



# Summary of FY 2024 Legislative Proposals

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The FY 2024 budget includes several legislative proposals that better support agency efforts to protect American consumers and patients, particularly during public health emergencies like the COVID-19 pandemic. The proposals include enhanced authorities related to shortages of drugs, medical devices, and foods, particularly requirements for manufacturers to notify FDA when they will be unable to supply an increase in demand; additional tools to allow FDA to continue certain oversight activities when inspections are not feasible; expanded authorities for information sharing with the states; and additional authorities for destruction of products which present a significant public health concern. The budget also proposes new authorities which would require animal drug sponsors to make post-approval safety changes, better support our Closer to Zero initiative and protect infants and young children from exposure to toxic elements, and expand FDA's mandatory recall authority to cover all human and animal drugs. Finally, the budget would provide FDA with additional authorities to increase oversight of dietary supplements to better protect consumers and to modernize the tobacco user fee framework to allow for a fair distribution of tobacco user fee assessments to all regulated tobacco products.

## Enhance Authorities Regarding Postmarket Safety of Animal Drugs

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FDA is proposing that the FD&C Act be amended to authorize the Center for Veterinary Medicine (CVM) to require animal drug sponsors to make safety-related labeling changes based on new safety information that becomes available after approval of an animal drug; to require animal drug sponsors to develop and implement a Risk Evaluation and Mitigation Strategy (REMS), a drug safety program for drugs with serious safety concerns and for which interventions beyond FDA-approved labeling are necessary to ensure the safe use of the drug; and to require animal drug sponsors to conduct post-approval studies of animal drugs to assess a known or potential serious safety risk. Currently, if multiple sponsors are marketing an animal drug or class of drugs with similar safety risks, the process of negotiating changes in labeling or ensuring implementation of other voluntary, post-approval actions to mitigate risks has been lengthy and created an uneven playing field as sponsors of similar drugs agree to different labeling changes on different timelines, resulting in inconsistent labeling information.

## Change in Agency Regulatory Oversight Responsibility for Certain Products

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FDA is proposing that the definition of "new animal drug" in section 201(v) of the FD&C Act be amended to provide the ability to exclude certain products or classes of products that FDA and EPA agree are more appropriately regulated by EPA as pesticides; and that section 512 of the FD&C Act be amended to facilitate an orderly transfer of regulatory responsibility from EPA to FDA of specified products that are currently registered as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) that FDA and EPA agree are more appropriately regulated by FDA as animal drugs. The first change would allow FDA, in consultation with EPA, to determine whether to exclude certain products from the definition of "new animal drug" so as to allow EPA to regulate these products as pesticides. The second change would eliminate the need for duplicative safety and effectiveness studies for certain parasiticides currently marketed as pesticides that are transferred to regulation by FDA as animal drugs. In 1975, Congress sought to reduce the regulatory burden of obtaining approval from both the EPA and FDA by amending the definition of "pesticide" in FIFRA to exclude "new animal drugs." This change has complicated FDA's and EPA's ability to regulate products in a way that both agree is appropriate and limits the way FDA can direct sponsors to the appropriate regulatory agency. The proposed changes to the FD&C Act would remove regulatory uncertainty and provide clarity to sponsors about which agency intends to regulate a given product or type of products.

## **Authority to 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**

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FDA is requesting express authority for the agency 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 or information, including untrue statements of material fact. FDA is increasingly identifying instances of fraudulent or unreliable data provided in premarket submissions for medical devices and marketing applications for drug and biological products, not only for requests for Emergency Use Authorization (EUA) during the COVID-19 pandemic, but also for premarket submissions generally and 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. FDA believes these new or clarified authorities would encourage applicants and manufacturers to more closely examine and monitor the information and data they submit to FDA, and generate to support the marketing of FDA-regulated medical products, improving the reliability of their data. More importantly, it would protect the public from medical products that have not been shown to be safe and effective due to the fraudulent or unreliable nature of the data relied on.

