FY25 LEGISLATIVE PROPOSALS

The FY 2025 budget includes several legislative proposals that better support Agency efforts to protect American consumers and patients. The proposals include enhanced authorities related to supply chain resiliency for drugs, medical devices, and foods. For example, requirements for manufacturers to notify FDA when they will be unable to supply an increase in demand and to provide manufacturing amount and supplier information; supporting innovation and competition, such as creating a new category for certain animal food substances to facilitate marketing of innovative products and amending certain exclusivity provisions for drugs to encourage meaningful innovation and timely competition; improving hiring authority for the FDA tobacco program to effectively meet its public health mandate; providing additional oversight tools, such as expanding authorities for information sharing with the states for requesting records or other information in advance of or in lieu of inspections to all FDA-regulated commodities, and for destruction of products which present a significant public health concern. The Budget also proposes new authorities that would require animal drug sponsors to make post-approval safety changes and that would 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.

FACILITATING COMPETITION

Amend the 3-Year Exclusivity Provisions to Encourage Meaningful Innovation and Timely Competition

Under current law, new drugs can qualify for exclusivity that can block or delay competition from follow-on products even when the new drug applicant is not affirmatively seeking exclusivity, or when the new clinical investigation that is the basis of exclusivity fails to demonstrate the hypothesized effect of the drug. FDA is seeking to encourage competition for new drugs by proposing to amend the Hatch-Waxman 3-year exclusivity provisions to ensure that this exclusivity is limited to situations where the new drug applicant is actually seeking such exclusivity and where the data supporting the exclusivity demonstrates the hypothesized effect of the drug, and to prevent information on new safety risks from blocking competition. This approach would continue to reward innovation, while also allowing for earlier access to generic drugs in certain situations.

Create a Safe Harbor for "Skinny Labeling"

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. FDA is concerned that the Federal Circuit's GSK v. Teva decision could significantly impact the timely availability of generic drugs.

Require Full Ingredient Disclosure for Drugs to Promote Generic Competition

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. To address this issue, FDA is seeking an amendment to the Federal Food, Drug, and Cosmetic (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. 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.

Amend the 180-day Forfeiture Provision Addressing Failure to Market

Under current law a first generic applicant may forfeit 180-day exclusivity if they fail to market within a certain time period, among other conditions. However, many first applicants are parking their exclusivity and delaying generic competition when there is no longer a patent-related impediment to generic market entry of either a first applicant or subsequent applicant. FDA is seeking to amend the 180-day exclusivity forfeiture provision regarding failure to market to specify that certain additional events can start the provision's 75-day period, possibly leading to forfeiture. Specifically, the amendments would specify that the provision's 75-day period can be triggered by the resolution of patent litigation without a finding of patent infringement or invalidity if there is no settlement agreement limiting the ability to market. Additionally, the amendments would provide that, when the terms of the resolution of patent litigation would allow the generic applicant to begin commercial marketing as of a certain date, the agreed-upon date would start the 75-day period leading to possible forfeiture. These amendments would allow the agency to use its authorities more effectively by addressing an exploitable loophole in the failure to market provision. FDA believes that this change will help enhance generic competition and choice by improving FDA's ability to use the failure to market forfeiture provision effectively to limit a first applicant's ability to park exclusivity and block generic competition.

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 biosimilars and interchangeable biosimilars 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. FDA is seeking to amend section 351 of the Public Health Service (PHS) 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 where biosimilars are interchangeable with their respective reference products upon approval. Further, this proposal is expected to increase uptake of biosimilars, with potential downstream effects of increasing competition, access, and affordability.

Explicitly Address Generic Drug-Device Combination Products

Section 505(j) of the FD&C Act does not explicitly address abbreviated new drug applications (ANDAs) for drug-device combination products, and the lack of clarity in certain statutory provisions in this section – which was established nearly 40 years ago at a time when most products were simpler – 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. 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.

Enhance Availability of Generic Animal Drugs

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.

SUPPORTING INNOVATION

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

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.

