March 4, 2024

Food and Drug Administration
Division of Freedom of Information
Office of the Executive Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Submitted electronically via https://www.accessdata.fda.gov/scripts/foi/FOIRequest/requestinfo.cfm

RE: FDA Request for Records Related to Investigations of Toxic Elements Based on Total Diet Study Results From 2018 to 2022

Dear FDA Coordinator:

Unleaded Kids submits this request for information under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, and the Food & Drug Administration ("FDA") FOIA regulations, 21 C.F.R. pt. 20. Unleaded Kids is the only national organization focusing on reducing the cumulative impact of all sources of children's exposure to lead. For more information see www.unleadedkids.org.

I. RECORDS REQUESTED

Unleaded Kids requests records regarding any follow-up investigation conducted by FDA staff or contractors based on the results of toxic elements testing as part of the Total Diet Study conducted from January 1, 2018 to March 1, 2026. This request includes but is not limited to data collected by FDA in a small exploratory internal survey conducted in 2022 of 20 baking powders of a variety of brands, analyzing each for arsenic, cadmium, lead and mercury.

For this request:

- "Toxic elements" are any form of cadmium, lead, mercury, arsenic, including inorganic arsenic.
- "Total Diet Study" refers FDA's Total Diet Study as described at https://www.fda.gov/food/reference-databases-and-monitoring-programs-food/fda-total-diet-study-tds on March 4, 2026.
- "Records" refers to includes receipts, images, lab results, reports, sampling plans, or memoranda prepared or received by the agency.

The response may be provided in parts as they are available.

II. A FEE WAIVER IS APPROPRIATE

Pursuant to 5 U.S.C. § 552(a)(4)(A)(iii) and 21 C.F.R. § 20.46, Unleaded Kids requests that FDA waive all fees associated with responding to this request because Unleaded Kids seeks this information in the public interest and will not benefit commercially from this request.

FOIA provides that fees shall be reduced "if disclosure of the information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester." 5 U.S.C. § 552(a)(4)(A)(iii).

FDA's FOIA regulations contain a nearly identical requirement and identify six factors to assess whether a requester is entitled to a waiver of fees under FOIA. 21 C.F.R. § 20.46.

FOIA carries a presumption of disclosure, and the fee waiver was designed specifically to allow nonprofit, public-interest groups, such as Unleaded Kids, access to government documents without the payment of fees. The courts have stated that the statute "is to be liberally construed in favor of waivers for noncommercial requesters." *See Judicial Watch v. Rossotti*, 326 F.3d 1309, 1312 (D.C. Cir. 2003). As explained below, Unleaded Kids meets the criteria for a fee waiver established in FOIA and outlined in FDA's implementing regulations.

A. Disclosure of this information is in the public interest because it will likely contribute significantly to public understanding of the operations or activities of the government.

Unleaded Kids qualifies for a fee waiver because the requested information will contribute significantly to public understanding of the operations or activities of the federal government. *See* 21 C.F.R. § 20.46(b). Unleaded Kids possesses the ability to disseminate the information to the general public, and, in fact, such dissemination is routine to their operations.

Unleaded Kids is active in informing their constituencies about chemical exposures and is well-positioned to enhance the public's understanding of potential exposures through food by analyzing and disseminating the requested information to its members and the general public.

1. The Subject Matter of the Requested Documents Pertain to Operations or Activities of the Federal Government

Under the first factor used to consider fee waivers, FDA must consider "[w]hether the records to be disclosed pertain to the operations or activities of the Federal Government." 21 C.F.R. § 20.46(b)(1). Unleaded Kids seeks documents regarding evaluations that resulted from FDA's Total Diet Study described at https://www.fda.gov/food/reference-databases-and-monitoring-programs-food/fda-total-diet-study-tds.

Moreover, we are requesting the records with reasonable specificity. *See Rossotti*, 326 F.3d at 1313 (D.C. Cir. 2003) (quoting *Larson v. Cent. Intelligence Agency*, 843 F.2d 1481, 1483 (D.C. Cir. 1988)) (noting that to satisfy the first prong of a fee waiver request, government operations or activities must only be identified with "'reasonable specificity'—all that FOIA requires"). Here, Unleaded Kids requests a reasonably specified set of records.

2. The Disclosure Would Likely Reveal Meaningful Information about Government Operations or Activities that is not Already Public Knowledge

Under the second factor used to consider fee waivers, FDA must consider "[w]hether disclosure of the records would reveal any meaningful information about Government operations or activities that is not already public knowledge." 21 C.F.R. § 20.46(b)(2). Disclosure of the requested records is likely to reveal "meaningful information" about government operations or activities by allowing the public to see FDA evaluates the results of its Total Diet Study that shed light on levels of toxic elements in the food supply.
This information is meaningful because there is wide public concern about exposure to toxic elements. Therefore, the foregoing request for documents meets the second factor for a fee waiver by seeking "meaningful information" that is not already public knowledge.

3. **The Disclosure Will Advance the Understanding of the General Public as Distinguished from a Narrow Segment of Interested Persons**

Under the third factor, FDA regulations state that it "may consider whether the requester has such knowledge or expertise as may be necessary to understand the information" and "whether the requester's intended use of the information would be likely to disseminate the information to the public." 21 C.F.R. § 20.46(b)(3). In determining whether the disclosure of requested information will advance the understanding of the general public, a guiding test is whether the disclosed documents will reach "a reasonably broad audience of persons interested in the subject." *Carney v. U.S. Dep't of Justice*, 19 F.3d 807, 815 (2d Cir. 1994). Unleaded Kids uses a variety of platforms to disseminate information to the public including its webpage at www.unleadedkids.org and its social media accounts. Unleaded Kids has the capacity to write a report analyzing and summarizing information obtained through the FOIA request and publicize the report to readers and activists through its blog and other publications.

