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A ProAssurance Company

November 15, 2023

RIPPED FROM THE HEADLINES: HOT TOPICS IN LIFE SCIENCES

Forward Looking Statements

This presentation contains Forward Looking Statements and other information designed to convey our projections and expectations regarding future results.

There are a number of factors which could cause our actual results to vary materially from those projected in this presentation. The principal risk factors that may cause these differences are described in various documents we file with the Securities and Exchange Commission, such as our Current Reports on Form 8-K, and our regular reports on Forms 10-Q and 10-K, particularly in "Item 1A, Risk Factors." Please review this presentation in conjunction with a thorough reading and understanding of these risk factors.

Non-GAAP Measures

This presentation contains Non-GAAP measures, and we may reference Non-GAAP measures in our remarks and discussions with investors.

The primary Non-GAAP measure we reference is Non-GAAP operating income, a Non-GAAP financial measure that is widely used to evaluate performance within the insurance sector. In calculating Non-GAAP operating income, we have excluded the after-tax effects of net realized investment gains or losses and guaranty fund assessments or recoupments that do not reflect normal operating results. We believe Non-GAAP operating income presents a useful view of the performance of our insurance operations, but should be considered in conjunction with net income computed in accordance with GAAP. A reconciliation of these measures to GAAP measures is available in our regular reports on Forms 10-Q and 10-K and in our latest quarterly news release, all of which are available in the Investor Relations section of our website, Investor.ProAssurance.com.

Drug Supply Chain Security Act (DSCSA)

- While the Drug Quality and Safety Act was enacted in 2013, the DSCSA component of the legislation is just now entering its final phase.

What do we need to know?

- The final implementation deadline for enhanced drug distribution security requirements is November 27, 2024.
  - This includes a one-year stabilization period from November 27, 2023 through November 27, 2024, during which companies can build, validate, and implement their systems and processes without immediate enforcement.
- Applies to all trading partners – manufacturers, wholesale distributors, dispensers, repackagers
- Goal is interoperable electronic tracing of drug products throughout the US supply chain, tracking chain of custody from manufacturer to dispenser

Modernization of Cosmetics Regulation Act of 2022 (MoCRA)

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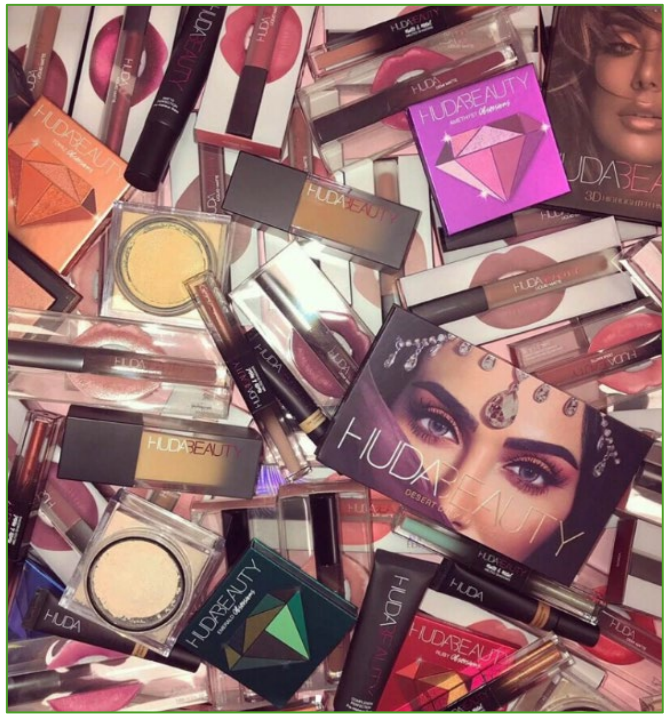
What happened with MoCRA?

- FDA published the Compliance Policy for Cosmetic Product Facility Registration and Cosmetic Product Listing in November 2023.
- FDA provided a 6-month extension to their December 29, 2023, deadline.
- What should industry participants be aware of as they prepare?