## **Explicitly Address Generic Drug-Device Combination Products in the FD&C Act**

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Section 505(j) of the FD&C Act does not explicitly address abbreviated new drug applications (ANDAs) for drug-device combination products, and certain statutory provisions in this section – which was established nearly 40 years ago at a time when most products were simpler dosage forms – make it difficult for companies to develop generic versions of these products and for FDA to efficiently approve ANDAs for these products. As a result, these products can be more expensive and less accessible to patients who need them. To address this, FDA is seeking to amend section 505(j) of the FD&C Act to explicitly address the submission and review of ANDA applications for drug-device combination products, as well as drug products submitted in an ANDA that are used with a device, but which are not submitted as combination products. Among other things, FDA seeks amendments to clarify that FDA can request and review data for such applications, that certain differences between the device constituent parts of the reference listed drug (RLD) and the proposed generic are permissible, and that differences in labeling between the RLD and the proposed generic as a result of permissible differences in the device are also permissible.

## **Provide a Structured and Tiered Risk-Based Framework for Biologic Products for Animals Subject to FDA Regulation**

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FDA is seeking to enact a structured and tiered risk-based statutory provision for FDA-regulated biologic products for animals. The current FDA statutory framework does not account for the unique attributes of these products. Partly as a result of the barriers inherent in the current statutory framework, FDA estimates that over 95% of animal products with characteristics of biologics are unapproved. A targeted statutory provision for FDA-regulated biologic products for animals would help protect human and animal health while encouraging significant innovation of these novel and promising products. The proposed amendments would help address safety concerns due to disease transmission, including zoonotic diseases, as well as provide appropriate quality standards. Of significant importance to stakeholders, this proposed pathway would also provide a path to market that entails minimal regulation for products that pose a low risk for adverse impact on human and animal health.

## Create a Safe Harbor for “Skinny Labeling”

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FDA is proposing that the provisions the Hatch-Waxman Amendments and the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) added to section 271 of title 35 of the U.S. Code be amended to create a safe harbor from patent infringement liability for human and animal generic drug applicants and 505(b)(2) applicants who market a drug with “skinny labeling,” by excluding such labeling from the evidence that can be used to support a claim of patent infringement, and by clarifying that statements regarding therapeutic equivalence cannot be used as evidence to support an infringement claim. In *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.*, No. 18-1976, the majority Federal Circuit decision held that substantial evidence supported a jury verdict finding that Teva induced infringement of a patent-protected method of use for its generic version of Coreg (carvedilol) tablets, including during a period when Teva had carved out the corresponding condition of use from its labeling. While the majority decision indicates that the decision is narrow and fact dependent and should not upset the careful balance struck by the Hatch-Waxman Amendments regarding labeling carve-outs, FDA is concerned that this decision imperils an important statutory marketing pathway that allows earlier generic drug market entry for conditions of use of a drug not protected by a patent. Without this change, FDA expects that the Federal Circuit’s *GSK v. Teva* decision could significantly impact the timely availability of generic drugs.

## Enhance Availability of Generic Animal Drugs

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FDA is proposing that the FD&C Act be amended to clarify labeling requirements for generic animal drugs by explicitly including an exception from the requirement that a generic animal drug’s labeling be the same as the labeling of a reference-listed new animal drug (RLNAD) where the RLNAD is approved in more than one “major species” as that term is defined in section 201(nn) of the FD&C Act. This exception would allow a generic sponsor to seek approval for only those major species on the RLNAD’s labeling for which bioequivalence information has been provided, so long as the generic sponsor also sought approval for use in any minor species for which the RLNAD has been approved for use. This proposal is intended to increase the availability of generic animal drugs particularly in situations where obtaining bioequivalence information for certain major species is impractical or scientifically challenging.

## Enhancing FDA’s Authority to Better Protect Infants and Young Children

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FDA is seeking to amend the FD&C Act to grant FDA new authority to establish binding contamination limits in foods, including those consumed by infants and young children, via an administrative order process. Under current law, FDA has limited tools to help reduce exposure to toxic elements in the food supply. This new authority to allow FDA to establish contamination limits in foods, including those consumed by infants and young children, via the administrative order process would improve the efficiency, timeliness, and predictability of issuing binding limits to reduce exposure to toxic elements by these vulnerable populations, and updating limits as new scientific information becomes available.