4. **The Contribution to the General Public Will Likely Be Significant**

As described above, Unleaded Kids communicates with supporters, members and the general public through a variety of means. Unleaded Kids plans to disseminate the pertinent information contained in the requested records to affected communities and stakeholders across the country. This type of dissemination has been held sufficient to satisfy this prong of the fee waiver determination. *See Judicial Watch, Inc. v. Gen. Servs. Admin*., CIV.A. 98-2223 (RMU), 2000 WL 35538030, at *9 (D.D.C. Sept. 25, 2000) (holding that an organization satisfied FOIA's requirement that information be disseminated to a reasonably broad segment of the public where the organization had an established history of disseminating information and proposed to post disclosed information for public review on its website); *see also D.C. Technical Assistance Org., Inc. v. U.S. Dep't of Hous. & Urban Dev*., 85 F. Supp. 2d 46, 49 (D.D.C. 2000) ("In this Information Age, technology has made it possible for almost anyone to fulfill [FOIA's dissemination requirement]."); *see also Or. Natural Desert Ass'n v. U.S. Dep't of Interior*, 24 F. Supp. 2d 1088, 1095-96 (D. Or. 1998) (relying on *Friends of the Coast Fork v. U.S. Dep't of the Interior*, 110 F.3d 53, 55-56 (9th Cir. 1997)) (finding that the organization established a prima facie case that "contribution to public understanding" was significant where organization sought a fee waiver request for monitoring data and gave a "lengthy articulation of its reasons for requesting the information," explained "what it would do with that information," "how [it] would disseminate" the information, and "to whom").

Furthermore, information about FDA's follow-up studies of Total Diet Study results is not publicly available. For example, Unleaded Kids only learned of the study of 20 brands of baking soda after contacting FDA staff with questions about the FDA's data release on the Total Diet Study that was announced in its January 27, 2026 Constituent Update at https://www.fda.gov/food/hfp-constituent-updates/fda-releases-new-interactive-tool-total-diet-study-tds-results-and-new-data?utm_medium=email&utm_source=govdelivery. After asking the results by email, FDA staff said Unleaded Kids had to submit a FOIA request. We expect there may be similar studies.

Disclosure and dissemination of this information would enhance the public's ability to make fully informed purchases of food. The current absence of the FDA's data in the public domain, coupled with Unleaded Kids' ability and intent to disseminate the records upon disclosure, is sufficient to satisfy the significance prong of a fee waiver request. *See Fed. CURE v. Lappin*, 602 F. Supp. 2d 197, 205–06 (D.D.C. 2009) (finding that, even in the

absence of a "specific plan for interpreting [] information before disseminat[ion]," the public's understanding will be significantly enhanced by disseminating information otherwise not in the public domain).

B. Obtaining the Information Is of No Commercial Interest to Unleaded Kids

The fifth and sixth factors FDA must consider relate to the possible existence and magnitude of a commercial interest in disclosure. *See* 21 C.F.R. § 20.46(c). Two questions must be addressed when determining whether the information requested is "primarily in the commercial interest of the requester." 5 U.S.C. § 552(a)(4)(A)(iii). The first question is whether the requester has a commercial interest that would be furthered by the requested disclosure. Here, as a 501(c)(3) nonprofit entity, Unleaded Kids has no commercial, trade, or profit interest in the material requested. Unleaded Kids will not be paid for or receive other commercial benefits from the publication or dissemination of the material requested. The requested material will be disseminated solely for the purpose of informing and educating the public and will not be used for commercial use or gain.

The final factor hinges on the primary interest in the disclosure. FDA must assess whether any commercial interest "outweighs the advancement of the public interest." 21 C.F.R. § 20.46(c). There is great public interest in the release of the materials sought because they will allow for a more thorough understanding of the uses and safety of post-consumer recycled plastic in contact with food. This information will contribute to the numerous other public interest organizations looking at recyclability of food packaging. The disclosure of the requested information is therefore "not primarily in the commercial interest of" Unleaded Kids, and a fee waiver is appropriate. 5 U.S.C. § 552(a)(4)(A)(iii).

Under these circumstances, Unleaded Kids fully satisfies the criteria for a fee waiver.

III. CONCLUSION

Pursuant to FOIA and FDA's FOIA regulations, the agency has 20 working days from the date of its receipt of this request to decide whether to grant the request, and it must notify the requester of the decision. *See* 5 U.S.C. § 551(a)(6)(A)(i); 21 C.F.R. § 20.41(b).

Please produce the requested records by emailing or mailing them to the address listed below.

Please also produce the records on a rolling basis; at no point should FDA's search for, or deliberations concerning, certain records delay the production of others that FDA has already retrieved and elected to produce.

If you have any questions about the records we are seeking, you can contact me at the information below. We also welcome the opportunity to clarify our request with FDA's FOIA Officer(s) via phone.

If for some reason the fee waiver is denied, please contact me before incurring any costs related to this request. If the fee waiver is not granted and costs are incurred prior to approval by Unleaded Kids, it will not be responsible for those costs.

Thank you in advance for your prompt reply.

For more information, please contact Tom Neltner at tneltner@unleadedkids.org or 317-442-3973.

Sincerely,

Tom Neltner
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317-442-3973