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ONE HUNDRED EIGHTEENTH CONGRESS

Congress of the United States
House of Representatives
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September 30, 2024

Mr. James "Jim" Jones
Deputy Commissioner for Human Foods
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Mr. Jones:

Thank you for appearing before the Subcommittee on Health on Tuesday, September 10, 2024, to testify at the hearing entitled "Evaluating FDA Human Foods and Tobacco Programs."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Friday, November 1, 2024. Your responses should be mailed to Emma Schultheis, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to Emma.Schultheis@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Brett Guthrie
Chair
Subcommittee on Health

cc: Anna Eshoo, Ranking Member, Subcommittee on Health

Attachment

Attachment — Additional Questions for the Record

The Honorable Cathy McMorris Rodgers

1. Mr. Jones, the Food and Drug Administration's (FDA's) proposed changes to the definition of "healthy" could potentially classify tart cherry products with added sugar as "unhealthy," even though they contain less total sugar than naturally sweet fruits like raisins. With this in mind, I request your response to the following questions:

    a. Can the FDA explain the scientific rationale for treating tart cherries with added sugar differently from naturally sweet fruit products like raisins, despite potentially lower total sugar content in the tart cherry products?

    b. Has the FDA conducted or reviewed any studies demonstrating that the human body processes added sugars in tart cherries differently from naturally occurring sugars in other fruits?

    c. How does the FDA reconcile its position on added sugars with that of the U.S. Department of Agriculture, which acknowledges the role of added sugars in enhancing nutrient-dense foods through preservation, browning, texture, and taste improvement?

    d. Has the FDA considered the potential economic impact on the tart cherry industry in states like Utah, and if so, what measures are being considered to mitigate any negative effects?

2. Mr. Jones, when questioned about whether it was accurate to say that products containing tetrahydrocannabinol (THC) were in violation of the Federal Food, Drug, and Cosmetic Act (FFDCA), you responded "That is correct." You also acknowledged that the FDA has not determined that THC is generally recognized as safe, and that the FDA has the authority to remove illegal products from the market. Given that products containing THC can easily be found in marketplaces in numerous states across the country, why has the FDA not issued guidance to people and businesses producing and selling products containing THC?

    a. What would you say to companies that are adding THC, whether from hemp or marijuana, to food and beverages products? Should those companies remove those products from shelves?

    b. What fines and punishments can individuals and businesses face for producing and selling products deemed illegal under the Federal Food, Drug, and Cosmetic Act? Are those fines and punishments made more severe if offenses are repeated or official guidance is ignored?

    c. What is the FDA's plan to ensure that products containing THC are not illegally found in the marketplace?

3. You also indicated that local law enforcement could play a role in removing illegal products from the marketplace. Has the FDA had any discussions with the Department of Justice, the Department of Education, or any other federal, state, or local law enforcement agency with regard to products containing THC that may violate the Federal Food, Drug, and Cosmetic Act?

    a. Is there any historical precedent to have state or local law enforcement agencies assist the FDA in removing illegal products from marketplaces?

4. Given the potential safety issues raised during recent litigation regarding the use of cow-milk based human milk fortifiers in premature infants under 1250 grams – how has the FDA engaged with product manufacturers and neonatologist to better understand data on the use of these products?

    a. Does the FDA plan to issue any sort of public communication regarding the use of cow-milk fortifiers for extremely premature infants to clarify appropriate use to providers and parents?

    b. Does the FDA have the authority under Section 412 of the FFDCA and *21 CFR 107.50* to require fortifier products to update their labels to clarify the appropriate populations for use? If so, is the FDA planning to use this authority?

    c. How is the FDA working with manufacturers to ensure a sufficient supply of human-milk based fortifiers for this subset of the premature infant population?

    d. Does the FDA have any plans to address this in a manner that would avoid shortages?

5. It is my understanding that 80 percent of vitamins are made in China. What visibility does the FDA have into the food additive supply chain, if any?

    a. Are there food additives necessary for human or animal health, such as certain vitamins, where it would make sense for the FDA to have greater authority and visibility into where those products are made?

6. What is the FDA doing to prevent shortages of critical ingredients for infant formula such as docosahexaenoic acid (DHA) and arachidonic acid (ARA), including in conjunction with agencies such as the Environmental Protection Agency (EPA) on timely regulatory clearance?

7. Mr. Jones, the Committee understands that the term "telework" refers to a work flexibility arrangement that allows an employee to work from an approved alternative worksite other than the employee's official duty location for an approved number of days each pay period.

a. Following the implementation of the unified Human Foods Program, within each office under your purview, what percentage of employees do you expect to telework?

b. What will be the range of approved telework days for each work period?

c. How will the specified number of days enforced?

d. Within the Human Foods Program, what percentage of employees will be fully remote?

e. Can you provide a summary of actions you are taking to increase the frequency and quality of interactions with interested stakeholders?