## Product Testing Requirements for Foods Marketed for Consumption by Infants and Young Children

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Under current law, industry is not required to test ingredients or final products marketed for consumption by infants and young children, which would help assess levels of toxic elements in such foods. FDA is seeking to amend the FD&C Act to: (1) require industry to conduct toxic element testing of final products marketed for consumption by infants and young children and maintain such records of these testing results for FDA inspection; and (2) provide FDA with new authority to remotely access records of these test results and to review these test results whenever necessary. This new authority would help FDA understand levels of toxic elements in such products, allow FDA to monitor industry progress in reducing levels of these toxic elements over time, and identify where FDA should devote more time and resources to better protect infants and young children. Additionally, FDA seeks new authority to require firms that manufacture foods marketed for

consumption by infants and young children to (1) under specified circumstances, notify FDA of anticipated significant interruptions in the supply of such products; (2) report final product positive test results for relevant pathogens; and (3) conduct more frequent environmental monitoring in their facilities to identify relevant pathogens and maintain the results of such testing for FDA inspection, either in person or remotely.

## **Modernization of Tobacco User Fees Framework**

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The Federal Food, Drug, & Cosmetic (FD&C) Act, Section 919, authorizes FDA to assess and collect tobacco user fees from domestic manufacturers and importers of six classes of products: cigars, pipe tobacco, cigarettes, snuff, chewing tobacco, and roll-your-own tobacco. Section 919 also authorizes the total amount of tobacco user fees FDA must assess and collect each year. However, because electronic nicotine delivery systems (ENDS) were a relatively new product category when the FD&C Act was amended to give FDA authority to regulate tobacco products in 2009, the budgets established by Congress under Section 919 did not take into account the resources required for the regulation of ENDS; since that time, these products have become the most used tobacco product category by youth. This presents two issues: 1) Manufacturers and importers of regulated tobacco products outside of the six product classes listed above, including ENDS, do not pay tobacco user fees for their regulatory oversight, and 2) FDA has had to spend a significant portion of the \$712 million in user fees it collects annually from the pre-existing six product classes to properly regulate tobacco products outside of the six product classes listed above, especially ENDS. This means fewer funds are available to be spent on important efforts related to those six product classes. For example, the agency has been forced to constrict funding for research, limit efforts to reduce youth initiation through enforcement and compliance efforts, and divert funds from efforts related to smoked and smokeless tobacco products. This proposal seeks to amend Section 919 of the FD&C Act to: authorize the agency to assess user fees on, and collect such fees from, each manufacturer and importer of any products subject to Chapter 9 of the FD&C Act, promoting a fair distribution of tobacco user fee assessments to all regulated tobacco products, including ENDS; increase the current limitation on total tobacco user fee collections by \$100 million; and index all future collections to inflation.

## **Amend the 180-Day Exclusivity Provisions to Encourage Timely Marketing of First Generics**

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FDA is proposing that the FD&C Act be revised to specify that 180-day patent challenge exclusivity for generic drugs does not block approval of subsequent applications from other generic drug manufacturers until a first applicant begins commercially marketing the drug; this revision should ensure that the exclusivity period lasts 180 days (i.e., from the date of first commercial marketing by a first applicant until 180 days later) rather than for multiple years, as can occur under current law (i.e., while the first applicant is eligible for 180-day exclusivity prior to commercial marketing in addition to the 180-day period itself). 180-day patent challenge exclusivity is intended to provide an incentive and a reward to the first generic drug applicant(s) to submit a substantially complete application with a certification that a patent listed for its reference listed drug is invalid, unenforceable or not infringed by the ANDA, and thus expose themselves to the risk of patent litigation. Forfeiture provisions, under which a first applicant may lose its eligibility for this exclusivity, also seek to motivate first applicants to begin marketing quickly in order to reap the benefits of this marketing exclusivity. In practice, however, the framework has not been operating to encourage early generic entry. First applicants often “park” their eligibility for this exclusivity either by declining to begin marketing their product for extended periods of time after ANDA approval, or by delaying receipt of final approval of their ANDAs for extended periods of time, while avoiding a forfeiture. FDA’s proposal would substantially increase the likelihood that generic versions of patent-protected drugs will come into the market in a timely fashion, and that multiple versions of generic products will be approved quickly (leading to significant cost savings).