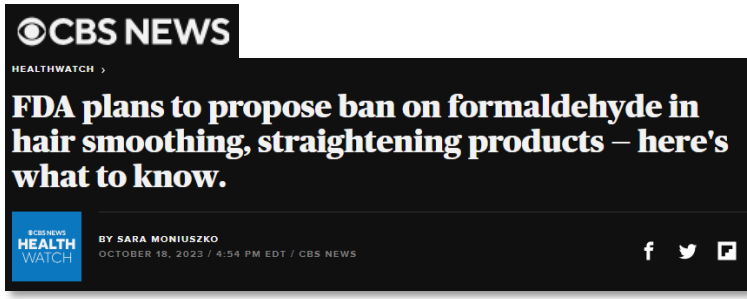
BM BeautyMatter

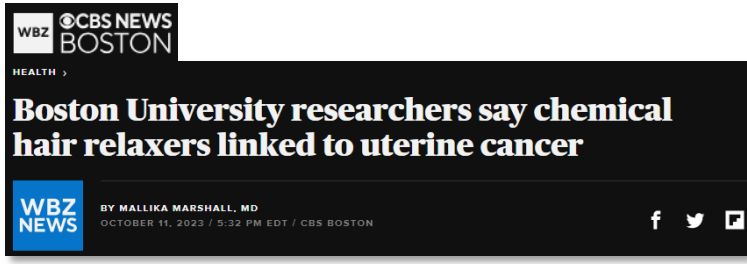
What You Need To Know About MoCRA Compliance Deadlines

As we waited for implementation updates as the December 29th deadline loomed the FDA delayed enforcement of the requirements for cosmetic...

Proposed Ban: Formaldehyde

- Products used to smooth the texture of hair have exploded in popularity over the last 25 years.
  - Process involves application of the relaxer solution or lotion to the hair, followed by a heat treatment to seal the product into the hair.
  - Relaxer solutions/lotions commonly contain formaldehyde, a chemical known to present a health hazard when inhaled or when in contact with the eyes or skin.
  - When the heat treatment is applied to the hair coated in the relaxer solution, the product – including formaldehyde – is released into the air as a gas, placing those in the salon at risk of inhaling unsafe levels of formaldehyde.
- Long-term exposure
  - Chemicals in hair relaxers can also be absorbed through the skin.
  - New research has found that frequent and long-term users of hair relaxers are significantly more likely to develop uterine cancer vs. those who reported never or rarely using such products.





Drug Shortages: The Battle Continues…

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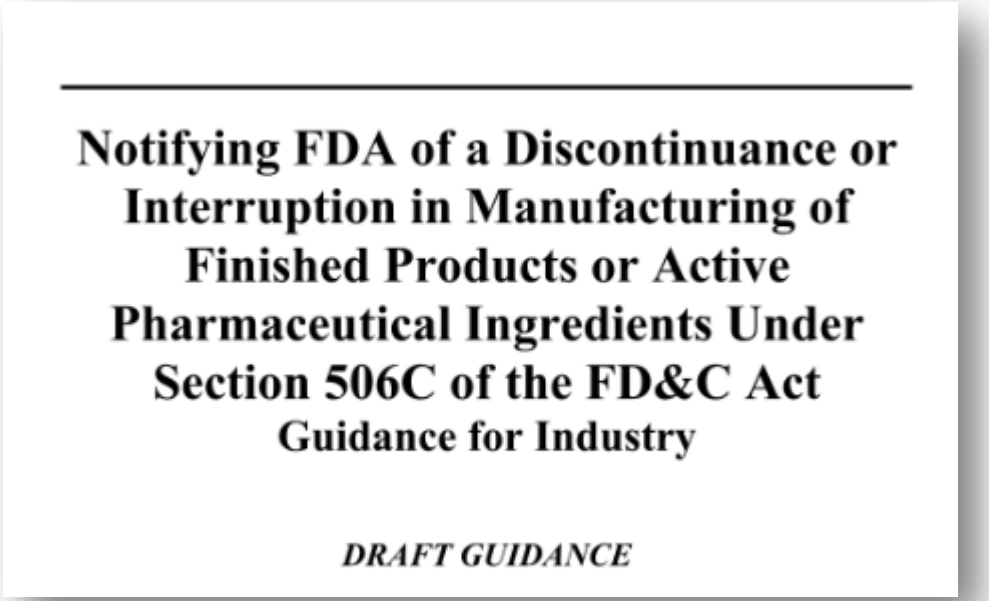
Drug Shortages in 2023

