"Under the Make America Healthy Again agenda, today HHS and FDA are publishing in the Federal Register a proposed rule to modernize FDA's generally recognized state regulatory framework, commonly known as GRAS, that's to increase transparency and consumer confidence in the food supply."

"If finalized, this rule would formally transition the GRAS framework from a voluntary program to a mandatory notification system. It would do so by requiring any person introducing a human or animal food substance into interstate commerce under the GRAS framework to notify the FDA of the basis for their conclusion, unless a specific exemption applies. Exemptions may include substances already covered by an existing FDA regulation, a prior agency letter or determination indicating we have no safety questions about the use of the substance, or an approved feed listing."

"To ensure efficient execution, the proposed rule establishes clear administrative timelines for agency review of grass notes required in a new. pre-filing decision within 45 days and capping post-filing valuation timelines. It also expands FDA's threshold of regulation framework to cover substances used in treatment, and it expands public online inventories to ensure greater transparency. For self-GRAS substances already in commerce at the time of a final rule, FDA is proposing a streamlined submission pathway. This pathway would allow industry to submit basic identity and use data to FDA to establish a public listing, provided that the substance has not previously received an adverse agency safety findings."

"I want to be very clear that this process, this new notification system does not establish a pre-market review program. We are respectful of our statutory requirements on that. What it does is require any companies or manufacturers that are introducing a new ingredient through the self-GRAS process to notify FDA of those conclusions."

"What FDA will do is review a notification within 45 days to ensure that the elements required are in there. We'll then docket that notification satisfying the requirement. FDA will then, within 180 days, review that notification substantively. If we have issues, we may either send a no questions letter or we may send we may send a letter determining that we don't believe that the threshold has been established. But again, this is not a pre-market notification program. Companies are not prohibited from entering the market during the tendency of that process, and they can continue to self-GRAS. What it does is require that companies notify us whenever they are self-GRASing an ingredient, and then we're going to make that limited information public that's set more than the regulation in 170.275."

"So, this framework announced today through regulation establishes a mandatory notification process, but it does not establish a pre-market review program. There is no requirement that the FDA must review or approve a GRAS conclusion. And companies under law, under the Federal Food, Drug, and Cosmetic Act, can continue to use the GRAS process and the self-GRAS. But what we're doing is requiring companies that utilize that pathway to notify us of their conclusions, so that we have greater visibility into those conclusions, and so that consumers have awareness. And we're going to put those that information found in the relevant regulation into a database or a listing very similar to our existing GRAS notification inventory."

"Additionally, HHS and the U.S. Department of Agriculture have submitted for final review a proposed definitive ultra-processed foods aimed at creating a stronger foundation for future federal nutrition research. Additional information on ultra-processed foods will be shared at a future time."

"Finally, though not part of today's announcement, with respect to microbiological food safety, FDA will be publishing tomorrow a final guidance document titled "Guide to Minimize Biological Hazards And ready-to-eat fresh-cut produce. This final guidance is intended to help manufacturers and processors of fresh-cut produce comply with applicable FDA requirements and 21 CFR Part 117 titles current good manufacturing practices, hazard analysis, and risk-based prevention controls for human food."