## **Authority to Require Destruction of Imported Products that Present a Significant Public Health Concern**

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FDA seeks to amend section 801 of the FD&C Act to give FDA the authority to require an owner or consignee to destroy any FDA-regulated product(s) offered for import that has been refused entry and presents a significant public health concern, thus removing their option to export such product under current section 801(a). FDA believes this new authority would prevent the potential re-importation of such products and would deter owners and consignees from offering products they know to pose a significant public health risk for import into the United States. FDA also believes this authority would increase efficiency when Customs and Border Protection (CBP) seizes an FDA-regulated product. Under current practice, when CBP seizes an FDA-regulated product, an FDA violation is used to support the seizure. CBP then consults with FDA to confirm that the product seized violates the FD&C or PHS Acts and/or FDA regulations. Additionally, if the seizure is successful, the government will likely end up paying for the destruction. Under this proposal, FDA would order the destruction based on the agency's admissibility review and evaluation of the significant public health concern presented by the products offered for import, thereby reducing the need for CBP consultations with FDA. Moreover, the importer of record would be required to pay the destruction costs up front so FDA and CBP do not have to file legal action to recoup the destruction costs.

## **Mandatory Recall Authority for All Drugs**

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FDA is seeking to expand FDA's mandatory recall authority under the SUPPORT Act so that it covers all human and animal drugs. The SUPPORT Act, enacted in 2018, provided FDA with authority to mandate recalls for controlled substances. FDA also has mandatory recall authority for biological products under the Public Health Service Act § 351(d) [42 U.S.C. § 262(d)], and recently received mandatory recall authority for cosmetics as part of the FDA Omnibus Reform Act. The agency lacks mandatory recall authority for other human and animal drugs. Under current law, the great majority of companies agree to recall their human or animal drug products when asked to voluntarily do so by FDA. However, there are cases where a company extensively delays initiating a recall or refuses to recall a violative drug product when asked to voluntarily do so. FDA believes that expanding its mandatory recall authority would help remove violative human and animal drugs more quickly thereby reducing harm to consumers due to exposure to dangerous products.

## **Modernizing Dietary Supplement Health and Education Act (DSHEA)**

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Since the Dietary Supplement Health and Education Act of 1994 (DSHEA) was enacted almost 30 years ago, the dietary supplement market in the U.S. has grown from approximately 4,000 products to more than 95,000 products. FDA is seeking to modernize DSHEA to provide for a transparent marketplace, help facilitate a risk-based regulation of dietary supplements, and clarify FDA's authorities relating to products marketed as "dietary supplements." Specifically, FDA is seeking to amend our authorities to: (1) require all dietary supplements to be listed with FDA, with information to include product label and other basic information; and (2) clarify FDA's authorities over products marketed as dietary supplements. These amendments would help FDA to know when new products are introduced and quickly identify dangerous or illegal products on the market to take appropriate action to protect consumers when necessary.

## **Require Full Ingredient Disclosure for Drugs to Promote Generic Competition**

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FDA is seeking an amendment to the FD&C Act to (1) require drug manufacturers to disclose full information about the name and amount of each inactive ingredient in their product in the product's labeling for applications (including supplements) submitted after the effective date of the legislative change, and (2) clarify that it is not an improper disclosure on FDA's part to provide a potential generic drug sponsor the names or amounts of inactive ingredients used in an approved reference listed drug's (RLD's) or reference listed new animal drug's (RLNAD's) formulation. Under current law, brand drugs are in many cases not required to disclose full ingredient information, including the amount of certain inactive ingredients, in their labeling. In

such cases, FDA is generally prohibited by federal law from disclosing that information to members of the public, including potential generic drug sponsors. However, generic drugs, particularly non-oral dosage forms, often need to have the same ingredients (both active and inactive) in the same amount as the brand drug they are duplicating in order to meet the requirements for approval. FDA believes this change would effectuate timelier and more cost-efficient generic drug development, thereby increasing competition and access to generic drugs for American consumers, pet owners, and animal producers.