8. Mr. Jones, failures by the FDA contributed substantially to the infant formula crisis in 2022. As one example, when a whistleblower made a complaint about the contaminated manufacturing site, the assessment conducted by the Reagan Udall Foundation – to which you contributed as an independent expert – concluded that there was no process within the FDA to escalate the complaint. Had the FDA responded quicker to any one of many early signals, this crisis could have been partially mitigated or completely averted. This failure had catastrophic implications for our most vulnerable babies who rely on formula as their sole source of nutrition. My home state of Washington was one of ten states to have out-of-stock rates at 90 percent or greater. This is unacceptable. What is the current process to escalate any complaints within the newly reorganized program? Please include any timelines outlined for your staff to escalate complaints.

9. Mr. Jones, my district is home to around 30 dairy farms operated by individuals who work hard to provide nutritious products to consumers. Over the years, we have seen more and more Americans turn to alternative products such as "almond milk," which do not actually contain any milk or dairy at all and therefore have different nutritional value. Do you believe that a product that contains no dairy should be labeled as a dairy product?

    a. Can you describe what criteria food would need to meet to be considered a dairy product?

    b. How do you intend to correct misleading labels in the marketplace?

10. Kid-friendly marijuana products, such as a "THC S'mores Chocolate Bar," are sold and advertised in legal states across the country. As it is within the FDA's authority to do so, has the FDA seized adulterated products like this? If not, why?

11. The Department of Justice is prohibited from interfering with some state marijuana laws due to a Congressional Appropriations rider. Many local law enforcement agencies are also unable to seize dangerous THC products due to state laws. The FDA, on the other hand, has no such prohibitions on taking these products off the shelves. Will the FDA develop a plan to confiscate illegal marijuana, especially those products that are kid-friendly?

The Honorable Michael Burgess, M.D.

1. You are aware that hemp products containing intoxicating levels of THC are now being sold in stores in a growing number of states across the country. Despite containing THC, the substance that makes consumers "high," these products can be found in retail environments outside of cannabis dispensaries, even grocery and convenience stores. Most products sold in these stores are approved by the FDA and generally considered safe for public consumption.

    a. Why are hemp food and beverage products containing THC getting on store shelves without your consent?

    b. Why are these products allowed on shelves outside of cannabis dispensaries?

    c. Do you agree that hemp THC products should be first approved by the FDA before they are allowed to be sold in grocery stores, alongside products that are already generally considered safe for human consumption?

    d. Would you consider an FDA action banning THC-infused products from retail stores where products are generally approved and recognized as safe by the FDA?

The Honorable H. Morgan Griffith

1. The FDA's website says that "any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by the FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excepted from the definition of a food additive." This legal requirement is also known as "GRAS" or generally recognized as safe.

    a. Has the FDA ever approved cannabidiol (CBD) or any intoxicating cannabinoids as a food additive for food or beverage products? If not, why and what is needed to create a regulatory framework to regulate?

    b. Why is the FDA allowing companies to add CBD or any intoxicating cannabinoids to food and beverages in interstate commerce without much enforcement?

        i. Is a new enforcement framework needed for these products?

    c. If the FDA hasn't taken any action, are you saying CBD or other intoxicating cannabinoids are GRAS?

The Honorable Earl "Buddy" Carter

1. Mr. Jones, the FDA's Food Traceability Rule will require costly, unprecedented tracking of individual lot codes on food products from farm to retail or restaurant, while creating tremendous recordkeeping requirements on all stakeholders in the food supply chain. The Food Traceability Enhancement Act (H.R. 7563) would address the most pressing concerns of stakeholders. The January 20, 2026, compliance date is currently unworkable for the food supply chain. Mr. Jones, will you commit to taking administrative steps before the end of this year to extend the compliance date until the completion of multiple pilot projects and work with the industry, so the FDA participates in these pilot projects?

    a. And will you commit to working with all stakeholders throughout the food supply chain that are subject to the Food Traceability Rule, to provide them with the implementation and compliance flexibilities necessary, as detailed by the Reagan-Udall Foundation's recent report and based on additional input from the forthcoming public meeting and comment period?

2. The FDA's website says that "any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excepted from the definition of a food additive." This legal requirement is also known as "GRAS" or generally recognized as safe. Has the FDA ever approved THC as a food additive for food or beverage products?

    a. Has the FDA ever determined that THC is "generally recognized as safe"?

    b. Assuming the answer is no, why is the FDA allowing companies to add THC to food and beverages in interstate commerce?

        i. Is the FDA choosing to ignore this portion of the Federal Food, Drug, and Cosmetic Act?

The Honorable Dan Crenshaw

1. In light of the FDA's experience with CBD, where a marketplace has developed without regard to product quality or standards, how does the FDA intend to learn from these lessons in relation to other substances with meaningful consumer demand?

2. Given the FDA's decision that effective regulation of CBD would require a legislative solution, how does this precedent affect future potential supplements and foods that the FDA determines do not satisfy the standards or requirements of dietary supplements or foods?

3. What is the FDA's next step in regard to kratom, given the FDA's completion of leaf kratom Single Ascending Dose (SAD) study earlier this year?

a. What is the end goal of the FDA doing kratom clinical work?