- Why do drug shortages arise?
- What is the FDA doing to mitigate risk of drug shortages?
- Which drugs were impacted in 2023 and why?
- What can industry participants do to combat this?



Notifying FDA of a Discontinuance or Interruption in Manufacturing of Finished Products or Active Pharmaceutical Ingredients Under Section 506C of the FD&C Act

Guidance for Industry

DRAFT GUIDANCE

RAPS

FDA updates guidance on reporting manufacturing disruptions for finished products and APIs

The US Food and Drug Administration (FDA) on Wednesday issued draft guidance that outlines how drugmakers should notify the agency of a...

Eye Drops: Safety and Enforcement

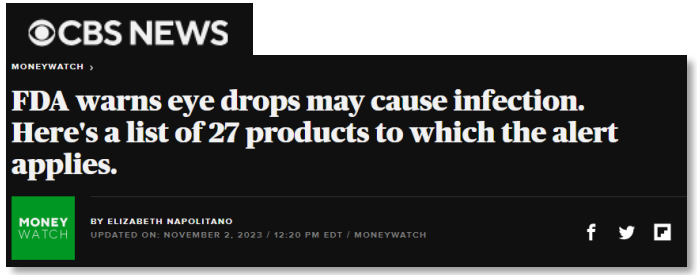
- Several significant eye drop alerts have hit the news in recent weeks, highlighting two significant issues:
  1. The prevalence of unapproved drug products on the market, and
  2. The critical importance of supply chain qualification and risk-shifting through contract.

Unapproved Products

- In the past, FDA has gone after the manufacturers of unapproved products directly, issuing Warning Letters that cite claims made on Amazon storefronts.
- In the last couple of years, FDA has changed tack, warning Amazon directly and placing the onus on the company to cease distributing products for unapproved indications.

Supply Chain

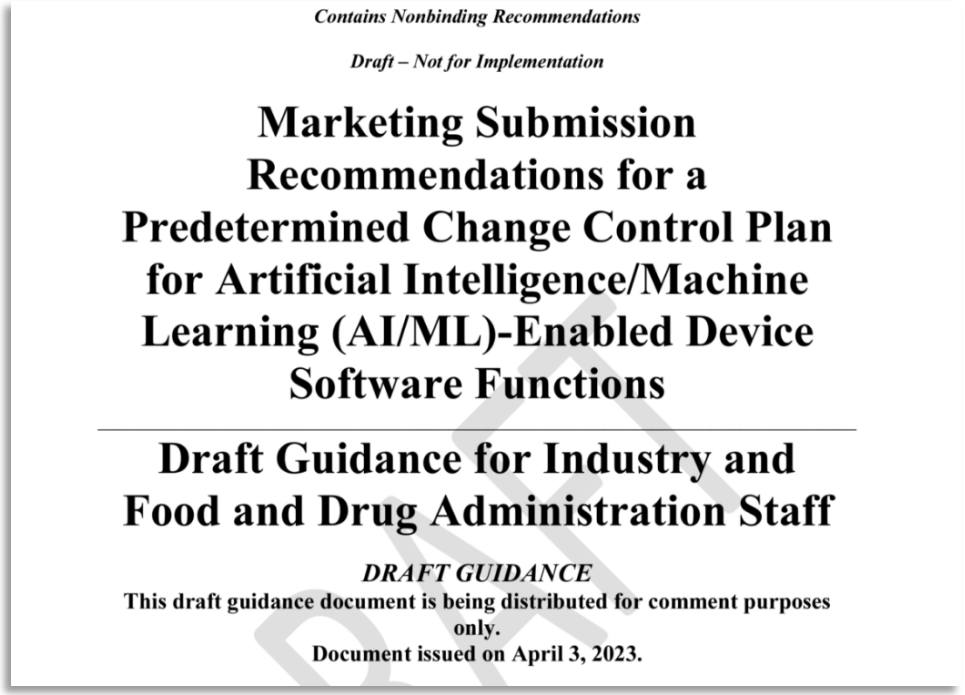
- As in many product categories, eye drop manufacturing appears to be concentrated in a small number of private label manufacturers.
- When one private label manufacturer's operations failed, resulting in contamination, many major retailers' house brands were impacted – including CVS, Rite Aid, Target, and Walmart.