Regulate Certain Articles as Zootechnical Animal Food Substances

Products are legally regulated as food or drugs for animals depending on characteristics of the article, how the article is intended to be used, and what the article claims to do. Novel substances for animals are being developed that are added to animal food or water, that affect the structure or function of the animal through a means other than nutrition, but that act only within the animal's gastrointestinal (GI) tract. Under the FD&C Act these substances are new animal drugs. FDA is proposing to amend the FD&C Act to create a new category of animal food additives called zootechnical animal food substances (ZAFS). Certain substances would meet the definition of ZAFS if they are intended to be added to animal food or drinking water and have no nutritive value or technical effect on the animal food but have other important benefits, such as affecting the byproducts of digestion, reducing foodborne pathogens in food animals, or altering the animal's GI microbiome. This legislative change would give FDA increased flexibility to provide risk-based oversight and facilitate more timely availability of innovative animal food additives. Under this proposal, ZAFSs would be deemed to be food additives, and would not be animal drugs, despite having intended uses that could otherwise make them animal drugs under the FD&C Act.

ENHANCING DATA, INFORMATION, AND POSTMARKET SAFETY

Require Retention of Data and Records Supporting Marketed Medical Products and Marketed Medical Product Applications and 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 and marketing applications for drug and biological products, 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. 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. These new or clarified authorities would improve the reliability of data by encouraging 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. 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.

Expand FDA's Ability to Disclose and Use Certain Information Related to Impurities in Drugs That Pose a Risk to the Public Health

FDA is seeking authority to confirm and expand FDA's ability to publicly disclose and use certain information from submissions to FDA related to impurities in drugs, including biological products, when such disclosure and use has been determined by FDA to be in the interest of public health. Early identification of impurities and disclosure of acceptable intake limits would enable the applicant or drug manufacturer to take quick corrective action (e.g., modify its manufacturing process or reformulate), which would help ensure continued availability of drug products and mitigate discontinuations in the marketing of affected products. This proposal would also provide a mechanism to enable FDA to quickly and readily disclose to sponsors such information, including in the form of recommendations, without additional steps and delay associated with current processes that may render information outdated. Further, the proposal would enable FDA to share safety-related information with international regulators more quickly and use certain information to develop internationally harmonized acceptable intake limits, where appropriate.

Require Site Master Files for Drug Manufacturing Facilities

FDA is seeking to amend the FD&C Act to explicitly require facilities at which human drugs (including both application and non-application products, drugs compounded under Section 503B, and biological products governed by section 351 of the Public Health Service Act that also meet the definitions of a drug 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 a 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 explicit 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.

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

FDA's authority to conduct mandatory records requests under section 704(a)(4) of the FD&C Act 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 lacks authority to require establishments to participate in remote

interactive evaluations. The agency relies on voluntary participation for remote regulatory assessments of establishments not covered under current mandatory authority but reliance on voluntary requests is not sufficient to achieve effective and efficient oversight, as for example, firms not subject to section 704(a)(4) can refuse to provide records or other information in advance of or in lieu of an inspection or to otherwise participate in remote regulatory assessments. This proposal is seeking to 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 FD&C Act to explicitly include food, tobacco product, and cosmetic establishments. Additionally, this proposal would add explicit authority to require remote regulatory assessments of 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. This proposal will expand FDA's authority 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. Further, this will help FDA to assess conditions at a facility without going onsite when an in-person visit is not feasible or deemed necessary by FDA.

Expanding Information Disclosure Authorities with States

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 is proposing to amend the 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 while ensuring confidentiality of non-public information (such as confidential commercial information) provided by FDA. This proposal would advance an integrated food safety system and more effectively leverage the oversight capabilities and resources of FDA's state, local and territorial regulatory partners to allow for expanded mutual reliance related activities and other partnerships. The limitations on sharing certain 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.

Evaluation of Non-Application Drug Manufacturers Before Marketing

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 a formal, designated opportunity to use a risk-based approach to determine if an inspection of the manufacturing facilities is necessary before the drug is first 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 formal, designated opportunity to inspect the manufacturing facilities before such products are first 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 a designated 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.

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

FDA is seeking 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, a violation of the FD&C or PHS Acts and/or FDA regulations 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.

