TITLE VI

RELATED AGENCY AND FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

The Food and Drug Administration [FDA] is a scientific regulatory agency whose mission is to promote and protect the public health and safety of Americans. FDA's work is a blend of science and law. The Food and Drug Administration Amendments Act of 2007 (Public Law 110–85) reaffirmed the responsibilities of the FDA: to ensure safe and effective products reach the market in a timely way and to monitor products for continued safety while they are in use. In addition, the FDA is entrusted with two critical functions in the Nation's war on terrorism: preventing willful contamination of all regulated products, including food; and improving the availability of medications to prevent or treat injuries caused by biological, chemical, radiological, or nuclear agents.

The FDA Foods program has the primary responsibility for assuring that the food supply, quality of foods, food ingredients, and dietary supplements are safe, sanitary, nutritious, wholesome, and honestly labeled and that cosmetic products are safe and properly labeled. The variety and complexity of the food supply has grown dramatically while new and more complex safety issues, such as emerging microbial pathogens, natural toxins, and technological innovations in production and processing, have developed. This program plays a major role in keeping the U.S. food supply among the safest in the world.

In January 2011, the Food Safety Modernization Act [FSMA] (Public Law 111–353) was signed into law. This law enables the FDA to better protect public health by strengthening the food safety system. It enables the FDA to focus more on preventing food safety and feed problems rather than relying primarily on reacting to problems after they occur. The law also provides the FDA with new enforcement authorities designed to achieve higher rates of compliance with prevention- and risk-based food and feed safety standards and to better respond to and contain problems when they do occur. The law also gives the FDA important new tools to hold imported food and feed to the same standards as domestic food and feed and directs the FDA to build an integrated national food safety system in partnership with State and local authorities.

The FDA Drugs programs are comprised of four separate areas: Human Drugs, Animal Drugs, Medical Devices, and Biologics. The FDA is responsible for the lifecycle of products, including premarket review and post-market surveillance of human and animal drugs, medical devices, and biological products to ensure their safety and effectiveness. For Human Drugs, this includes assuring that

all drug products used for the prevention, diagnosis, and treatment of disease are safe and effective. Additional procedures include reviewing and evaluating investigational new drug applications; evaluation of market applications for new and generic drugs and labeling and composition of prescription and over-the-counter drugs; monitoring the quality and safety of products manufactured in, or imported into, the United States; and regulating the advertising and promotion of prescription drugs. The Animal Drugs and Feeds program ensures only safe and effective veterinary drugs, intended for the treatment and/or prevention of diseases in animals and the improved production of food-producing animals, are approved for marketing.

The FDA Biologics program assures that blood and blood products, blood test kits, vaccines, and therapeutics are pure, potent, safe, effective, and properly labeled. The program inspects blood banks and blood processors; licenses and inspects firms collecting human source plasma; evaluates and licenses biologics manufacturing firms and products; lot releases licensed products; and monitors adverse events associated with vaccine immunization, blood products, and other biologics.

The FDA Devices and Radiological program ensures the safety and effectiveness of medical devices and eliminates unnecessary human exposure to man-made radiation from medical, occupational, and consumer products. In addition, the program enforces quality standards under the Mammography Quality Standards Act (Public Law 108–365). Medical devices include thousands of products from thermometers and contact lenses to heart pacemakers, hearing aids, and MRIs. Radiological products include items such as microwave ovens and video display terminals.

The FDA's National Center for Toxicological Research [NCTR] in Jefferson, Arkansas, serves as a specialized resource, conducting peer-review scientific research that provides the basis for the FDA to make sound, science-based regulatory decisions through its premarket review and post-market surveillance. The research is designed to define and understand the biological mechanisms of action underlying the toxicity of products and lead to developing methods to improve assessment of human exposure, susceptibility, and risk of those products regulated by the FDA.

In 2009, Congress granted the FDA new authority to regulate the manufacture, distribution, and marketing of tobacco products. The FDA exercises this responsibility by protecting the public health from the health effects of tobacco, setting scientific standards and standards for tobacco product review, conducting compliance activities to enforce its authority over tobacco, and conducting public education and outreach about the health effects of tobacco products.

SALARIES AND EXPENSES

(INCLUDING TRANSFERS OF FUNDS)

[In thousands of dollars]

	Appropriation	User fees	Total
Appropriations, 2023	3,530,150	3,032,643	6,562,793
Budget estimate, 2024	3,896,028	3,074,880	6,970,908

[In thousands of dollars]

	Appropriation	User fees	Total
Committee recommendation	3,550,150	3,074,880	6,625,030

COMMITTEE RECOMMENDATIONS

The Committee recommends an appropriation of $3,550,150,000 for salaries and expenses of the Food and Drug Administration.

The Committee also recommends $3,074,880,000 in definite user fees, including: $1,336,525,000 in Prescription Drug user fee collections; $331,273,000 in Medical Device user fee collections; $33,500,000 in Animal Drug user fee collections; $25,000,000 in Animal Generic Drug user fee collections; $712,000,000 in Tobacco Product user fee collections; $594,150,000 in Generic Drug user fee collections; and $42,432,000 in Biosimilar user fee collections. The Committee recommendation does not include permanent, indefinite user fees for the Mammography Quality Standards Act; Color Certification; Export Certification; Priority Review Vouchers Pediatric Disease; Food and Feed Recall; Food Reinspection; Voluntary Qualified Importer Program; the Third Party Auditor Program; Outsourcing Facility; or Over-the-Counter Monograph. The Committee includes bill language that prohibits the FDA from developing, establishing, or operating any program of user fees authorized by 31 U.S.C. 9701. The Committee recommendation does not include proposed user fees requested in the President's budget for food facility registration and inspection, food import, food contact substance notification, cosmetics, and international courier imports. None of these user fee proposals have been authorized by Congress. The Committee will continue to monitor any action by the appropriate authorizing Committees regarding these proposed user fees.

