

The FY 2023 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 (including infant formula); 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 medical device manufacturers to address cybersecurity issues, ensure that confirmatory studies under the accelerated approval pathway progress in a timely manner, and encourage timely marketing of first generics that leads to cost savings. Finally, the Budget would provide FDA with additional authorities to increase oversight of cosmetics, dietary supplements, and to modernize the tobacco user fee framework to allow for a fair distribution of tobacco user fee assessments to all regulated tobacco products.

Legislative Proposals

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

In practice, 180-day patent challenge exclusivity is not operating as expected to encourage early generic entry, because this exclusivity is often “parked” by first applicants who either receive approval but do not begin marketing for extended periods of time following approval, or by first applicants who delay receiving final approval of their ANDAs for extended periods of time. This 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). FDA is proposing to amend sections 505(j)(5)(B)(iv) and (D)(i)-(iii) of the FD&C Act, which govern the 180-day patent challenge exclusivity provisions, to specify that FDA can approve subsequent applications unless a first applicant begins commercial marketing of the drug, at which point approval of subsequent applications would be blocked by 180 days, ensuring that the exclusivity actually 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.

Ensuring Feasibility and Timeliness of Confirmatory Studies and Enhancing Withdrawal Procedures for Prescription Drugs Approved through Accelerated Approval

The FD&C Act does not provide FDA with easily implementable legal authorities to help target the problem of accelerated approval confirmatory studies that progress too slowly. A statutory provision would help provide greater assurance at the time of a drug product’s accelerated approval that the confirmatory study will progress in a timely manner, and reap high-quality, interpretable results.

Enhancing the timeliness and quality of confirmatory studies will help support FDA's regulatory decision-making for drugs approved through the accelerated approval pathway and minimize the time that a product is marketed based on accelerated approval before its clinical benefit can be confirmed. To this end, FDA is seeking to amend the accelerated approval provisions of the FD&C Act to 1) revise section 506(c)(2)(A) of the FD&C Act such that FDA may require, as a condition of a drug product application's acceptance for filing, or as a condition of a drug product's receipt of accelerated approval, that a drug sponsor must first demonstrate that a proposed post-approval (i.e., confirmatory) study is adequately designed to verify and describe clinical benefit and can be completed in a timely manner; and 2) revise section 506(c)(3) so that FDA can follow its dispute resolution procedures for drug applications when withdrawing a drug product's accelerated approval. FDA is also proposing a technical fix to 3) revise the withdrawal standard at FD&C Act 506(c)(3)(C) so that it mirrors the analogous withdrawal standard set forth in section 505(e) for drugs with traditional approvals.

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

FDA is requesting to revise 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) that has been refused 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 U.S. 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.

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

FDA's authority to conduct remote regulatory assessments is limited to requests for records and other information in advance or in lieu of drug 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 medical device, food, tobacco product, and cosmetic establishments, and to clarify applicability for biomedical research monitoring (BIMO) inspections. 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.

Medical Device Cybersecurity

Currently there is no statutory requirement (pre- or post-market) that expressly requires medical device manufacturers to address cybersecurity, yet cybersecurity incidents put patients at great risk, and also have the potential to cause supply chain disruptions that can cripple our health care system. This proposal would advance medical device safety by explicitly requiring that medical device manufacturers design cybersecurity into their devices and by ensuring that FDA and the public have certain information about device cybersecurity. Specifically, FDA seeks to have express authority to require: that premarket submissions to FDA include evidence demonstrating reasonable assurance of the device's safety and effectiveness for purposes of cybersecurity; that marketed devices demonstrate a reasonable assurance of the device's safety and effectiveness for purposes of cybersecurity; that devices have the capability to be updated and patched in a timely manner; that manufacturers provide a device Software Bill of Materials (SBOM) with their devices so users know which components of their devices are or may be subject to cyber threats; and that device manufacturers publicly disclose when they learn of a cybersecurity vulnerability so users know when a device may be vulnerable, and to provide direction to users to reduce their risk. These authorities are critical, as FDA has already seen and responded to several ransomware and other malware incidents within the health care sector. Stronger cybersecurity protections are necessary to ensure we remain prepared to protect patients and our health care workers on the front lines. Enacting FDA's proposal would reduce the likelihood of harm to patients, interrupted access to devices, and loss of market share or market withdrawal for devices for which a vulnerability is identified as a result of cybersecurity incidents.

