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ANALYSIS

# Advancing The FDA's Human Foods Program Through Additional Authorities And User Fees

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**ABSTRACT** **The Food and Drug Administration (FDA) lacks certain authorities and is persistently underresourced to fulfill its mission of protecting the public by ensuring that foods are safe, wholesome, sanitary, and properly labeled. Particularly concerning gaps exist in pre- and postmarket oversight of food ingredients that are often found in ultraprocessed foods. Numerous substances either have evidence of harm or are unknown to the FDA and the public. Additional authorities and resources are necessary. User fees have been successfully implemented to provide resources to the FDA for other programs under its purview. This legal and policy analysis evaluates the FDA's food-related authorities that would be amenable to a new user fee program. It reviews policy domains where new or enhanced user fees may be warranted. We find that a new comprehensive FDA user fee program for food may benefit industry and generate targeted new resources to strengthen the agency's oversight.**

The Food and Drug Administration (FDA) is persistently underresourced and lacks certain authorities to oversee the Human Foods Program, as recently documented in a report issued by the Reagan-Udall Foundation, an organization created by Congress to advance the FDA's mission.[1] The report identified several deficiencies in the FDA's authorities,[1] and acute concerns exist over the agency's inability to fulfill critical food safety activities related to its pre- and postmarket review of substances added to food.[2] These include food additives, color additives, and ingredients deemed "generally recognized as safe" (GRAS) by industry but that might not necessarily be safe.[2,3] Because of these gaps in the FDA's oversight, several states recently started to unilaterally ban specific food ingredients with evidence of health harms.[2] Yet numerous other substances in food have evidence of harm or, worse, are unknown to the FDA and the public.[2] The FDA also has insufficient resources (including funding and staff), which creates barriers to it exercising its existing authorities.[4] The sum effect is a food supply that is increasingly unsafe and unhealthy.[5,6]

The FDA primarily relies on congressional appropriations to fund its food-related activities. In 2024, the United States Supreme Court recognized that this annual process forces federal agencies "to regularly implore Congress to fund their operations for the next year."[7] In contrast, for other programs under the FDA's purview, the FDA's congressional appropriations are meaningfully supplemented or substituted with user fees. For instance, in 2022, user fees made up 66 percent of the $2.116 billion human drugs budget and 100 percent of the $680 million tobacco budget, compared with only about 1 percent of the $1.145 billion foods program budget.[1,8]

Fees are charges imposed by government on the regulated industry (for example, manufacturers and importers) to recoup costs associated with government regulatory activities or services that directly benefit the fee payer.[9] Fees may be structured as fee-for-service (such as color addi-

tive certification) or to support regulatory activities related to the program. For instance, over-the-counter drug user fees are pooled, and the FDA can use the money for authorized activities.[10]

Congress established all of the FDA's user fees, which cover the costs of various pre- and postmarket processes corresponding to FDA regulatory activities, such as the agency's registration of companies, review of applications, and reinspection, among others (online appendix exhibit 1).[11] Fees do not ensure a specific outcome for the payer (such as a positive FDA review) but, rather, fund the regulatory process.[12]

The FDA has explained that user fees facilitate "timely availability of innovative FDA-regulated products without compromising the agency's commitment to scientific integrity, public health, regulatory standards, patient safety, and transparency."[12] Frequently, industry entities initially oppose the imposition of user fees but then later support fees that establish efficient regulatory implementation for the industry (such as timely FDA review of drug applications).[13,14] In these cases, user fees have brought stability to programs and benefits to regulated entities, allowing companies to anticipate timelines and bring products to market more efficiently.

The FDA has the authority to collect limited food-specific user fees under the Food Safety Modernization Act of 2011. However, a food-related user fee program must be comprehensive to support the FDA's Human Foods Program and, as envisioned here, to support additional authorities that the agency needs to fulfill its food-related mission.[15] A more comprehensive user fee was proposed more than a decade ago, but it was ultimately not implemented partially because of industry opposition.[16] However, much has changed since then, on several fronts. First, hundreds of new substances of potential concern have been introduced into the food supply and are primarily added to ultraprocessed foods, which are associated with multiple chronic diseases[5] and now make up 57 percent of adult calories and 67 percent of youth calories in the US.[17] Second, new state bans on ingredients have highlighted the limits of the FDA's oversight and created regulatory inconsistency.[2] Third, public and congressional interest in a safer food supply is growing.[6,18,19] Fourth, new science has emerged on both harmful and beneficial food compounds.[20] Finally, new data indicate that the FDA does not meet both statutory and regulatory timelines set out for its review of premarket submissions, including food and color additive petitions, proposed labeling claims, and new infant formula notifications.[21,22]