Streamlining the Collection Process for FSMA Reinspection and Recall Fees

The Food Safety Modernization Act (FSMA) authorized FDA to collect fees to cover reinspection-related costs from domestic facilities, foreign facilities, and importers subject to reinspection for non-compliance related to a food safety requirement, and from a domestic facility and an importer who does not comply with a recall order. To date, FDA has not collected fees, in part due to the complexity of structuring a fee program in alignment with the statute. FDA is proposing to amend section 743 of the FD&C Act (21 U.S.C. 379j-31) to revise the Agency's reinspection and recall fee authority to allow the Agency to collect a fixed fee from the responsible party for each domestic facility, the U.S. agent for each foreign facility, and each importer subject to a reinspection to cover the estimated cost of conducting a reinspection for such facilities and importers and to collect a fixed fee from the responsible party for each domestic facility and importer who does not comply with a recall order issued under section 423 or 412(f) of the FD&C Act (21 U.S.C. 350l, 350a(f)) to cover the estimated cost of food recall activities associated with a recall order for such facilities and importers. FDA is also proposing to amend the definition of 'reinspection' to provide more clarity to industry. The proposed amendments would also provide flexibility for FDA to set and collect a reduced fee for small businesses. Streamlining the collection of reinspection and recall fees would strengthen the ability of FDA to collect these fees and enable the Agency to target resources currently being used for reinspection to other high-priority activities, such as securing the safety of the food supply.

Require Public Health Data Reporting Authority to Utilize Postmarket Health Information

While FDA can request public health data, including to request that IIS (immunization information systems), health plans, or healthcare providers voluntarily provide Protected Health Information (PHI), however, because we are operating under a voluntary system, we face significant delays or may never receive the data we request. Further, in some cases where we have sought information under this voluntary system, state or local entities have asserted that state laws prevent the state or local entities from sharing data or do not permit sharing patient-level data and only permit sharing aggregate data. FDA is seeking to amend the Public Health Service (PHS) Act to provide FDA with additional authority to require certain public health data reporting to more effectively utilize postmarketing health information to support medical product postmarketing safety and effectiveness monitoring, including preventive vaccines and therapeutic products. It would also help the Agency to more promptly identify adverse event patterns and trends associated with the use of vaccines or other medical products (e.g., medical countermeasures (MCMs)), and more swiftly communicate with health care providers and patients about safety signals. In addition, this authority could potentially help FDA more quickly obtain death investigation reports with autopsy and post-mortem toxicology results in overdose cases of opioids and other substances involved in the opioid public health emergency.

Enhance Postmarket Safety of Animal Drugs

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. Unlike for human drugs, FDA does not currently have these authorities for animal drugs. Additionally, these authorities would address the situation where multiple sponsors are marketing an animal drug or class of drugs with similar safety risks. In such cases, FDA has found the current process for negotiating changes in labeling or ensuring implementation of other voluntary, post-approval actions to mitigate risks to be lengthy and to create an uneven playing field as sponsors of similar drugs agree to different post-approval actions on different timelines, resulting in inconsistent practices and labeling information.

ADDRESSING MEDICAL PRODUCT SHORTAGES AND SUPPLY RESILIENCY

Lengthen Expiration Dates to Mitigate Critical Drug Shortages

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 a manufacturer 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 a manufacturer fails to comply.

Expand FDA's Mandatory Recall Authority to Cover All Human and Animal Drugs

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 in certain circumstances. 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. Currently, 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.

Require Drug Manufacturers to Notify FDA of an Increase in Demand

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 without meaningful shortfall or delay. 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 due to manufacturing interruptions). 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 occurred during the COVID-19 public health emergency for certain drugs needed to treat hospitalized patients.

Enhanced Drug Manufacturing Amount Reporting Information

FDA is seeking to enhance the manufacturing amount information required to be reported under section 510(j)(3) of the FD&C Act by adding an express requirement that registrants provide data identifying the suppliers they relied on to manufacture a listed drug and the extent of such reliance. Section 510(j)(3),

which was added by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), requires drug manufacturers registered under section 510 of the 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. Notably, the information required to be submitted under section 510(j)(3) of the FD&C Act is insufficient to help FDA understand the extent of registrant reliance on suppliers used in the registrant's manufacture of its listed drugs. 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 in this respect provided to FDA under section 510(j)(3) and, for application products, in the approved applications.