Medical Device Shortages

The COVID-19 pandemic demonstrated that by the time there is an emergency, it is often too late to prevent or mitigate shortages. Under the CARES Act, FDA received device shortages authority during or in advance of a public health emergency (PHE). While the new authority has been helpful, the tie to public health emergencies limits FDA's ability to respond to any early signs of supply constraints or a potential shortage situation. Supply chain disruptions were already beginning to occur even before COVID-19 cases were identified in the U.S., as other nations had outbreaks and needed personal protective equipment (PPE), testing supplies, and other equipment in excess of supply. Moreover, there are situations, such as product recalls and natural disasters, that may not rise to the level of a PHE, but for which device shortages could significantly impact patient care. To assure a more resilient domestic supply chain and help reduce dependence on foreign production, FDA needs additional authorities including (but not limited to): specifying that notifications should be made to FDA any time there is the potential for a shortage and should include production volume

information; providing fuller oversight of supply chain disruptions, including requiring manufacturers to perform risk assessments, implement risk management plans, and identify alternate suppliers and manufacturing sites; permitting FDA to allow temporary importation of unapproved devices, with appropriate scientific and regulatory controls, when in the interest of the public health; clarifying which entities should notify FDA; and authorizing FDA to allow devices to be distributed past their labeled shelf life, with appropriate, supportive scientific data, when needed to prevent or mitigate a shortage.

Modernizing the Dietary Supplement Health and Education Act

In the more than 25 years since the Dietary Supplement Health and Education Act of 1994 (DSHEA) was enacted, the dietary supplement market in the U.S. has grown from approximately 4,000 products to somewhere between 50,000 and 80,000 products. FDA is seeking to modernize DSHEA to strengthen FDA's implementation and enforcement of DSHEA and clarify FDA's authorities relating to products marketed as "dietary supplements." Specifically, FDA is seeking to amend DSHEA to: (1) require annual listing with FDA of individual dietary supplement products, including basic information about each unique product; and (2) clarify FDA's authorities over products marketed as dietary supplements to facilitate enforcement against unlawfully marketed products. These amendments would allow FDA to know when new products are introduced, quickly identify dangerous or illegal products on the market, and take appropriate action to protect consumers when necessary.

Update Legislative Authorities and Authorize Registration Fees for Cosmetics

FDA's regulatory authority for cosmetics dates to the 1938 FD&C Act, which gives FDA very limited post-market authority over cosmetic safety. FDA is seeking to update legislative authorities to modernize and enhance the FDA Cosmetic Safety Program. Specifically, FDA proposes that legislation be enacted to: (1) require domestic and foreign cosmetic firms to register their establishments and list their products with FDA; (2) require domestic and foreign cosmetic firms to report serious and frequently occurring adverse events to FDA; (3) provide explicit authority for FDA to promulgate Good Manufacturing Practices regulations; (4) require domestic and foreign cosmetic firms to allow FDA access to records (including consumer complaints and safety data) during a routine or for-cause inspection; (5) provide FDA mandatory recall authority for cosmetics that pose serious risk to the public health; (6) provide explicit authority for requiring listing of known cosmetic allergens in the ingredient list on the product label; and (7) authorize FDA to collect registration fees from the cosmetic industry to provide increased resources for FDA's Cosmetic Safety Program. This new authority would significantly strengthen FDA's post-market surveillance systems and better protect the public health by helping to ensure the safety of cosmetic products and ingredients that are in use in the United States.

Enhancing FDA's Authority to Better Protect Infants and Young Children

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

Under current law, industry is not required to test ingredients or final products marketed for consumption by infants and young children to help assess levels of toxic elements in such foods or to measure progress reducing exposure to the lowest possible levels. 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.

Modernizing of Tobacco User Fees Framework

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 include tobacco in 2009, the budgets established by Congress under Section 919 could not have taken into account the resources required for the regulation of ENDS, which are currently 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 reallocate a significant portion of the \$712 million in user fees it collects annually from the existing six product classes to properly regulate deemed products, especially ENDS. 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 all products subject to Chapter 9 of the FD&C Act, promoting a fair distribution of tobacco user fee assessments to all regulated tobacco products; increase the current limitation on total tobacco user fee collections by \$100 million; and index all future collections to inflation.

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 must be discarded because they exceed a labeled shelf-life due to unnecessarily short expiration dates. This proposal would expand FDA's authority to require, when likely to help prevent or mitigate a shortage, that an applicant evaluate, submit studies to FDA, and label a product with the longest possible expiration date (shelf-life) that FDA agrees is scientifically justified. The proposal also seeks authority for FDA to levy a civil money penalty if an applicant fails to comply.

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 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.

Preventing Food Shortages, Including Infant Formula and Certain Medical Foods

No law requires manufacturers of infant formulas or essential medical foods to notify FDA when they become aware of a circumstance that could lead to a shortage of these products. FDA is seeking authority to require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods for patients with certain inborn errors of metabolism (e.g., phenylketonuria, medium chain acyl-coenzyme A dehydrogenase deficiency). This proposal would ensure FDA routinely receives timely and accurate information about likely or confirmed shortages in the U.S. of infant formulas and essential medical foods for patients with certain inborn errors of metabolism to help FDA to take steps to promote the continued availability of these foods. Additionally, FDA is seeking authority to require firms to provide shortage notification for other FDA-designated categories of food during a declared public health emergency. The recent COVID-19 pandemic has demonstrated the need 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.