The Honorable Dianna Harshbarger

1. Mr. Jones, the 2018 Farm Bill clearly intended to provide an avenue for industrial hemp to go to market. But many have exploited this narrow policy to bring forward intoxicating food and beverage items containing tetrahydrocannabinol (THC). In fact, you may be aware that earlier this year 21 State Attorneys General shared their concerns with Congress about intoxicating hemp products proliferating in their communities and asked that lawmakers clarify that there is no federal loophole for these products. Why are you not doing more to stop this abusive practice?

    a. Isn't some level of oversight for these products appropriate?

2. It seems nearly every week I read about children who are overdosing on THC gummies and other intoxicating substances that are not clearly labeled, and where no oversight is being provided by the FDA. If you do believe there is legitimate confusion around the law, do you support efforts to close the loophole, as passed by the House Agriculture and Appropriations Committees this summer?

The Honorable Mariannette Miller-Meeks, M.D.

1. Deputy Commissioner Jones, like my colleagues, I share your desire for the full implementation of the Food Modernization Act. In fact, I suspect this entire committee shares the desire to prevent, track and quickly respond to any food borne illnesses. I believe the middle supply chain concerns need to be addressed in the Section 204 rule, specifically what steps are you taking to address standardization of third-party logistics and storage firms that handle and process food.

    What steps is the FDA taking before implementation to address the lack of standards which could create "dirty & diverse forms of data" at the source (first land-based receiver or harvest location)? This would or could, in turn, lead to a cascade of events at the 3PL and elsewhere that could disrupt the supply chain.

2. What steps does the FDA plan to take to address any disruption of the supply chain would be due to increased IT burden and lack of protection (indemnification) from non-compliance with the FDA expectations?

3. Has the FDA considered the cost of duplicative and uncoordinated IT and tracking systems that would bottle neck for 3pl logistics providers?

The Honorable Anna Eshoo

1. The FDA has spent the past two years reorganizing and restructuring its Human Foods Programs following the agency's lackluster infant formula response in 2022.

    a. What are the main changes the FDA made during the reorganization?

    b. How will these changes strengthen the agency's ability to regulate the U.S. food supply?

    c. Most Centers at the FDA collect user fees to fund their work. How would user fees for the Human Foods Program better support your work?

2. In its December 2022 assessment of the FDA's Human Foods programs, the Reagan-Udall Foundation recommended separating the "Food" from the "Drug" Administration by creating a new Federal Food Administration under HHS.

    a. You were one of the authors of the Reagan-Udall Foundation's report. Do you support creating a new agency focused on regulating food?

    b. It often takes the FDA more than five years to issue new food regulations. How can the FDA speed its regulatory process? Would creating a separate agency focused only on food help?

The Honorable Raul Ruiz

1. Mr. Jones, could you speak to how FDA protects consumers by ensuring compliance with standards such as in H.R.1750?

2. Mr. Jones, do you foresee any potential challenges with implementation of H.R.1750?

The Honorable Ann Kuster

1. The FDA's website says that "any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excepted from the definition of a food additive." This legal requirement is also known as "GRAS" or generally recognized as safe. Since the FDA has determined that THC additives are not GRAS, what steps is the FDA taking to remove food and beverages with THC additives from the market?

The Honorable Nanette Barragán

1. Our office continues to monitor the infant formula crisis and appreciates the FDA's work to ensure that all families have access to formulas that meet their specific medical needs. Companies are now developing plant-based infant formulas designed for infants with unmet need who have unique dietary or lifestyle restrictions.

    a. What steps are the FDA taking to ensure that there is a clear and consistent regulatory guidance specific for plant-based infant formulas, including on protein efficiency?

    b. What steps is the FDA taking to partner with the private sector to establish regulatory pathways for plant-based infant formula products?

The Honorable Lori Trahan

1. The National Strategy on Food Loss and Waste states that FDA will continue to support private efforts to standardize quality date labels on food products. How is FDA addressing confusion concerning sell by dates and safety dates?

2. Around 48% of all food waste occurs in our own homes and is preventable. With food prices and inflation as high as they are, what is FDA doing to support households in reducing the food they are unnecessarily wasting?

3. For the first time, the recent Food Code expressly stated that food donation is allowed. Is the FDA considering further updates to the Food Code to give regulated entities more guidance about how to safely donate surplus, wholesome food?

The Honorable Jan Schakowsky

1. Arsenic is often found in rice-based foods — infant rice cereal, rice dishes and rice-based snacks. These popular baby foods are not only high in inorganic arsenic, the most toxic form of arsenic, but also are nearly always contaminated with three additional toxic heavy metals, lead, cadmium, and mercury. Arsenic is a potent human carcinogen and a neurotoxin shown to permanently reduce children's IQ. Ensuring the safety of food specifically marketed to infants and toddlers is critical. When the FDA set a standard for the maximum amount of arsenic allowed in baby foods back in 2020, that was a start to keeping babies safe — but the 100 ppb limit is still far too high. No amount of arsenic, lead or other toxic heavy metal is safe for babies. Mr. Jones**,** why has the FDA not placed a ban on arsenic in foods despite evidence it is harmful to humans, and especially harmful to babies?