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FDA Enforcement: Business as Usual or Is FDA Leaving It to the States?

On December 4-5, the Food and Drug Law Institute (FDLI) held its annual Enforcement, Litigation, and Compliance Conference: For the Drug, Device, Food and Tobacco Industries in Washington, D.C. The conference brought together about 300 industry regulators (the U.S. Food and Drug Administration (FDA), the U.S. Department of Justice, and the Federal Trade Commission (FTC), attorneys, litigators, academics, and consultants and other stakeholders to discuss trends and issues in enforcement and compliance of FDA-regulated products.

The initial FDA-regulator-focused panel suggested that FDA has been business as usual or has been streamlining or improving its procedures with the reorganization of a more unified Office of Inspections and Investigations (OII). The FDA, however, did not address this author's questions about the impact of FDA's decision to disclose Complete Response Letters (CRLs), and how FDA plans to defend this practice when industry lodges its inevitable challenge to this potential violation of trade secret or commercial confidential information disclosure by the agency.

When the panels did not include FDA speakers, however, many of the industry and attorney / consultant speakers (many who are ex-FDA) indicated that FDA has been punting a lot of its enforcement to the states, and the FTC has been missing in action, whereas before it was a partner with FDA for enforcement with consumer goods. This state-based enforcement model has resulted in a confusing patchwork of regulatory requirements, leaving industry struggling to come up with compliant labeling. This author asked panelists how FDA is managing the confusing information, e.g., state requirements may require labeling about state (but not federal)-banned colors or comments about trace amounts of arsenic or nuts without explaining to consumers the impact. For example, how many rice crackers

with arsenic would you need to consume to be affected by the trace amount?

FDA's significant change in the workforce that has disproportionately removed FDA's seasoned inspectors and regulators, moreover, has left FDA with a staff of generalists struggling to understand more nuanced areas like cybersecurity risks caused by increased use of artificial intelligence (AI) / machine learning (ML). When this author asked an anonymous question about how FDA is conducting cybersecurity inspections, for example, the speakers said the newbie inspectors will rely on more general questions like "How do you manage risk in your computer systems?" than actually knowing how to pressure test systems. As a result, it will be increasingly important to have trained staff available to explain cybersecurity systems to generalist inspectors, who will need a lot of education along the way to understand if a system poses a risk or not. In this author's opinion, FDA will need to mind its own shop when it comes to cybersecurity and the risks of over relying on AI/ML that can introduce its own errors/hallucinations given the Agency's increased use of AI for product reviews and other repetitive tasks, perhaps including tasks like redacting CRL letters.

FDA's high priority compliance areas (just three top ones per center here):

- Human Drugs
  - Illegally compounded medicines (especially GLP-1 products) including false or misleading advertising/promotion claims
  - Failure to comply with current Good Manufacturing Practices (cGMPs) linked with supply chain vulnerabilities
  - Unapproved clinical trials (linking back to clinicaltrials.gov)
- Human Biologics
  - Facility and associated contractor readiness for inspection
  - Unapproved regenerative medicine products
  - Trying to incentivize more clinicaltrials.gov reporting
- Medical Devices
  - Failures in adequate complaint handling indicative of weak risk post-market surveillance and potential safety issues
  - Increased number of unapproved medical devices in the "gray web" as evidenced by a lack of compliance with unified device identifier (UDI) requirements

    - Clinical data integrity issues (i.e., clinical data submitted with errors)
- Tobacco
    - Illicit tobacco products targeted toward youth with unknown ingredients, manufacturing practices aimed at creating the next generation of tobacco users
    - Electronic Nicotine Delivery Systems (ENDS), commonly known as e-cigarettes, many of which are also illicit and go unregulated.
    - Supply chain vigilance including more retail store inspections and new FDA authorities to prevent illegal products from being imported in the first place (like for drugs), so they do not need to be detained and destroyed after arriving.
- Animal Products
    - Fly, worm, Salmonella, and E.coli and other contaminants in animal feed causing harm to animals and humans handling food products
    - Animal drug compounding and other unapproved animal drugs with inappropriate advertising/promotion claims
    - Animal food standard operating procedures (SOPs) need increased compliance.
- Human Foods
    - Kratom products containing dangerously high levels of 7-hydroxymitragynine (7-OH) available in gas stations with products that appeal to children (e.g., gummies) that requires increased federal/state inspection collaboration
    - Cesium-137 (Cs-137) contamination in shrimp
    - Tiered state / federal coordinated inspections to protect food supply and monitor dietary supplements, where FDA is struggling to manage botanicals, new ingredients, and false labeling claims (especially ingredient content, potential dangerous or contaminated ingredients, and counterfeit products).

Given the myriad of topics and concerns affecting all FDA-regulated products, we recommend you follow up with your trusted advisor for more details.

As the final keynote speaker, former FDA Chief Counsel Mark Raza noted, “FDA history matters,” “FDA enforcement matters,” and “It is not a matter of if but when FDA will bring its cases of high priority.”

This blog was drafted by Brian J. Malkin, an attorney in the Spencer Fane Washington, D.C. office. For more information, visit spencerfane.com.

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