## **Pandemic and All-Hazards Preparedness Act (PAHPA) Proposals**

### **Require Drug Manufacturers to Notify FDA of an Increase in Demand**

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FDA is seeking an amendment to the FD&C Act to expand the notification requirements to include notifying FDA of an increase in demand for drugs described in section 506C(a) of the FD&C Act that the manufacturer likely will be unable to meet. Currently, FDA generally does not receive notice or adequate information from drug manufacturers regarding increases in demand that would position the agency to assist in preventing or mitigating drug shortages driven by an increase in demand (in contrast to drug shortages driven by a disruption in supply). FDA believes that receiving such notifications would better position FDA to take steps to prevent or mitigate shortages resulting from increased demand, such as those that have occurred during the COVID-19 public health emergency for certain drugs needed to treat hospitalized patients.

### **Site Master Files for Drug Manufacturing Facilities**

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FDA seeks to amend the FD&C Act to explicitly require facilities at which human drugs (including both application and non-application products, and drugs compounded under Section 503B and biological products subject to the Public Health Service Act that also meet the definitions of drugs under the FD&C Act), and animal drugs are manufactured to create, submit, and maintain Site Master Files (SMFs). SMFs typically contain specific information about the firm's quality management policies and activities and the production or quality control of manufacturing operations carried out at the named site and identify any closely integrated operations at adjacent and nearby buildings. Currently, FDA has no authority to require the submission of a SMF. Without a SMF, FDA may not capture ancillary changes within the covered manufacturing facilities that are not directly associated with an approved application or license, yet still potentially impact the safety of the approved or licensed products. SMFs can improve FDA understanding of quality management practices and supply chain management, which will improve overall supply chain resiliency. SMFs can further assist FDA when conducting risk identification for sites for surveillance and for-cause based inspections. In addition, FDA believes that requiring SMFs for facilities manufacturing would assist its preparation for inspections, thereby making inspections more efficient.

### **Evaluation of Non-Application Drug Manufacturers Before Marketing**

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FDA is seeking an amendment to authorities with respect to non-application drugs (finished dosage forms and active pharmaceutical ingredients (API)) to provide the agency time to use a risk-based approach to determine if an inspection of the manufacturing facilities is necessary before the drug can be distributed, and to conduct the inspection if it is necessary. Under this proposal, a manufacturer that intends to distribute a non-application drug in interstate commerce from an establishment for the first time would be required to notify FDA of its intent at least six months prior to its first distribution. Additionally, manufacturers that intend to distribute sterile, non-application drugs in interstate commerce for the first time and have not previously been inspected for sterile manufacturing operations would be required to submit such a notice at least six months prior to their first distribution of a non-application sterile drug in interstate commerce, even if they already distribute other non-sterile drugs in interstate commerce. Under current law, for drugs that are not subject to premarket approval requirements, FDA typically does not have a feasible opportunity to inspect the manufacturing facilities before such products are shipped to or distributed in the U.S. A recent focus on firms manufacturing

non-application drugs has identified a high rate of non-compliance with current good manufacturing practice (CGMP) requirements, especially when a facility is first inspected. FDA believes that ensuring it has an opportunity for an inspection before distribution would help identify potential safety issues related to manufacturing before a drug product is distributed into interstate commerce and ultimately to patients.

## **Preventing Food Shortages**

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FDA is seeking authority to require firms to provide shortage notification for FDA-designated categories of food during a declared public health emergency. The recent COVID-19 pandemic has demonstrated the need for timely and accurate information about confirmed or likely supply chain challenges to help ensure the continuity of the food supply so that consumers have access to a safe and adequate food supply during public health crises.

