CORE REQUESTS:

FDA must protect all Americans with food allergy and deny the ED05 based reference dose proposal for PAL that would leave 1.6 million Americans unsafe. Instead, FDA must delay PAL guidance by one year to: (1) conduct a survey of food industry to inspect their allergen controls; (2) conduct a national survey of allergic consumers about their knowledge of thresholds, risk assessments and specific action levels for PAL. If FDA believes adopting risk assessment for PAL is ripe, then it should adopt the ED01 based reference dose (protecting 99% of the allergic community), not the ED05 action level, which leaves 5% of the community unprotected.

BACKGROUND P

- 33+ million Americans have food allergies (1 in 10 children; 1 in 13 adults).[1] Therapeutic advances may increase protection, but accurate and transparent food labeling remains critical to ensure strict avoidance, particularly for highly sensitive individuals.[2]
- FALCPA (2004),[3] FSMA (2011),[4] and the FASTER Act (2021)[5] established labeling and allergen control requirements, yet food allergens remain a leading cause of FDA recalls today.[6]
- As of 2019, even after FSMA's effective date, 77% of allergen recalls stem from mislabeled ingredients; 16% from cross-contamination.[7] Industry compliance remains inadequate.
- PAL statements (e.g., "may contain") are currently voluntary, inconsistent, and a source of confusion for allergic consumers worldwide.[8]
- Allergic consumers do not know their thresholds and are not educated about the concept in general.[9]

WHY DELAY IS NEEDED: GAPS IN THE SCIENCE

- **Study Population:** Data limitations:
  - Less than one-third of the oral food challenges reviewed were usable for the studies, ie 1102 out of 3,445 oral food challenges reviewed;[10] participants were predominantly Northern European children. Adults, highly sensitive individuals, and diverse populations were excluded.[11]
- **Real-World Gaps:** Co-factors not studied:
  - Asthma, sleep deprivation, exercise, alcohol, medications, and hormones all lower thresholds [12]— none were accounted for.[13]
- Thresholds do not predict reaction severity,[14] and population based thresholds do not provide reaction risk at the individual level.[15]
- Industry and Consumer surveys needed: US consumers have not been asked about using specific reaction level cut-offs for PAL.[16] An updated FDA survey of food industry's recalls and allergen control practices from 2020-2025 would inform better training methods to mitigate against mislabeling issues.

WHY ED05 IS THE WRONG ACTION LEVEL

- ED05 excludes 5% of allergic Americans— approximately 1.6 million people — who will react at lower levels.[17]
- Reported reactions at or below ED05 include vomiting, throat tightening, urticaria, and anaphylaxis.[18]
- Study expects mild and moderate reactions to resolve without medication.[19] In the real world, allergic individuals activate emergency action plans and use epinephrine.[20] Delayed use is a leading cause of fatal reactions.[21]
- Unlike supervised oral challenges, consumers eating grocery products do not know the dose of allergen they are ingesting.[22]

IF FDA PROCEEDS NOW: ADOPT ED01

If FDA determines implementation cannot wait, it should adopt **ED01 — not ED05**. This protects 99% of the allergic community, is scientifically measurable, and provides a uniform, meaningful label. The PAL statement should read:

"May contain [allergen]"

- Where risk based reference doses do not yet exist for certain allergens, the industry should develop the required tools before those allergens fall under the framework.

ED05 VS. ED01 AT A GLANCE

	ED05 Action Level (FAO/WHO Proposed)	ED01 Action Level (Recommended)
% Protected	95%	99%
Americans left unprotected	~1.6 million	~330,000
Reaction risk at threshold	Includes anaphylaxis cases	Includes anaphylaxis cases
Analytics available	Yes	Yes
Science-based	Yes	Yes

Endnotes

1 Ilana Galant, *Food Allergy Fund's Statement on New White House Report*, Food Allergy Fund (May 22, 2025), https://www.foodallergy.org/resources/facts-and-statistics; Food Allergy Research and Education, *Facts and Statistics*, FARE, https://www.foodallergy.org/resources/facts-and-statistics.

2 W.M. Blom et al., *Symptoms at Population Eliciting Doses ≤ED05 for 11 Priority Allergenic Foods Are Mild to Moderate*, **197 Food & Chem. Toxicology** 115250 (2025).

3 Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), Pub. L. No. 108-282, 21 U.S.C. § 301 note; *id.* §§ 321(qq), 343.

4 Food Safety Modernization Act (FSMA), Pub. L. No. 111-353, 21 U.S.C. § 2201 *et seq.*

5 Food Allergy Safety, Treatment, Education, and Research (FASTER) Act of 2021, Pub. L. No. 117-11, 21 U.S.C. § 321(qq)(1).

6 Irdhari M. Sharma, Yinqing Ma & Stefano Luccioli, *Recalls Associated with Food Allergens and Gluten in FDA-Regulated Foods from Fiscal Years 2013 to 2019*, **86 J. Food Protection**, no. 4, 2023, at 100069.

7 *Id.*; *see also* FDA Virtual Public Meeting and Listening Session on Food Allergen Thresholds and Their Potential Applications (Feb. 18, 2026), https://www.fda.gov/food/nutrition-food-labeling-and-critical-foods/approaches-establish-thresholds-major-food-allergens-and-gluten-food.