This article reviews the deficiencies in the FDA's oversight over food that could be addressed with increased authorities and additional resources. Although we primarily focus on the FDA's pre- and postmarket authorities to address risks associated with chemicals in the food supply, the FDA both has and lacks additional authorities that are amenable to a user fee program, so we include these to ensure that a comprehensive user fee program is considered. Our article identifies current authorities for food-related user fees, with a direct comparison to over-the-counter drug fees; proposes mechanisms for a food-related user fee program; and presents outstanding questions for policy implementation and future research.

## Food-Related Regulatory And Funding Deficiencies

An identifying feature of ultraprocessed foods is the inclusion of industrial ingredients not common in home cooking, including those classified as food additives, color additives, and GRAS substances. The FDA's oversight over these varies based on ingredient type, which determines the FDA's pre- and postmarket authorities (see appendix exhibit 2).[11] In addition, the agency has authority over infant formula and food labeling claims.

**PREMARKET AUTHORITIES** Under the 1958 Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act of 1938, manufacturers are required to submit petitions to the FDA for the approval of food and color additives before introducing them into the food supply.[23,24] Under this process, the FDA reviews the premarket petition and promulgates a regulation laying out the conditions of safe use.[23,24] However, the agency does not have the resources to respond in a timely manner to such petitions and frequently does not meet its 180-day statutory deadline for a final decision.[21]

For new GRAS substances, notification to the FDA is voluntary.[2,3] Manufacturers may opt to submit a premarket GRAS notification to the FDA with evidence showing that the substance is generally recognized "among experts qualified by scientific training and experience" to be safe under the conditions of its intended use.[25] The agency either issues a "no question" letter stating that it does not question the company's conclusion that a substance is GRAS or an "insufficient basis" letter stating that it finds insufficient information to substantiate a GRAS claim.[2,3] In the latter case, the company can withdraw its notification and still go to market with the substance.[2,3] Alternatively, a manufacturer can determine for itself that a substance is GRAS

(termed "self-GRAS") and add the substance to food without any FDA notification or oversight.[2] Although companies are technically required to rely on "scientific procedures" for such a GRAS designation,[26] these can be internally held and based on "unpublished" data.[27]

The FDA has not promulgated regulations that define which substances should go through premarket food additive review and which can be designated as GRAS. Industry has leveraged this deficiency in regulatory clarity to use the self-GRAS pathway and add thousands of new compounds to food, many without FDA oversight or public knowledge. This has been termed the "GRAS loophole."[2] In addition, ingredients may be labeled generically (such as corn oil)[28] or broadly (such as spices, flavorings, and colorings), so they are not specifically identifiable on food labels.[29]

Industry entities may use the self-GRAS pathway for competitive reasons—for example, to protect trade secrets and prevent other entities from using the ingredient, or to increase speed of product development and market release, based on concerns that the FDA's public regulatory process may be slow and costly. Alternatively, they may have concerns that the science would not support a GRAS determination, meaning that the substance should be classified as a food additive subject to FDA regulation or prohibited from use altogether.

The FDA's position, which was upheld by a federal district court in 2021, is that it lacks express statutory authority to require premarket review or notification of GRAS ingredients.[30] However, some experts have concluded that the FDA has the authority to require premarket notification for GRAS substances and that the agency's interpretation to the contrary is not valid.[31] In 2024, the US Supreme Court overturned the Chevron doctrine, which directed courts to provide deference to agencies' reasonable interpretation of their own authorities.[32] Thus, judicial deference to this FDA interpretation is no longer required. Yet Congress could more explicitly require that the FDA engage in premarket review or notification of GRAS substances[18,19] and provide a revenue stream for efficient and timely premarket review of all ingredients.