Artificial Intelligence in Medical Devices

How can the FDA regulate a medical device that is constantly changing?

- Which types of changes need to be reported?
- What are some implementation challenges that may arise?
- What can industry participants do to combat this?



Contains Nonbinding Recommendations

Draft – Not for Implementation

Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on April 3, 2023.

JD Supra

FDA Releases Guidance on Submissions for AI/ML-Enabled Devices

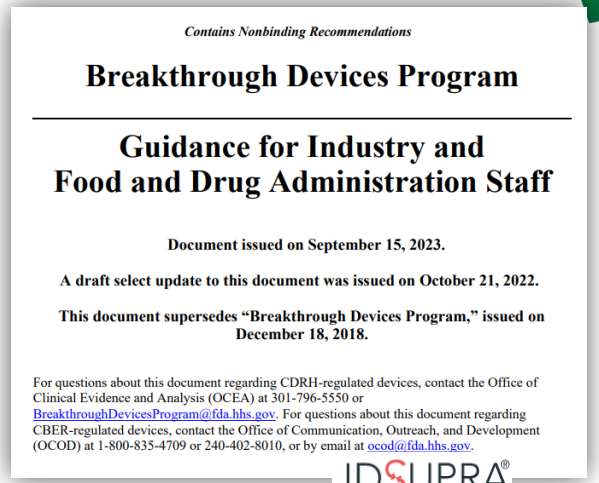
On April 3, 2023, the Food and Drug Administration (FDA) published in the Federal Register an announcement of availability for the draft...

Breakthrough Devices: An Update

What is the Breakthrough Devices Program?

- Voluntary program for devices and device-led combination products that provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions
  - Replaces Expedited Access Pathway and Priority Review for medical devices
- Goal is to speed patient access by streamlining development and approval/clearance through premarket interaction with FDA

- FDA recently issued an update to its final guidance on the Breakthrough Devices Program
  - Application to devices promoting health equity
  - Non-addictive medical products to treat pain or addiction



Contains Nonbinding Recommendations

Breakthrough Devices Program

Guidance for Industry and Food and Drug Administration Staff

Document issued on September 15, 2023.

A draft select update to this document was issued on October 21, 2022.

This document supersedes "Breakthrough Devices Program," issued on December 18, 2018.

For questions about this document regarding CDRH-regulated devices, contact the Office of Clinical Evidence and Analysis (OCEA) at 301-796-5550 or BreakthroughDevicesProgram@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.

