FDA Signals Potentially Evolving Stance Toward Compounding of Certain Peptides

 On April 15, 2026, the U.S. Food and Drug Administration ("FDA") announced that it will convene a public meeting of the Pharmacy Compounding Advisory Committee ("PCAC") on July 23-24, 2026, to consider whether to recommend seven (7) peptide bulk drug substances for inclusion on the list of substances that may be used in compounding under Section 503A of the Federal Food, Drug, and Cosmetic Act. Five (5) additional peptide and peptide-derived substances are also slated for separate PCAC evaluation through early 2027. On the same date, FDA also republished its interim 503A Bulks List, indicating its intent to remove 12 peptides from its Category 2 list ("Bulk Drug Substances that Raise Significant Safety Concerns"). This removal took effect following a seven calendar-day notice period.

These FDA actions follow comments in February by HHS Secretary Robert F. Kennedy Jr. on a show hosted by Joe Rogan, during which he expressed concerns about the gray-market nature of the current supply of certain peptide products and that he hoped there would be a pathway for consumers to obtain these products from "ethical suppliers".

The seven (7) peptide bulk drug substances expected to be considered by the PCAC in July, together with the uses identified for evaluation, are:

July 23, 2026:

- **BPC-157** (free base and acetate): ulcerative colitis
- **KPV** (free base and acetate): wound healing and inflammatory conditions
- **Thymosin Beta-4, Fragment (LKKTETQ)("TB-500")** (free base and acetate): wound healing
- **MOTs-C** (free base and acetate): obesity and osteoporosis

July 24, 2026:

- **Emideltide (DSIP)** (free base and acetate): opioid withdrawal, chronic insomnia, and narcolepsy
- **Semax** (free base and acetate): cerebral ischemia, migraine, and trigeminal neuralgia
- **Epitalon** (free base and acetate): insomnia

The peptide substances scheduled for consideration at the July 23-24, 2026, PCAC meeting are among those identified for removal from Category 2. FDA has also identified five (5) additional peptide and peptide-derived substances, including Cathelicidin LL-37, Dihexa acetate, GHK-Cu (injectable), Mechano Growth Factor (PEG-MGF), and Melanotan II, for removal from Category 2 and for later consultation with the PCAC at an advisory committee meeting expected before February 2027.

For those substances removed from the Category 2 list, such removal does not, in itself, establish eligibility for compounding under Section 503A. The regulatory status of these substances remains subject to further evaluation by FDA. FDA had previously identified a range of potential safety considerations associated with these substances, including risks related to immunogenicity, peptide-related impurities, and, in some cases, limited human exposure data. Against that backdrop, FDA's removal of these substances from the Category 2 list and its decision to seek PCAC input regarding their potential inclusion on the 503A bulks list suggests that the Agency is continuing to evaluate how such considerations should be weighed in light of other available data.

Inclusion of any substance on the 503A bulks list historically has been implemented through rulemaking, with advisory committee input forming part of that process. Although PCAC's recommendations are not binding, they generally have informed FDA's ultimate determinations. Accordingly, the upcoming PCAC deliberations may provide an important indicator of how FDA intends to approach these substances going forward.

FDA has also opened a **public docket** (FDA-2025-N-6895) in connection with the upcoming PCAC meeting. Comments submitted by July 9, 2026 will be provided to the Committee for consideration, and the docket will remain open for submissions through July 22, 2026.

If you have any questions or would like to submit a comment to the public docket, please contact the authors or the Goodwin attorney with whom you typically work.

Navigating the EU Data Act: Key Obligations and a Spotlight on Switching Rights

Regulation (EU) 2023/2854 (the Data Act) entered into force across the EU on 12 September 2025. It forms a key part of the EU's broader data strategy and establishes a comprehensive framework for how data is accessed, used, and shared across connected products, digital services, and data processing services, including cloud and edge computing services. It applies to a wide range of businesses, such as connected product manufacturers, software as a service (SaaS), and infrastructure service providers, as well as third-party data recipients and public bodies. Read the full alert **here**.

