



Highlights from FDA Commissioner Dr. Marty Makary's First 100 Days

Embracing Gold-Standard Science, Transparency and Common Sense

- ✓ **Petroleum-based food dye removal** – Took action to phase out petroleum-based synthetic food dyes from the U.S. food supply, which are linked to numerous health risks.
- ✓ **Revised Covid-19 vaccine regulatory framework** – Adopted a new evidence-based approach to Covid-19 booster approvals, replacing a one-size-fits-all regulatory framework and broad marketing authorizations with a risk-stratified approach that is already embraced by most doctors and parents. Updated labeling of mRNA shots to include new safety information about myocarditis and pericarditis.
- ✓ **AI-assisted review** – Completed a successful pilot of the first AI-assisted scientific review, proving that internal AI tools can greatly reduce the time reviewers spend on mundane tasks or non-productive busywork.
- ✓ **Food chemical review** – Initiated a robust, transparent review of chemicals currently in the food supply, such as BHT, BHA and ADA; and expedited the review of chemicals currently under review, such as phthalates, propylparaben and titanium dioxide.
- ✓ **Commissioner's National Priority Vouchers** – Announced a pilot program to expedite drug review processes from 10-12 months to 1-2 months for U.S. companies addressing U.S. national priorities, such as tackling a major health crisis or unmet public health need, increasing domestic drug manufacturing, and delivering more innovative cures for the American people.

- ✓ **Reducing animal testing** – Published a roadmap to transition away from animal testing for investigational new drug applications wherever possible and use more effective, human-relevant methods, such as organ-on-a-chip systems, advanced computer simulations, and pre-existing international data. Announced the intent to launch a pilot program in which select monoclonal antibody developers may pursue a primarily non-animal-based testing strategy, under close FDA consultation.
- ✓ **Improving infant formula** – Continued the work of Operation Stork Speed by hosting an expert roundtable on infant formula and exploring new ways to bring additional and healthier options without ingredients like seed oils, added sugars and heavy metals to market.
- ✓ **Began revising broken dietary guidelines** – Launched the Nutrition Regulatory Science Program in partnership with NIH to better address highly relevant questions for Americans’ health, such as the impact of ultra-processed foods and the effect of certain food additives.
- ✓ **Building a better adverse event reporting database** – Launched a comprehensive effort to consolidate disparate adverse event reporting databases, which will enable far more effective post-market monitoring of drug products.
- ✓ **Addressed industry influence** – Limited the circumstances where individuals employed at FDA-regulated companies, such as pharmaceutical companies, may serve as members of FDA advisory committees, where statutorily possible, to mitigate perceived conflicts of interest and strengthen integrity to the review process.