Remove the Temporal Limitation on FDA's Medical Device Shortages Authorities and Require Manufacturers to Maintain and Share Risk Management Plans

Under the CARES Act, FDA received new authority relating to device shortages codified in section 506J of the FD&C Act. By the end of the COVID-19 public health emergency (PHE), FDA received 477 potential and actual shortage signals, which translates to hundreds of thousands of device units that have been or could have been in shortage. We used the information we collected under these new authorities to help mitigate approximately 359 of the 477 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 PHE. However, shortages of critical medical devices have persisted even after the COVID-19 PHE ended. 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 PREVENT Pandemics Act 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 build resiliency and mitigate future supply chain disruptions.

Require Labeling to Include the Original Manufacturer and Supply Chain Information

FDA is proposing to amend 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 is proposing to amend 502 to deem finished drug products misbranded if the original manufacturer isn't included on the finished drug product label, and if certain additional supply chain information is not included in the broader finished drug product labeling. Finally, FDA is proposing to amend section 502 to require that the label for certain excipients designated as high-risk by the Secretary identify the name and address of the excipient's original manufacturer. 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 or finished drug product that is found to be adulterated or misbranded and take appropriate action to address poor quality products from circulation. Requiring the same transparency for high-risk excipients would allow FDA to ensure adequate oversight to help prevent contaminated products from entering the U.S. drug supply.

Prevent Animal Drug Diversion and Misuse

Diversion and misuse of animal drugs has led to increasingly high-profile incidents where there is serious harm to humans, and which also threaten the availability of critical animal drugs (either directly by the diversion or misuse itself reducing inventory or indirectly due to stakeholders' reactions). FDA is aware of a wide range of diversion and misuse of animal drugs including: APIs or finished products; approved or unapproved animal drugs; OTC (e.g., ivermectin) or prescription animal drugs (e.g., xylazine); and animal drugs that are at risk of diversion while in the supply chain (e.g., xylazine API) or animal drugs that are primarily misused after legal retail sale (e.g., ivermectin). The human drug supply chain authorities (e.g., the Drug Supply Chain Security Act) do *not* cover animal drugs and are not adaptable to solve this problem because they are designed primarily to address a different problem, in this instance counterfeit human drugs, rather than diversion/misuse of legitimate animal drugs by humans. FDA seeks new authority under the FD&C Act to prevent the diversion and/or misuse of animal drugs (including those containing xylazine) by humans to decrease the potential for harm to humans by these animal drugs while protecting the legitimate veterinary drug supply. This proposal will achieve certain parts of the Fentanyl Adulterated or Associated with Xylazine Response Plan that are under FDA's jurisdiction.

Prevent Food Shortages, Including Critical Foods

FDA is seeking authority to clarify that we can impose additional conditions on notifications submitted by manufacturers of critical foods when there is a permanent discontinuance or interruption in manufacture that is likely to lead to a meaningful disruption in the U.S. supply, including requirements to submit specific information as part of the notification. Critical foods are of public health importance, as they often are the sole or substantial source of nutrition for those who consume them, and this new authority will provide FDA with additional tools to help mitigate and prevent future shortages. Additionally, FDA is seeking new authority to designate additional categories of foods for which notification of anticipated interruptions in the supply chain is appropriate during a declared public health emergency. The COVID-19 pandemic 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. Such information would help FDA better ensure the continuity of the food supply and avoid shortages of nutritionally important food products.

Modernize the Tobacco User Fees Framework to Apply to All Regulated Tobacco Products

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) 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, as well as the total amount of tobacco user fees FDA must assess and collect each year. For the first ten years of the FDA tobacco program, the total amount of user fee collections increased each year; however, beginning in FY2019, the authorized amount of $712 million is fixed for each subsequent fiscal year and is not indexed to inflation. Moreover, because electronic nicotine delivery systems (ENDS) were a relatively new product category when the Tobacco Control Act was enacted to give FDA authority to regulate tobacco products in 2009, the authorized funding 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 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 enforcement and compliance efforts and divert funds from efforts related to smoked and smokeless tobacco products. This proposal is seeking 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 $114 million; and index all future collections to inflation.