DOJ-HHS Announces False Claims Act Working Group, Emphasizes Healthcare Fraud Enforcement Priorities

The Trump administration recently announced the renewal of a new cross-agency collaboration between the Department of Justice (DOJ) and the Department of Health and Human Services (HHS) in the form of the **DOJ-HHS False Claims Act Working Group**. The Working Group will be jointly led by Deputy Assistant Attorney General (DAAG) of the Commercial Litigation Branch Brenna Jenny, HHS Acting General Counsel Sean Keveney, and HHS Office of Inspector General Acting Chief Counsel Susan Edwards, and will include the Centers for Medicare & Medicaid Services (CMS) Center for Program Integrity and U.S. Attorneys' Offices.

Read the full alert **here.**

FDA's Push for "Radical Transparency": Key Takeaways from the Agency's Publication of Complete Response Letters

On July 10, 2025, the U.S. Food and Drug Administration (FDA) **announced** publication of over 200 complete response letters (CRLs) issued in response to applications submitted to FDA for approval of drugs or biologics between 2020 and 2024. The FDA has described this move as a step toward the Agency's "broader initiatives to

modernize and increase transparency."

CRLs are formal communications sent to applicants when the FDA has completed its review of an application but determined that it cannot approve the application in its current form. Until now, the Agency has only made CRLs available as part of larger approval package files on the Drugs@FDA online database (i.e., after product approval). While the CRLs released this week continue to be limited to approved products—and have been redacted to remove trade secrets and confidential commercial information—the FDA has, for the first time, provided these documents in a central database on **openFDA**. A few key highlights:

- While many of these CRLs have already been disclosed as part of the "Other Action Letters" section of publicly posted drug approval packages, some have not.
- There are multiple CRLs for supplemental New Drug Applications (sNDAs) that had not yet been disclosed, reflecting the fact that approval packages for sNDAs are not consistently posted in the same manner as original NDA approvals.
- Some of these CRLs were issued for products approved before 2020, suggesting that the CRL database scope may exceed the time frame identified in the FDA's announcement.
- At least one CRL has been posted for a product approved as recently as June 2025. For this product, no other portions of the approval package (beyond the label and approval letter) have yet been posted on Drugs@FDA.

Notably, the FDA's announcement references a 2015 analysis conducted by FDA researchers, which found that sponsor disclosures of CRLs did not consistently provide full detail regarding the Agency's specific concerns. The FDA's highlighting of this finding, coupled with the Agency's statement that it plans to publish additional CRLs from its archives, warrants attention from sponsors, especially public company sponsors.

Sponsor disclosures regarding CRLs are always closely scrutinized, and the FDA's move to (1) centralize and regularly release CRLs, and (2) publish additional CRLs (e.g., those for sNDAs, or very recently approved products) is likely to invite further scrutiny—by investors, analysts, competitors, and patient communities. Sponsors should prepare disclosures around receipt of a CRL with the expectation that the CRL itself will become public upon approval of an application. Even where a product is ultimately approved, third parties may make comparisons between a sponsor's characterization of a CRL and the later-posted CRL itself.

According to the FDA, publication of CRLs is just one step in the Agency's broader transparency push. Our team will continue to monitor the frequency and scope of additional releases, as well as any opportunities for interested stakeholders to provide comments or feedback to FDA on its plans.

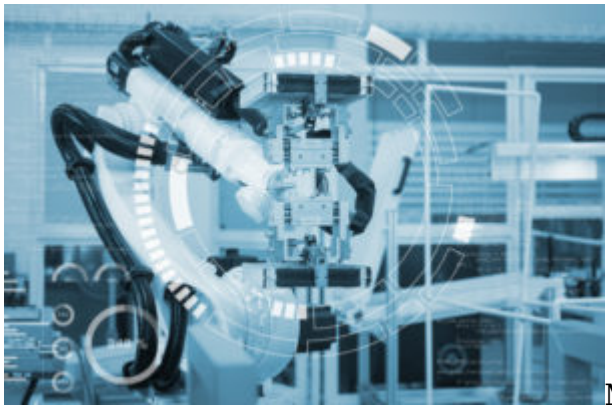
Charting a Conditional Approval Pathway for Rare Disease Drugs – A Top Priority for a Revamped FDA?