## **Expanding Information Disclosure Authorities with States**

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State, local, and territorial governments play an important role in the protection of public health, particularly as FDA partners with them in the regulation of products, helping to ensure the safety and integrity of supply chains, and assisting in enforcement against products that are being unlawfully sold. FDA works closely with our state partners to employ complementary authorities to achieve fast and effective action to protect the public health during national public health emergencies such as the COVID-19 crisis, other state/local disaster declarations, outbreaks or other public health events, and for routine regulatory oversight. FDA proposes to amend the Federal Food, Drug, and Cosmetic Act (FD&C Act), to allow for disclosure of non-public information to state, local, and U.S. territorial government agencies with counterpart functions related to FDA-regulated products by preempting any and all related state, local, or territorial disclosure laws in order to keep confidential non-public information provided by FDA (such as confidential commercial information). This proposal would advance an integrated food safety system and more effectively leverage the oversight capabilities and resources of FDA's state regulatory partners to allow for expanded mutual reliance related activities and other partnerships. The limitations on sharing all regulated commodity information seamlessly and in real time with states prevents FDA from taking swift action to ensure a robust product supply and protect the integrity of supply chains. The agency anticipates this authority will also benefit FDA partners conducting inspections and regulated industry by reducing the burden related to duplicative inspectional activities.

## **Expansion of FDA Tools to Provide Oversight of FDA-Regulated Products**

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FDA's authority to conduct remote regulatory assessments is limited to requests for records and other information in advance or in lieu of drug, device, and biomedical research monitoring (BIMO) inspections and FDA currently lacks authority to require any establishment to participate in remote interactive evaluations. The agency relies on voluntary participation for remote regulatory assessments of non-drug establishments but reliance on voluntary requests is not sufficient to achieve effective and efficient oversight, as firms can refuse to provide records or other information in advance of or in lieu of an inspection or to participate in remote regulatory assessments. This proposal would expand FDA's authority to request records or other information in advance of or in lieu of inspections to include all FDA-regulated products by revising section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to explicitly include food, tobacco product, and cosmetic establishments. Additionally, this proposal would add explicit authority to conduct remote regulatory assessments with establishments, which may include remote interactive evaluations such as livestreaming video of operations, teleconferences, and screen sharing, so FDA may interact virtually with an establishment and assess its compliance with applicable laws and regulations. This proposal will promote regulatory compliance and help to protect the public health, particularly during a public health emergency like the COVID-19 pandemic where in-person inspections and investigations were limited, by allowing FDA to conduct certain oversight activities prior to arriving for or instead of an inspection, thus improving the efficiency of FDA resources and reducing FDA's on-site inspectional time, and by allowing the FDA to assess

conditions at a facility without going onsite when an in-person visit is not feasible or deemed necessary by FDA. For example, during a recent recall of infant formula, FDA has found that the inability to remotely request records delayed FDA's response to complaints about adulterated products.

## **Lengthen Expiration Dates to Mitigate Critical Drug Shortage**

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Shortages of drugs that are life-supporting, life-sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition can be exacerbated when drugs are discarded because they exceed a labeled shelf-life. This proposal would expand FDA's authority to require, when likely to help prevent or mitigate a shortage, that an applicant evaluate existing data, submit studies to FDA, and label a product with the longest expiration date (shelf-life) that FDA agrees is scientifically supported. The proposal also seeks authority for FDA to levy a civil money penalty if an applicant fails to comply.

## **Device Shortages**

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Under the CARES Act, FDA received new authority relating to device shortages codified in section 506J of the FD&C Act. As of December 2022, we have received over 455 potential and actual shortage signals, which translates to hundreds of thousands of device units that have been in shortage. We used the information we collected under these new authorities to help mitigate approximately 350 of the 455 shortages. Unfortunately, the requirement for manufacturers to provide this critical information is temporally limited as it is only required to be provided to FDA during or in advance of a public health emergency (PHE), which means it will cease when the COVID-19 PHE ends in May 2023. However, shortages of critical medical devices will persist beyond the end of the COVID-19 PHE, Medical device shortages occur in many situations that fall outside of or are unrelated to PHEs, including natural or human-made disasters, recalls, geopolitical conflicts, production shutdowns, and cybersecurity incidents. Each of these events and others that fall outside of a PHE can lead to device shortages that significantly impact patient care and jeopardize healthcare worker safety. Moreover, as we saw with the onset of COVID-19, by the time there is an emergency, it is often too late to prevent or mitigate shortages. The fiscal year (FY) 2023 Consolidated Appropriations Act (FY23 Omnibus) clarified the ability of FDA to receive voluntary notifications from manufacturers about certain device discontinuances and interruptions, but the lessons of this pandemic have demonstrated that relying solely on voluntary information-sharing deprives FDA and the public of critical supply chain information. To protect patients, build a more resilient domestic supply chain, and help reduce dependence on foreign sources, it is critical that Congress remove the temporal limitation in section 506J that only requires manufacturers to notify FDA about interruptions or discontinuances in the manufacture of certain devices *during or in advance* of a PHE. Furthermore, COVID-19 also showed us that manufacturers are not always prepared for situations where their ability to manufacture product may be disrupted or may be insufficient to meet increases in demand, especially where they are dependent on one source for a critical raw material or component that was in shortage. Providing FDA clear authority to review risk management plans (RMPs) would help ensure manufacturers have plans in place to ensure resiliency and mitigate future supply chain disruptions.

