Summary of FY 2026 Legislative Proposals

The FY 2026 budget includes several legislative proposals that support agency efforts to protect American consumers and patients. The proposals include enhanced authorities to address the import of problematic medical devices and ensure data quality in medical product applications. The proposals would change labeling requirements for active pharmaceutical ingredients to include original manufacturer and supply origin and enhance the utility of drug manufacturing amount information to be reported to the Agency. The Agency also seeks authority to ensure that data supporting application and non-application medical products are reliable and verifiable for as long as the product may be legally marketed and has sufficient tools to act on findings of fraudulent or unreliable data. The budget would also expand the type of information required to prevent drug shortages and resolve a statutory distinction between biosimilar products and interchangeable biosimilar products. The budget would also give FDA the authority to require an importer to destroy any FDA-regulated product(s) refused entry into the United States that presents a significant public health concern, thus removing their option to export such product(s).

Disrupt the Flow of Problematic Imported Medical Devices

Despite extensive efforts utilizing all of FDA's existing oversight authorities, the United States continues to see an influx of problematic imported devices from China and other nations that puts patients and healthcare providers at substantial risk of harm. This compromises the U.S. healthcare system and the supply chain for critical medical devices upon which our hospitals, providers, and patients depend. This risk from problematic imported devices is particularly concerning in outbreak situations when supplies are limited and the U.S. healthcare system is more vulnerable to reliance on foreign suppliers and imported products that may not meet premarket and postmarket requirements under the Federal Food, Drug, and Cosmetic Act (FD&C Act). This poses a substantial national security risk and diminishes U.S. preparedness. FDA is seeking additional authorities that would give the Agency greater assurances that foreign firms are manufacturing devices intended for import into the United States in compliance with quality systems requirements. In addition, FDA is seeking additional authorities to address when the Agency becomes aware that shipments of devices from a particular country, territory, or region may be adulterated, misbranded, or otherwise violative, and pose a threat to U.S. healthcare providers and patients. These new authorities will enhance FDA's ability to ensure safety, effectiveness, and quality of medical devices entering the U.S. market, support patient health and safety, and advance U.S. preparedness and national security.

Require Labeling to Include the Original Manufacturer and Supply Chain Information

Transparency regarding the drug supply chain is critical for FDA, industry, and other stakeholders. FDA needs additional supply chain information to investigate quality and safety problems. Manufacturers, compounders, and purchasers such as hospitals and patients could make better-informed decisions when evaluating and selecting suppliers and manufacturers with this additional information. FDA proposes to amend section 502 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to clearly require that the label and any accompanying certificate of analysis for an active pharmaceutical ingredient (API) for use in drug manufacturing, including

human drug compounding, identify the name, address, and unique facility identifier of the API's original manufacturer. In addition, FDA proposes to amend section 502 to clearly require that the label for a finished drug product identify the name, address, and unique facility identifier of the finished drug product's original manufacturer. FDA also proposes to amend section 502 to clearly require that the labeling for a finished drug product or API identify the original manufacturer of each API, each manufacturer involved in the production of a finished drug product (if different from the original manufacturer), and the packer or distributor, if any. Finally, FDA proposes to amend section 502 to require that the label for certain excipients designated as high-risk by the Secretary identify the excipient's original manufacturer. The Secretary may provide for reasonable variations or an alternative placement for certain drug product labeling requirements, including by electronic means. We anticipate that information about API sources, other manufacturers, and packers and distributors could be provided on a website or other electronic format.

Enhance the Utility of Drug Manufacturing Amount Information Required to be Reported to FDA

The Coronavirus Aid, Relief, and Economic Security Act (CARES Act) requires drug manufacturers registered under section 510 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to report annually to FDA the amount of each listed drug they manufactured, prepared, propagated, compounded, or processed ("manufactured") for commercial distribution. However, this information is not sufficient to allow FDA to assess the extent of a manufacturer's reliance on suppliers used in the manufacture of a listed drug, which is critical to better understand potential vulnerabilities of the drug supply chain. Accordingly, FDA seeks to expressly require registrants to provide, by a statutory deadline, data identifying the suppliers they relied on to manufacture the listed drug and the extent of such reliance in each annual report. These authorities will help FDA utilize our limited resources more efficiently to address potential drug shortage risks and enable timely action against companies that fail to comply with this reporting requirement.