On April 18, U.S. Food and Drug Administration (FDA) Commissioner Marty Makary **announced plans** to roll-out a new approval pathway for rare disease drugs. Commissioner Makary's comments build on sentiments expressed across both the patient community and industry that rare disease drug development needs greater regulatory flexibility in order to speed access to treatments for patients with no or limited options. This is an initiative that has also been **trumpeted by Janet Woodcock**, former Principal Deputy Commissioner and Acting Commissioner of the FDA, in her work since retiring from the FDA. Prior legislative proposals (including the "Promising Pathway Act" **proposed** in 2024) have attempted to create a time-limited conditional approval pathway in the rare disease space, and Commissioner Makary's remarks may signal a renewed push for action.

In last week's interview, Commissioner Makary emphasized the following potential eligibility factors in how he is thinking about a new "conditional" approval pathway: rare conditions affecting only a small number of people, where a randomized clinical trial has not been conducted and is not feasible, but where a "plausible mechanism" physiologically exists. Commissioner Makary also noted that post-approval monitoring of adverse events and other data may be an important tool to support more flexible regulatory decision making about drug approvals.

Whether *and when* the FDA or Congress will take further steps in outlining a conditional approval pathway, and what form that outline may take (e.g., Agency guidance, expansion of the current accelerated approval authorities, or new legislation), remains unclear at this time. This is an area rare disease researchers and developers should monitor for developments, including any opportunities to provide comments to the FDA on its potential plans.

Medtech M&A and VC Signal Positive Momentum Entering 2025


Medtech mergers and acquisitions (M&A) and venture capital (VC) showed signs of life in 2024, contributing to an overall optimistic outlook for the sector

this year despite lingering headwinds.

Strategic investments are expected to continue as medtech companies innovate, particularly in areas such as AI-driven diagnostics, wearables and remote monitoring devices, and advanced surgical technologies.

Private, venture-backed M&A activity for medical devices—which picked up in the second half of last year and started 2025 strong with two ten-digit acquisitions and two spin-offs by strategics—could continue rising amid a more deregulatory backdrop under the new presidential administration.

Still, challenges persist that could slow growth. Early-stage VC deals in the sector have faced difficulties, and private M&A exit timelines have increased. Uncertainty regarding the path of interest rates and the broader economy also muddy the outlook.

Read the full insight **here**.

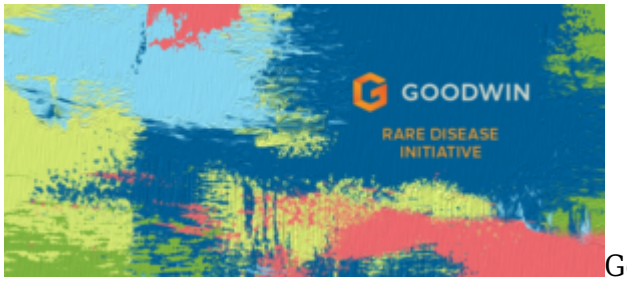
FDA Publishes Its First Draft Guidance On Use of Artificial Intelligence in the Development of Drugs and Biological Products

On January 7, 2025, the FDA issued a draft guidance called **Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products**. The document clarifies how sponsors, manufacturers, and other industry developers should approach artificial intelligence (AI) to support safe, effective development and marketing of AI-based tools.

The guidance discusses the use of AI models in the nonclinical, clinical, post-marketing, and manufacturing phases of the drug product life cycle, where the specific use of the AI model is to produce information or data to support regulatory decision-making as it relates to safety, efficacy, or the quality of the product. It does not cover AI use in drug discovery or operational efficiencies that do not affect patient safety, drug quality, or study reliability.