## **Require Labeling to include the Original Manufacturer and Supply Chain Information**

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FDA proposes amending section 502 (21 U.S.C. 352) of the FD&C Act to provide that active pharmaceutical ingredients (APIs) are misbranded if they are introduced into interstate commerce and the original manufacturer and unique facility identifier are not included on the API label (i.e., label of the bulk drug substance), other labeling, and on the certificate of analysis. FDA also proposes amending 502 to deem finished drug products misbranded if the original manufacturer of the API isn't included on the finished drug product label or if certain additional supply chain information is not included in the broader finished drug product labeling. FDA believes there is a lack of supply chain accountability and transparency due to APIs and finished drug products, including repackaged and relabeled APIs, lacking information regarding the original manufacturer of the API. End purchasers of repackaged API may therefore be unaware of whether

the API they purchase is adulterated (for example if it was originally manufactured by a firm that has not met drug current good manufacturing practice requirements). In FDA's experience, lack of supply chain oversight of APIs and finished drug products can cause serious vulnerabilities in the supply chain since FDA and other supply chain stakeholders are not always able to identify the source of the drugs to address manufacturing or safety concerns and may thus lead to patient safety issues. FDA believes this proposal would allow compounders, conventional drug manufacturers, and the FDA itself to quickly identify the original manufacturer of an API that is found to be adulterated or misbranded and take appropriate action to address poor quality products from circulation.

## **Enhanced Drug Manufacturing Amount Information and Reporting**

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FDA is seeking to enhance the manufacturing volume information required to be reported under Section 510(j)(3) of the FD&C Act to expressly require registrants to provide data identifying the suppliers they relied on to manufacture the listed drug and the extent of such reliance. The Coronavirus Aid, Relief, and Economic Security Act (CARES Act), added section 510(j)(3) to the FD&C Act which requires drug manufacturers registered under section 510 of 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, FDA still has gaps in its understanding of the drug supply chain. Specifically, the information required to be submitted under section 510(j)(3) of the FD&C Act is insufficient to help FDA understand which suppliers registrants are relying upon and how reliant they are on them. FDA believes the information from the proposed authority would help identify vulnerabilities in the supply chain that may be hidden due to the limited information provided to FDA under section 510(j) and, for application products, the approved applications.

## **Emerging Pathogens Preparedness Program**

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FDA proposes to create a specialized program within the Center for Biologics Evaluation and Research (CBER) to defend against emerging pathogens so the agency is better positioned to respond to identified threats of concern and focus experienced resources to work quickly on medical countermeasure development to address these concerns. The program would enhance regulatory capabilities and readiness to respond to emerging pathogens, ensure blood safety and availability, and expeditiously review new vaccines, new uses of existing vaccines and other medical products. In consultation with Health and Human Services partners, the program would: provide recommendations and guidance to developers of vaccines and other medical products and relevant federal partners; use real-world data or real-world evidence to study the safety and effectiveness of products for addressing biological incidents and identify which products may be best suited for specific pathogens or for use in different populations; and facilitate product development including advances in manufacturing. It would also support scientific research within CBER that contributes to development and review of biological products to counter biological incidents and emerging pathogens. The program would also maintain and build on enhancements to FDA's post-marketing active and passive safety and effectiveness surveillance programs.