Require Retention of Data and Records Supporting Marketed Medical Products and Marketed Medical Product Applications and to Act Upon Submissions Containing Fraudulent or Unreliable Data

FDA is increasingly identifying instances of fraudulent or unreliable data provided in premarket submissions for medical devices, in marketing applications for drug and biological products, and in support of non-application medical products (e.g., OTC monograph drugs), including during inspections and remote regulatory assessments of manufacturing establishments. In many instances, the fraudulent or unreliable nature of the data is not discovered until after marketing authorization is granted or a non-application medical product is distributed. This may be because the nature of the unreliable data is not apparent until after an inspection is conducted or a pattern is discovered. As a result, FDA seeks express authority to ensure that data supporting application and non-application medical products are reliable and verifiable for as long as the product may be legally marketed, including throughout the lifetime of the application or market authorization, and to ensure that FDA has appropriate tools to act on findings of fraudulent or unreliable data, including untrue statements of material fact, during premarket review and across the total product life cycle. These new or clarified authorities would help protect the public from medical products that have not been shown to be safe and effective.

Eliminate the Statutory Distinction Between the Approval Standard for Biosimilar and Interchangeable Biosimilar Products and Deem that Approved Biosimilars are Interchangeable

The statutory distinction between biosimilar products and interchangeable biosimilar products has led to confusion and misunderstanding, including among patients and healthcare providers, about the safety and effectiveness of biosimilars and about whether interchangeable biosimilars are safer or more effective than other biosimilars. Interchangeability pertains to pharmacy substitution of an interchangeable biosimilar for its reference product. However, both biosimilars and interchangeable biosimilars are just as safe and effective as their respective reference products and can be used in place of their respective reference products. Accordingly, FDA seeks to amend section 351 of the Public Health Service Act to no longer include a separate statutory standard for a determination of interchangeability and to deem all approved biosimilars to be interchangeable with their respective reference products. This proposal would make the U.S. biosimilar program more consistent with current scientific understanding, as well as with the approach adopted by other major regulatory jurisdictions such as the European Union that permit interchangeability of biosimilars with their respective reference products upon approval. This proposal is expected to increase uptake of biosimilars, with potential downstream effects of increasing competition, access, and affordability.

Require Destruction of Imported Products that Pose a Significant Public Health Risk

Under section 801 of the Federal Food, Drug, and Cosmetics Act, importers have the option to export an entry refused by FDA within 90 days of the refusal regardless of the seriousness of the public health concern posed by the product. FDA proposes to amend section 801 to give the Agency authority to require an importer to destroy any FDA-regulated product(s) refused entry into the U.S. that presents a significant public health concern, thus removing their option to export such product(s). The Agency has observed importers exporting or attempting to re-import commercial-sized shipments that pose a significant public health concern including food contaminated with *Salmonella*, *Listeria* and carcinogenic unapproved animal drugs; human drugs such as hand sanitizer contaminated with methanol; and misbranded or adulterated devices such as contact lenses, COVID-19 test kits, and personal protective equipment. In May 2023, a high-volume importer/wholesaler pled guilty to attempting to re-import 2100 cartons of frozen eels from China that were refused by FDA because testing confirmed contamination with a carcinogenic unapproved animal drug. FDA believes this new authority would prevent re-importation of refused products and would deter importers from seeking to import products they know or have reason to believe would pose a significant public health risk and could be ordered destroyed. This authority would also increase efficiency by reducing the need to involve the Customs and Border Protection in the seizure of unsafe FDA-regulated products and allow the Agency to require importers to pay the destruction costs up front, thereby avoiding additional legal action to recoup such costs.