Read the full alert **here**.

Goodwin Invites You to Join Us For Our Rare Disease Symposium 2025



Goodwin's **Life Sciences** team is excited to host its Annual Rare Disease Symposium in Boston on February 5, 2025. Participants are invited to join for an afternoon of engaging fireside chats, inspirational presentations, and networking with peers in the rare disease community.

Please see the agenda below and register to attend **in-person** or via our **virtual webinar** to join us.

Agenda

12:00 PM – 1:00 PM EDT | Welcome & Networking Lunch

1:00 PM – 4:30 PM EDT | Rare Disease Symposium Program

- **The Patient View**
  - David Downing, GRIN1 Dad
  - Jaime McHugh, Rare Disease Mom and NORD Running for Rare Champion
- **The Research View**
  - Dr. Shira Rockowitz, PhD, Data Science Director, Boston Children's Hospital, Children's Rare Disease Collaborative Co-Leader
  - Dr. Piotr Sliz, PhD, Vice President, Chief Research Information Officer & Associate Professor, Boston Children's Hospital, Children's Rare Disease Collaborative Co-Leader
- **The FDA View**
  - Amy Rick, Director of Strategic Coalitions for FDA's Rare Disease Innovation Hub
- **The Policy View**
  - Karin Hoelzer, Senior Director, Patient Advocacy, BIO
  - Jack Kalavritinos, Founder, JK Strategies and the Washington Health Innovation Council, and Former Director, HHS Office of Intergovernmental & External Affairs
  - Judy Stecker, SVP, Burson, and Former HHS Deputy Chief of Staff for Strategy & Operations – Rare Disease Parent & Founder, Wheeler's Warriors
- **The View from the National Organization for Rare Disorders**
  - Pamela Gavin, Chief Executive Officer, NORD
- **The View from the Rare As One Network**
  - Heidi Bjornson-Pennell, Senior Program Manager, Science in Society, and Lead, Rare As One Network

- **The Biotech CEO View**
  - Paula Ragan, PhD, CEO, X4 Pharmaceuticals

4:30 PM – 5:30 PM EDT | Networking Reception

We look forward to kicking off **Rare Disease Month** with you!

FDA Platform Technology Draft Guidance Highlights Utility of Obscure Patent Term Extension Provision

 As discussed in a **prior Goodwin Alert**, the US Food and Drug Administration (FDA) recently released **Draft Guidance for designating a platform technology for drug development** pursuant to § 560k of the Federal Food, Drug, and Cosmetic Act. The platform technology program was included as part of the PREVENT Pandemics Act "to bring significant efficiencies to the drug development or manufacturing process." Specifically, a platform technology must have the "potential to be incorporated in, or utilized by, m**ore than one drug** without an adverse effect of quality, manufacturing or safety."

Read the full insight **here**.

Common FDA Bioresearch Monitoring (BIMO) Violations: Updates from FY 2023 to Now

The Bioresearch Monitoring (BIMO) Program, operated by the U.S. Food and Drug Administration (FDA), conducts on-site inspections and data audits in order to effectively monitor the compliance of all FDA-regulated research.

As a follow up to our **July 2023 post**, we highlight the most common violations identified in Fiscal Year (FY) 2023, in addition to those observed thus far in FY 2024. BIMO conducted **1073** inspections in FY 2023. The majority of these inspections (approximately 79%) were of drug, biologic, or medical device study clinical investigators, institutional review boards (IRBs), sponsors, clinical research organizations (CROs), and sponsor-investigators. Some of the most common inspection outcomes are highlighted in our alert linked below. Our methodology included a search of FDA's Warning Letter database for FY 2023 and 2024, to date, for letters issued by BIMO and the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health to IRBs, CROs, clinical investigators, sponsors, and sponsor-investigators.

Read the full alert **here**.