8 Mary Jane Marchisotto et al., *Food Allergen Labeling and Purchasing Habits in the United States and Canada*, **5 J. Allergy & Clinical Immunology: In Practice** 345 (2017).

9 *Id.*

10 B.C. Remington et al., *Updated Population Minimal Eliciting Dose Distributions for Use in Risk Assessment of 14 Priority Food Allergens*, **139 Food & Chem. Toxicology** 111259 (2020).

11 *Id.* See G.F. Houben et al., *Full Range of Population Eliciting Dose Values for 14 Priority Allergenic Foods*, 146 **Food & Chem. Toxicol.** 111831 (2020); Food & Agric. Org. of the United Nations (FAO) & World Health Org. (WHO), *Risk Assessment of Food Allergens* (2022). Blom et al., *supra* note 2, at 4 fig. 1; Imad Neal Saab, Wendelyn Jones, *Trends in Food Allergy Research Regulations and Patient Care,"* **57, No. 2 Nutrition Today** 64, 68 (2022)(stating, "Clinical trials should also be expanded to include representation of all ethnic backgrounds, ages, and sensitivity levels so that response thresholds are representative of the makeup of the US population.").

12 J.A. Lieberman, *Identifying Thresholds of Reaction for Different Foods*, **6 J. Food Allergy** 21 (2024); J.C. Li et al., *Utility of Food Allergy Thresholds*, **132 Ann. Allergy, Asthma & Immunology** 321, 322–23 (2024); Dua et al., *Effects of Exercise and Sleep Deprivation on Reaction Severity During Oral Peanut Challenge: A Randomized Controlled Trial*, **150 J. Allergy & Clinical Immunology** 2404 (2022) (demonstrating that in the presence of cofactors, threshold dropped in approximately 40% of participants, with a subset reacting to ED01 levels after previously reacting at ED05).

Endnotes continued

13 Remington et al., *supra* note 10; Blom et al., *supra* note 2, at 4 fig. 1.

14 M.S. Shaker, G.W. Sanders & K. Anagnostou, *Food Allergy Thresholds, Context, and Balance in 2025*, **7 J. Food Allergy** 27 (2025); Piletta-Zanin et al., *The Severity of Allergic Reactions in a Real-World Environment Is Independent of the Eliciting Amounts of Foods*, **80 Allergy** 238 (2025); Svendsen et al., *Self-Reported Accidental Allergic Reactions Among Patients with Challenge-Verified Food Allergy*, **Clin. & Translational Allergy**, 2025, e70067; Lieberman, *supra* note 12, at 21–25; Li et al., *supra* note 12, at 323; Arasi et al., *WAO Consensus on Definition of Food Allergy Severity (DEFASE)*, **World Allergy Org. J.** (2023); Pettersson et al., *Prediction of the Severity of Allergic Reactions to Foods*, **73 Allergy** 1532 (2018).

15 Li et al., *supra* note 12, at 324.

16 *See* P.J. Turner et al. (World Allergy Organization Consensus on the Use of PAL (ACT-UP!) Working Group), *Time to ACT-UP: Update on Precautionary Allergen Labelling (PAL)*, **World Allergy Org. J.** 1, 21 (Oct. 2024); P.J. Turner et al., *Peanut Can Be Used as a Reference Allergen for Hazard Characterization in Food Allergen Risk Management: A Rapid Evidence Assessment and Meta-Analysis*, **10 J. Allergy & Clinical Immunology: In Practice** 59, 69 (Jan. 2022)(stating that "whether reactions at ED05 exposure constitute a tolerable risk requires further consensus").

17 *Id.* At 61, 68; Blom et al., *supra* note 2; *see* FAO & WHO, *Risk Assessment of Food Allergens – Part 2: Review and Establish Threshold Levels in Foods for the Priority Allergens* 94 (Food Safety & Quality Series No. 15, 2022); Patel et al., *Using Data from Food Challenges to Inform Management of Consumers with Food Allergy: A Systematic Review with Individual Participant Data Meta-Analysis*, **J. Allergy & Clinical Immunology** (June 2021).

18 Blom et al., *supra* note 2, at 5; Patel et al., *supra* note 17.

19 Blom et al., *supra* note 2, at 7.

20 Turner et al. (ACT-UP!), *supra* note 16, at 21 (noting that when allergic individuals experience mild symptoms following exposure, they cannot know whether those symptoms will remain mild or progress to anaphylaxis); *see also* Anaphylaxis Emergency Care Plan, Food Allergy & Anaphylaxis Connection Team, https://www.foodallergyawareness.org/media/user/living-with-food-allergies; https://downloads.aap.org/AAP/PDF/AAP_Allergy_and_Anaphylaxis_Emergency_Plan.pdf

21 M.S. Shaker et al., *Anaphylaxis—A 2020 Practice Parameter Update, Systematic Review, and Grading of Recommendations, Assessment, Development and Evaluation (GRADE) Analysis*, **145 J. Allergy & Clinical Immunology** 1082 (2020); Turner et al., *supra* note 16 (Peanut Meta-Analysis), at 66 fig. 3.

22 Svendsen et al., *supra* note 14, at 7; F. Graham & A. Fiocchi, *The Importance of Threshold Dose-Distribution Data for Priority Allergens and the Need for Future Studies*, **Allergy** (May 2022), https://doi.org/10.1111/all.15387; Li et al., *supra* note 12, at 322.