JDSUPRA

FDA on pace for a Record Number of Breakthrough Devices in 2023

Regulatory Focus A RAPS Publication

FDA's final breakthrough devices guidance now includes technologies that address health disparities

Regulatory News | 15 September 2023 | Joanne S. Eglovitch

Medical Design & OUTSOURCING

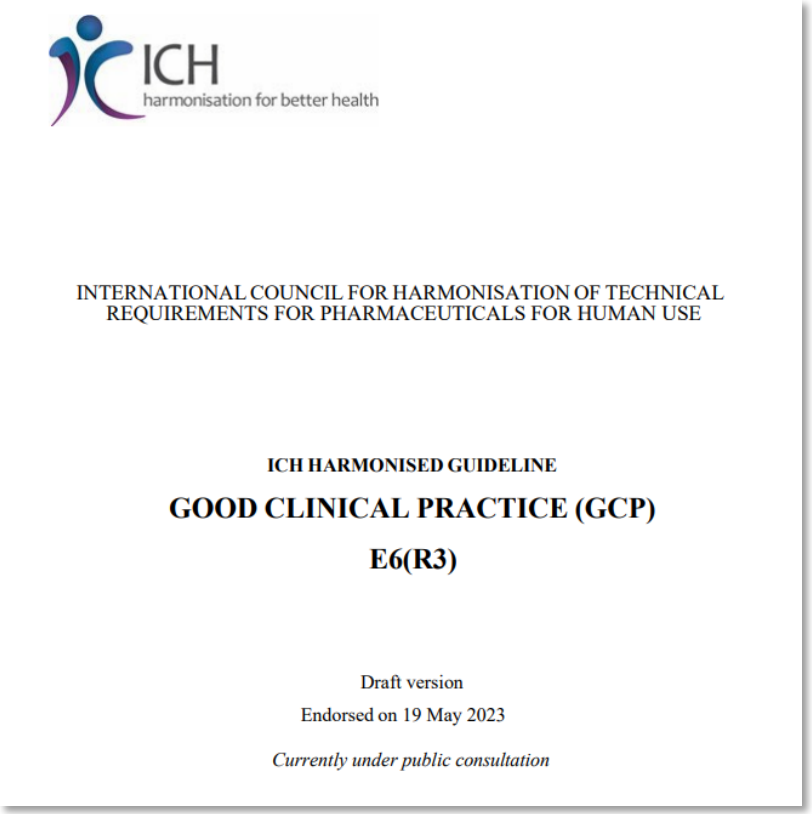
CMS proposes new TCET pathway for Medicare coverage of breakthrough devices

June 23, 2023 By Jim Hammerand

Steps to Modernize Clinical Trials

FDA implements the International Council for Harmonisation's (ICH's) guidelines on good clinical practice (GCP)

- What does the draft guidance say?
- How will this impact clinical trials in the US?
- How does this impact the use of digital health technologies (DHTs) like wearable sensors for data collection?


ICH harmonisation for better health

INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED GUIDELINE

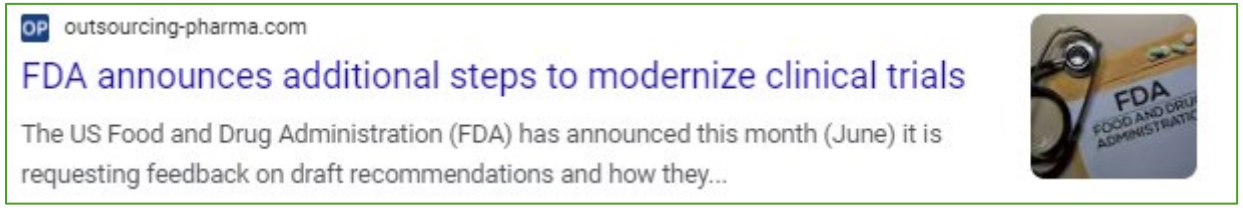
GOOD CLINICAL PRACTICE (GCP)

E6(R3)

Draft version

Endorsed on 19 May 2023

Currently under public consultation


outsourcing-pharma.com

FDA announces additional steps to modernize clinical trials

The US Food and Drug Administration (FDA) has announced this month (June) it is requesting feedback on draft recommendations and how they...

THANK YOU!

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