Additional premarket food-related activities include the FDA responding to industry requests for it to promulgate regulations for health claims and issue letters of enforcement discretion for qualified health claims (see appendix exhibit 2 for definitions),[11] both of which take years for the FDA to finalize, potentially delaying industry innovation.[33] In addition, infant formula manufacturers must notify the FDA of a "new" infant formula (which includes major changes to existing formulas) at least ninety days before going to market.[34] However, the FDA has consistently failed to meet the ninety-day statutory deadline to respond, leaving infant formula manufacturers with challenges in planning their product development and market activities.[22]

**POSTMARKET AUTHORITIES** The FDA has postmarket authority to review all ingredients in the food supply to address safety concerns and ensure that food is not adulterated.[24,35–37] However, the agency has not comprehensively implemented this authority. The FDA recently proposed a process to engage in postmarket review on its limited budget,[38] which was criticized as vague and insufficient by stakeholders at a September 2024 public meeting. The lack of a formal, well-resourced postmarket review process is especially concerning for self-GRAS ingredients, as these substances have never been evaluated by the FDA.

When the FDA does act, it often takes decades to remove substances even when the evidence is clear that they are no longer "generally recognized" as safe. One example is the use of industrial trans fats from partially hydrogenated vegetable oils. Evidence of harm was identified in a seminal 1993 *Lancet* article,[39] followed by numerous scientific reports also demonstrating evidence of harm, including, among others, the 2000 Dietary Guidelines for Americans[40] and a 2005 Institute of Medicine report concluding that intake should be as low as possible.[41] In 2001, the Office of Management and Budget took the unprecedented step of prompting the FDA to act on the basis of the strength of the economic argument against partially hydrogenated vegetable oils.[42] Use of these oils was also banned by other countries, as well as in restaurants in the US by state and local jurisdictions.[43] In 2006, a scientific report calculated that 72,000–228,000 heart attacks in the US each year were associated with these oils.[44] Yet it was not until 2015 that the FDA revoked partially hydrogenated vegetable oils' GRAS status, with the final rule not taking effect until December 23, 2023.[45] This thirty-year timeline starkly demonstrates the inefficiencies and lack of timeliness of the FDA's postmarket review process.

Additional postmarket concerns became evident in 2023, when California banned ingredients with concerning evidence for harms, including red dye no. 3, potassium bromate, brominated vegetable oil, and propylparaben, all of which were previously banned in Europe.[2] One month after California's law was passed, the FDA revoked the approved food additive status, effective July 2024, for brominated vegetable oil, which is linked to nervous system damage.[46]

**A new comprehensive FDA user fee program for food may provide benefits to industry and generate targeted new resources for appropriate oversight.**

Yet this action occurred fifty-three years after the FDA determined that brominated vegetable oil was no longer GRAS. Instead of removing it from the food supply at that time, the agency designated it as an approved food additive, allowing it to remain in certain products.[2] Many additional examples exist, such as nonnutritive sweeteners implicated in metabolic risk.

Postmarket review is also critical for monitoring the appropriate dose of GRAS compounds. For example, caffeine is designated as GRAS "when used in cola-type beverages" at levels up to 0.02 percent by volume (about seventy milligrams per twelve ounces).[47] However, numerous marketed beverages have levels far exceeding this GRAS level, including energy drinks that have been linked to serious cardiac complications and death.[48] Yet the FDA has not used its postmarket authority to review the safety of caffeine doses used in these products.

The FDA has additional authority over "unapproved food and color additives" under the Food Safety Modernization Act. An unapproved food or color additive is a substance found in food that does not conform to an authorizing regulation and, in the case of an unapproved food additive, is found by the FDA to not be GRAS.[49] The Food Safety Modernization Act requires facilities that manufacture, process, pack, or hold food for US consumption to identify and evaluate known or reasonably foreseeable hazards associated with the facility.[50–52] A hazard is an "agent that has the potential to cause illness or injury,"[53] including "unapproved food and color additives."[51] Facilities must implement preventive controls, establish recall plans, and keep records of their hazard analyses in their food safety plans available for FDA review at inspection.[50] It is unclear the extent to which the FDA evaluates the use of hazardous unapproved food and color additives (such as cancer-causing dyes) during its inspections, pursuant to the law. However, this authority could ostensibly be a method for additional FDA oversight.

Beyond known compounds with evidence for harms, the self-GRAS process complicates postmarket review, contributing numerous compounds added to foods without public knowledge, let alone evidence to ensure their safety.[2]

The absence of sufficient resources and postmarket authorities also contributes to challenges in the timely implementation of the FDA's postmarket authority to review food labeling to address misbranded products. In addition, the agency's position is that it does not have the authority to regulate "structure/function" claims on food, which results in unsubstantiated structure/function claims on a wide range of food products.