Request Improved Hiring Authority for FDA's Center for Tobacco Products

FDA is seeking to extend the agile hiring authorities and salary flexibility of the 21st Century Cures Act for the Center for Tobacco Products (CTP) to improve its ability to recruit, hire, and retain personnel with the needed skills to effectively meet its public health mandate. FDA estimates that at least an additional 400 staff members, mostly in scientific and compliance and enforcement positions, are needed to fully complete its tobacco program mission. CTP believes that securing the Cures Act authorities would permit CTP to competitively compensate and retain experienced scientists and other personnel to avoid delays or impact to mission critical activities.

MODERNIZING FOODS AUTHORITY

Modernize Regulation of Critical Foods and Other Foods Marketed for Consumption by Infants and Young Children

A modern regulatory framework is critical for FDA to help ensure the safety of foods consumed by vulnerable populations. Under current law, FDA has limited tools to effectively regulate foods marketed for consumption by infants and young children. FDA is seeking new authority to establish binding contamination limits in foods, including those consumed by infants and young children, via an administrative order process. This new authority would provide a faster way to set binding limits and update limits as new scientific information becomes available. Additionally, FDA is seeking to amend the FD&C Act to grant authority to: (1) require industry to conduct testing of final products, including those marketed for consumption by infants and young children, for contaminants and maintain such records of these testing results for FDA inspection; (2) remotely access records of these test results and to review these test results whenever necessary in a more streamlined fashion; and (3) require a mandatory recall when FDA determines through any means that there is a reasonable probability that an article of infant or toddler food (other than infant formula) bears or contains a contaminant that renders the product adulterated. This would help FDA better understand levels of contaminants in foods, allow FDA to monitor industry progress in reducing levels over time, and identify where FDA should devote more time and resources. FDA also seeks new authority to require industry to report all product positive test results for relevant pathogens in critical foods (i.e., infant formula or medical foods) and conduct more frequent environmental monitoring in their facilities to identify the presence of relevant pathogens on surfaces from which the risk of critical food contamination is the greatest and maintain the results of such testing for FDA inspection, either in person or remotely. The combination of these new authorities would empower FDA to work with firms in real time to resolve issues around product positive findings and better ensure the safety of critical foods entering the market.

Modernize the Dietary Supplement Health and Education Act (DSHEA)

Since the Dietary Supplement Health and Education Act of 1994 (DSHEA) was enacted 30 years ago, the dietary supplement market in the U.S. has grown from approximately 4,000 products to well over 100,000 products. FDA is seeking to modernize DSHEA to provide for a more 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, including by providing the 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.

OTHER

Provide Medical Assistance and Evacuation Insurance for the Department of Health and Human Services (HHS) Employees

Existing HHS authorities do not permit HHS or FDA to purchase medical assistance and evacuation insurance coverage for full-time federal, uniformed, and intermittent HHS or FDA employees on official government foreign travel. As a result, travel-related medical assistance insurance when needed in an emergency is considered a personal expense and must therefore be borne by the employee. Absent this coverage, the employee must cover the costs of medical emergencies when on official travel overseas – which can be substantial. Factors such as the employee covering unforeseen foreign medical expenses and foreign travel insurance affect morale and affect an employee's willingness to conduct foreign travel to support mission requirements. In addition, these factors may also deter outside candidates from joining the Federal Government. Specifically, as it relates to HHS/FDA, we are seeking this authority to permit the purchase of medical assistance and evacuation insurance coverage for FDA employees on official government foreign travel. The ability to provide medical assistance and evacuation insurance for FDA's employees, especially those investigators conducting foreign inspections on multiple week trips on multiple occasions during a calendar year, will better support employees by providing points of contact for medical emergencies, ensuring that the employee receives appropriate medical care, and ensuring that expenses are paid when needed in a timely fashion. For example, at FDA, during the decade leading up to the COVID-19 pandemic, foreign inspections almost quadrupled (from 1,102 in FY 2010 to 3,766 in FY 2019). More specifically, in FY 2019, there were 1,189 foreign trips by employees from FDA's Office of Regulatory Affairs (ORA) with most of these inspectors going overseas approximately once or twice a year for 3-4 weeks. In addition, this insurance can serve as a retention tool for staff fulfilling mission requirements and act as a recruitment tool for those conducting foreign healthcare missions.

Change in Agency Regulatory Oversight Responsibility for Certain New Animal Drug Products

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 ° 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.