UNDERSTANDING THE FDA'S AUGUST 1, 2025 NITROSAMINE DEADLINE

Aptar CSP Technologies

The FDA has set a firm deadline of August 1, 2025 for pharmaceutical manufacturers to ensure that any Nitrosamine Drug Substance-Related Impurities (NDSRIs) in drug products meet the agency's Acceptable Intake (AI) limits. This applies to all manufacturers of drug products marketed in the U.S., including generics, branded pharma, CDMOs, and APIs.

What the Deadline Means

- After August 1, 2025, the FDA expects full compliance with AI limits for all nitrosamines identified in drug products.
- Products found to exceed these limits may be subject to regulatory action including recalls, import alerts, warning letters, or market withdrawal.
- Temporary AI adjustments made in prior years will no longer be accepted unless exceptional, case-by-case justification is provided (e.g., no therapeutic alternatives).

What Should Manufacturers Be Doing Now?

- Complete a thorough nitrosamine risk assessment across your portfolio.
- Confirm root cause and sources of NDSRIs (APIs, excipients, packaging, processes).
- Implement mitigation strategies including formulation, process, **or packaging changes**.

How Can CSP Help?

Aptar CSP's N-Sorb technology is a proprietary material designed to passively scavenge nitrosamines and nitrites from the packaging environment offering a fast, low-risk compliance path for products **without CMC or formulation delays.**

The Countdown is On!

Use this window of time to act decisively and let Aptar CSP help you mitigate risk, maintain compliance, and protect patient safety.

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