## User Fee Programs

The FDA assesses user fees under most of its programs, including human drugs (prescription, generic, and over-the-counter drugs), animal drugs, medical devices, and tobacco. Appendix exhibit 1 elaborates on the FDA's user fee programs.[11]

**CURRENT FOOD-RELATED USER FEES** At this time, the FDA has statutory authority to collect food-specific user fees through the Food Safety Modernization Act, as well as export and color certification fees under the Federal Food, Drug, and Cosmetic Act. The Food Safety Modernization Act's user fee program intends to recoup costs for reinspection of domestic food facilities, failure of a domestic facility or an importer to comply with a recall order, and voluntary third-party accreditation and importers programs. Yet even in these cases, the FDA does not collect all statutorily authorized user fees.

The Food Safety Modernization Act requires the FDA to publish proposed guidelines considering the fee burden on small business and use notice-and-comment rulemaking to adjust the fee schedule for small businesses.[54] The FDA stated that it will not issue invoices for reinspection or recall order fees until it publishes this small business guidance outlining the process to request a fee reduction.[55] The agency initiated this rulemaking in 2011 but has not finalized the guidance. Therefore, it has conducted reinspections but has not collected these fees, leaving behind an estimated $9 million in 2023 from reinspection fees alone (appendix exhibit 1).[11]

The FDA also collects user fees for color certification and requires certain color additives to undergo enhanced review (called "batch certification") based on the agency's determination that an additional "level of control" is necessary "to protect the public health."[56]

**LESSONS FROM OTHER FDA USER FEE PROGRAMS** The FDA's user fee programs provide resources to the agency to accomplish tasks that benefit the respective industries, such as enabling it to more expeditiously review applications, allowing companies to go to market more quickly. Based on such benefits, the pharmaceutical industry supported the Prescription Drug User Fee Act of 1992 because the fees were dedicated to accelerating the FDA's review of new drug applications and supplemented (instead of replacing) existing congressional appropriations.[13,57]

The generic drug industry initially opposed user fees until they observed the benefits of prescription drug user fees for predictability of review timelines and for leveling the playing field with foreign facilities.[57] The generic drug industry then negotiated user fees directly with the FDA, and after public input from stakeholders, the FDA and the industry jointly requested that Congress implement user fees.[14,58] After the passage of the Generic Drug User Fee Amendments in 2012, the median annual number of generic drugs approved by the FDA more than doubled.[58] Such benefits to industry could inform a user fee program for food and color additives, where there is currently a backlog of petitions.[21]

Enactment of the Over-the-Counter Monograph Drug User Fee Program in 2020 provides a useful lens to view the potential for Congress to grant the FDA additional premarket authority over GRAS ingredients and provide user fees to fund this activity. As established in 1972, the FDA's original over-the-counter drug monograph process required a three-phase public rulemaking culminating in a final regulation with conditions under which over-the-counter drugs were considered generally recognized as safe and effective.[59,60] However, the FDA lacked resources to support these over-the-counter drug monograph activities.[56] To streamline the over-the-counter drug process and provide appropriate resources to the agency, Congress passed the Over-the-Counter Monograph Drug User Fee Program. The program allows "companies to request changes to or propose new conditions of use for drugs that are [generally recognized as safe and effective] through the administrative order process rather than rulemaking,"[60] and it authorizes the FDA to collect user fees from qualifying manufacturers of over-the-counter monograph drugs and submitters of over-the-counter monograph order requests.[10] The FDA also agreed to adhere to specific timelines for conducting certain over-the-counter monograph activities.[60]

The program succeeded in being less burdensome, and it allows the FDA to issue administrative orders either on request or by its own initiative determining that a drug is or is not generally recognized as safe and effective, rather than through the more time-consuming notice-and-comment rulemaking.[59] In addition, the process provides for eighteen months of marketing exclusivity for certain monograph changes that are industry requested (such as a new active ingredient or new indication).[59] Further, the user fees themselves are authorized in five-year intervals, which provides Congress with an opportunity to adjust fees and address stakeholders issues at that time. These administrative efficiencies and marketing protections seem highly relevant for a user fee program for new food ingredients.

