 U.S. at 295. Substantive regulations—in contradistinction to mere interpretive regulations—"'affect[] individual rights and obligations.'" *Id.* at 302 (quoting *Morton v. Ruiz*, 415 U.S. 199, 232 (1974)). The Supreme Court's decision in

Chrysler Corp. establishes that regulations "govern[ing] the public's right to information"—as would regulations issued to enforce section 375(b)—satisfy this rubric. *Id.* at 303. Substantive regulations must also be "issued by an agency pursuant to statutory authority [to] implement the statute." *Batterton v. Francis*, 432 U.S. 416, 425 n.11 (1977) (cleaned up). FDA regulations permitting disclosure of confidential commercial information under section 375(b) would satisfy this requirement because they would be issued pursuant to section 371(a), which empowers the Commissioner "to promulgate regulations for the efficient enforcement" of the statute. "[T]he distinct reference . . . to enforcement" in the statutory grant dispels any contention that FDA's regulatory authority "merely concerns agency procedures" or "is solely administrative" rather than substantive. *Am. Trucking Ass'ns v. United States*, 344 U.S. 298, 311 (1953).

Here, the category of information FDA is authorized to disseminate under section 375(b) encompasses confidential commercial information. The statute speaks of all "information regarding food, drugs, devices, tobacco products, or cosmetics," without distinctions based on confidentiality or privilege. 21 U.S.C. § 375(b). The word "regarding," like its synonym "respecting," has "a broadening effect, ensuring the scope of a provision covers not only its subject but also matters relating to that subject." *Lamar, Archer & Cofrin, LLP v. Appling*, 584 U.S. 709, 717 (2018). Because supply chain information—as well as other confidential commercial information collected by FDA—relates to regulated products, there can be no serious doubt that it is subject to disclosure under section 375(b).

As for the circumstances that may trigger a lawful dissemination, section 375(b) specifies that there must be "imminent danger to health or gross deception of the consumer." This provision places important limits on the Commissioner's authority to permit disclosure of confidential commercial information. For example, a regulation purporting to authorize disclosure after a foodborne illness outbreak has already ended would likely be inconsistent with section 375(b) and hence unlawful. But by using the words "in the opinion of the [Commissioner]," 21 U.S.C. § 375(b), the statute "clearly entrusts the decision" of when imminent danger exists "to the [Commissioner's] discretion," within the boundaries set by the statute itself, *Kalkouli v. Ashcroft*, 282 F.3d 202, 204 (2d Cir. 2002) (interpreting a similarly worded immigration statute); *see also Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 394 (2024) ("[T]he

statute's meaning may well be that the agency is authorized to exercise a degree of discretion."). The grant of authority is not limited to instances where disclosure is "necessary to effectuate" an enforcement action, 21 C.F.R. § 20.91, or where current regulatory exceptions otherwise apply. Thus, FDA is free to revise its regulations, removing unnecessary restrictions on disclosure of confidential commercial information and affirmatively authorizing disclosure of such information when, in the Commissioner's opinion, either of the statutory conditions—imminent danger to health or gross deception of the consumer—has attained. So revised, the regulations would constitute "authoriz[ation] by law," making disclosure of supply chain information pursuant to the regulations consistent with the Trade Secrets Act.

Modifying such regulations would hardly be a "transformative expansion" of FDA's powers. *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014). Indeed, as described above, current FDA regulations allow disclosure of proprietary information in limited circumstances, and FDA has in fact disclosed such information. Although dissemination of food-related information arguably affects "a significant portion of the American economy," *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 159 (2000), Congress clearly authorized such action "in situations involving . . . imminent danger to health or gross deception of the consumer," 21 U.S.C. § 375(b).

To the extent other statutes limit disclosure authorized by 21 U.S.C. § 375(b), FDA is bound to observe such limitations. Two possible statutory restrictions have been suggested, but neither operates to restrain disclosure authorized by section 375(b). 21 U.S.C. § 331(j) does not limit disclosure, because it forbids revealing only certain information collected by FDA "concerning any method or process which as a trade secret is entitled to protection." Under the foregoing analysis, confidential commercial information properly authorized for disclosure pursuant to 21 U.S.C. § 375(b) is not entitled to protection and therefore is not covered by section 331(j). Likewise, 5 U.S.C. § 552(b)(4)—the FOIA exemption pertaining to confidential commercial information—does not prohibit FDA from disclosing such information as authorized by law. It merely means that FDA is not compelled to disclose such information at the public's request. *Chrysler Corp.*, 441 U.S. at 292 ("By its terms, subsection (b) demarcates the agency's obligation to disclose; it does not foreclose disclosure.").

Under both statutes, FDA retains its authority, and obligations, to protect and disclose information consistent with the law.

III.

Under current regulations, FDA is generally not authorized to disclose supply chain information, and therefore the Trade Secrets Act prohibits divulging such information. But FDA has statutory authority to amend its regulations to allow broader disclosure of supply chain information in situations involving imminent danger to health, or gross deception of the consumer. Under properly issued regulations, such disclosure would not violate the Trade Secrets Act but would instead be authorized by law.

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