A voluntary user fee program in which a fee is required only when a company decides to participate may also be relevant for food, such as manufacturer requests for FDA review of proposed health claims and qualified health claims, for which new resources could accelerate current multiyear review timelines.

## Potential New Food-Related Authorities And User Fees

An increase in resources could support the FDA in meeting statutory and regulatory deadlines in its premarket review of petitions and notifications and in creating a more efficient and effective regulatory process for its postmarket review of substances in the food supply. However, funding alone will not address the gaps in the agency's premarket oversight for GRAS ingredients. Even with increased postmarket funding, the agency would still be faced with the initial task of identifying an unknown number of self-GRAS ingredients already in the food supply before embarking on a safety review. Congress has consistently failed to increase appropriations to the extent needed to cover the FDA's food-related activities,[4] so a user fee program is highly relevant.[1] Appendix exhibit 3 sets forth proposed new authorities and food-related user fee funding mechanisms,[11] summarized in exhibit 1.

Any FDA user fee must be authorized through an act of Congress. The US Supreme Court issued two decisions in 2024 indicating that the FDA cannot unilaterally require user fees and that congressionally mandated user fees are constitutional. In the first decision, the Court found that a user fee assessed on the fishing industry by a federal agency was not authorized by Congress and that without such express statutory authority to impose fees, agencies such as the FDA may not be able to unilaterally impose them.[32] In the second decision, the Court upheld a fee-based funding scheme established by Congress.[7] The Court identified fee-based models dating back

**EXHIBIT 1**

**Potential new Food and Drug Administration (FDA) user fees and authorities for food**

| Topics | Current authorities | Potential new authorities and funding needs, including user fees |
|---|---|---|
| Premarket authority: additives, claims, infant formula | The FDA has premarket authority to approve food additives, color additives, and health claims, and it exercises enforcement discretion for qualified health claims; infant formula manufacturers must submit a notification 90 days before going to market. | Congress could provide the FDA the authority to collect user fees to cover the cost of these premarket regulatory activities and services to speed up review times and provide industry with precise timelines to enable them to anticipate and plan for products' and claims' entrance to the market. |
| Premarket authority: generally recognized as safe (GRAS) substances | Industry has the option to self-GRAS or voluntarily submit a premarket notification to the FDA for GRAS review. The FDA lacks express authority to require industry to submit premarket GRAS petitions or notifications, but some experts conclude that the agency has implicit authority to require premarket GRAS submissions. User fees would not be beneficial if attached to the current voluntary GRAS notification, as it could further dissuade industry from submitting GRAS notifications. | Congress could direct the FDA to evaluate GRAS submissions pre-market. Congress should require GRAS determinations to be based on published (as opposed to unpublished) scientific data and direct the FDA to consider cumulative effects. The agency could issue guidance differentiating between food additives and GRAS substances, or Congress could require the agency to promulgate regulations clearly distinguishing between the two. Congress could require the FDA to conduct an initial determination as to whether a substance is GRAS or must go through food additive review or heightened GRAS review. Congress may consider penalties for failure to submit a food additive petition when the FDA discovers an unapproved food or color additive that industry self-designated as GRAS. Congress should fund any new premarket GRAS authority with user fees or additional appropriations. |
| Postmarket authority: ingredients in the food supply | The FDA has the postmarket authority to evaluate the safety of substances in the food supply (GRAS ingredients, food and color additives, food contact substances, and contaminants); however, it does not consistently or thoroughly use this authority. | Congress could create, or require the FDA to create, a formal robust consistent framework for postmarket review of all substances in food with user fees or appropriations to resource such a consistent and comprehensive review. |
| Food Safety Modernization Act (FSMA) | The FDA has the authority to review food safety plans, which include identification of unapproved food and color additives, issue recall orders, and reinspection of facilities to oversee compliance with hazard mitigation. | Congress could expand FSMA to require that the FDA be given access to all ingredient information and authority to inspect ingredients for unapproved food additives (including substances that the facility determined to be GRAS but should be subject to a food additive regulation) and color additives. The agency should explore how it could leverage FSMA to further identify and address unapproved food and color additives. The agency should finalize its small business guidance and assess statutorily permitted fees for reinspection and recall-order noncompliance. |
| Food labeling claims | All claims must be truthful and not misleading. Nutrient content claims and health claims must abide by FDA regulations and qualified health claims must abide by an FDA letter. The FDA issues warning letters to address inappropriate use of these claims. It issues guidance for structure/function claims for infant formula but does not regulate structure/function claims on food. | Congress could provide the FDA with additional authorities for structure/function claims on food, including the ability to regulate their use, and require companies to submit evidence to substantiate structure/function claims. Congress could allow user fees for the agency's premarket work on claims and include other claims if additional authorities are provided. |
| Food facility registration | Facilities engaged in manufacturing, processing, packing, or holding food for US consumption must register with the FDA biennially. No fees are assessed. | Congress could provide the FDA the authority to collect user fees for food facility registration. User fees would allow the agency to recoup the costs associated with registration of the 220,111 registered food facilities. |

**SOURCE** Authors' analysis of existing laws, regulations, and FDA documents.

to the nation's First Congress and confirmed that Congress is able to set up a fee-based system for a defined set of regulatory activities, with the fee assessed on the entity that benefits from the agency's activities.[7]

User fees could at a minimum cover the FDA's current premarket activities, including food and color additive petitions, health claims, qualified health claims, and new infant formula notifications, to increase speed and provide industry

with secure timelines to go to market. However, the current GRAS loophole remains a concern and needs to be closed. Otherwise, user fees could further dissuade industry from submitting GRAS notifications and drive industry to pursue the self-GRAS pathway instead of submitting food additive petitions. At a minimum, the FDA should require premarket GRAS notification. Congress alternatively could provide the FDA with clearer and expanded premarket authority to review GRAS substances, including the ability to charge user fees. Such resources and expanded authority could be similar to the over-the-counter drug user fee program's administrative process and funding mechanism.

Congress or the FDA may alternatively consider, at a minimum, mandatory premarket review to determine whether a substance must go through the food additive approval process or an enhanced GRAS review. In addition, the FDA should consider how it might leverage the Food Safety Modernization Act to strengthen its oversight for unapproved food and color additives.

User fees or increased appropriations are also necessary to sufficiently resource the FDA's postmarket review of all ingredients already in the US food supply. Although the agency expressly has the authority to conduct such reviews, it has not used this authority consistently, comprehensively, or in a timely manner, partially because of funding constraints. In the absence of either user fees or a substantially increased budget from Congress, the industry will continue to police itself, as the FDA is unlikely to be able to engage in timely, robust pre- or postmarket oversight of substances added to foods, resulting in continuing decades-long delays in identifying, preventing, and removing unsafe substances from the food supply.

Several questions remain for policy implementation and future research. First, a common argument against user fees is that they increase the cost of products. This can be a political barrier in the context of food. In 2022, the Department of Health and Human Services (HHS) evaluated this question in the context of medical devices and prescription drugs and found that user fees make up less than 1 percent of expected revenue for both.[58] Its literature review "did not find any papers linking user fees to high prices of brand drugs."[58] HHS concluded that user fees are not likely "commonly a driving factor" in decisions about bringing products to market or the products' pricing.[58] However, this should be evaluated for food.

Second, the role of small business exceptions should be considered. These exist for several current FDA user fees (appendix exhibit 1),[11] although Congress rejected a small business exception under the Generic Drug User Fee Amendments because it would increase administrative costs and the majority of generic companies are small companies that benefit from reduced review time, certainty, and program efficiency.[61] Yet one study concluded that generic drug user fees are regressive and that new and small companies pay relatively large fees compared with large and established companies.[57] For food, stepped fee programs based on company revenues, with possible exemptions for the smallest facilities, could be implemented to alleviate similar concerns for a new user fee program.

Finally, the relevant political willpower for and industry opposition against food-related user fees remain unclear. FDA user fees for other sectors are often directly negotiated with industry trade groups. This may also be possible for the food sector, although its relative fragmentation across many trade groups may increase the complexity of such negotiations. During the 2012 implementation of the Food Safety Modernization Act, thirty food industry trade groups wrote to the FDA opposing user fees proposed for other purposes than discussed here.[16] Yet it seems feasible that certain companies and sectors within the food industry might welcome user fees to speed up regulatory processes and help create a more level playing field.

## Conclusion

The FDA is severely underresourced to ensure the safety of the food supply and meet its public health mission. Congressional and public interest is growing to address the agency's insufficiencies in this regard. A new comprehensive FDA user fee program for food may provide benefits to industry and generate targeted new resources for appropriate oversight. ■

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