The Committee expects the FDA to continue all projects, activities, laboratories, and programs as included in fiscal year 2023 unless otherwise specified. The Committee provides a net increase of $7,000,000 for Cosmetics, $3,750,000 for Food Safety activities, $3,750,000 for Drug Device Shortages and Supply Chain, $3,000,000 for Neuroscience, and $2,500,000 for ALS.

The following table reflects the Committee's recommendations, as compared to the fiscal year 2023 and budget request levels:

FOOD AND DRUG ADMINISTRATION SALARIES AND EXPENSES

[In thousands of dollars]

	Fiscal year 2023 enacted	Fiscal year 2024 budget request	Committee recommendation
Centers and related field activities:.			
Foods	1,196,097	1,348,852	1,198,263
Center for Food Safety and Applied Nutrition [CFSAN]	401,867	508,623	416,242
Field Activities	794,230	840,229	782,021
Human Drugs	760,494	775,446	720,963
Center for Drug Evaluation and Research [CDER]	551,493	560,040	515,745
Field Activities	209,001	215,406	205,218
Biologics	271,515	277,570	266,015
Center for Biologics Evaluation and Research [CBER]	223,465	228,128	218,886
Field Activities	48,050	49,442	47,129
Animal Drugs	230,093	257,689	231,378
Center for Veterinary Medicine [CVM]	148,141	172,423	150,532
Field Activities	81,952	85,266	80,846

FOOD AND DRUG ADMINISTRATION SALARIES AND EXPENSES—Continued

[In thousands of dollars]

	Fiscal year 2023 enacted	Fiscal year 2024 budget request	Committee recommendation
Medical and Radiological Devices	449,297	477,990	447,604
Center for Devices and Radiological Health	356,062	380,952	355,738
Field Activities	93,235	97,038	91,866
National Center for Toxicological Research	76,919	80,154	77,388
Other Activities	224,940	301,264	237,126
Rent and related activities	154,509	220,377	207,377
Rental payments to GSA	166,286	156,686	166,286
Total, FDA salaries and expenses, new budget authority	3,530,150	3,896,028	3,550,150

Acetaminophen.—The Committee continues to be concerned that labeling for over-the-counter [OTC] single-ingredient acetaminophen does not contain weight-based dosing instructions for children ages 6 months to 2 years despite the recommendations of the FDA Nonprescription Drugs Advisory Committee [NDAC] and Pediatric Advisory Committee in 2011 that data supported this information being added to the label. The Committee is concerned that the lack of dosing information for this vulnerable population may lead to dosing errors, adverse events, and inadequate treatment of fever and pain. While the Committee is encouraged that FDA has included this important issue among its annual forecast of planned monograph activities, this list is nonbinding and the issue remains pending after multiple decades despite its importance for public health. As such, the Committee directs FDA to provide to the Committee an update no later than 30 days after the enactment of this act on the timing of amending the monograph label for acetaminophen to include weight-based dosing instructions for children ages 6 months to 2 years.

Alzheimer's Disease.—There are more than 6 million Americans aged 65 and over living with dementia due to Alzheimer's disease, and that number is predicted to double by 2050. FDA has approved Alzheimer's therapies through the accelerated approval pathway that could benefit a subset of these patients living with early Alzheimer's disease, adhering to the same standards for establishing safety and efficacy as medicines receiving a traditional FDA approval. The Consolidated Appropriations Act, 2022 (Public Law 117–103) explanatory statement noted the contributions of the accelerated approval pathway in expediting access to critical therapies for patients with cancer and certain rare diseases and encouraged FDA to clarify the use of the pathway to ensure it remains available for these patients and also encourage its use for other serious conditions that are unmet medical needs. Further, Congress gave FDA the authority to ensure that the accelerated approval pathway continues to ensure early access to safe and effective new therapies for individuals with serious or life-threatening illnesses. The Committee supports FDA's authority to approve therapies under the accelerated approval pathway based on surrogate endpoints or intermediate clinical endpoints and remains concerned about other HHS agencies discouraging the use of the pathway and thus patient access, particularly related to Alzheimer's disease therapies.

ALS.—The Committee recognizes the FDA's Orphan Drug Program is one of the few agencies in the Federal Government that funds phase 1 and phase 2 clinical trials for new ALS therapies. In addition, FDA-sponsored research can expedite ALS drug development through innovative trial designs that can speed the FDA regulatory processes for new ALS treatments. The Committee provides an increase of $2,500,000 to implement the Accelerating Access to Critical Therapies for ALS Act (Public Law 117–79), including implementation of the act for ALS Action Plan, operation of the Public Private Partnership, and supporting the FDA Rare Neurodegenerative Disease Grant Program which is authorized to provide grants for clinical trials for ALS and other neurodegenerative diseases. Funding for this program will further scientific knowledge to inform product development to allow more ALS patients to participate in the clinical testing process and have access to experimental therapies.

Animal Biotechnology.—The Committee encourages the FDA to expand upon its flexibility in regulation of the DNA of animals containing gene edits that could have occurred naturally or resulted from conventional breeding as animal drugs. The Committee directs FDA to consider how it can use its authorities in a flexible manner to these innovations and to continue consulting with the Secretary of Agriculture to ensure FDA's regulation is coordinated with USDA's approach to these technologies.

Animal Food Ingredients.—Animal food ingredients are subject to review and approval by the Center for Veterinary Medicine before they can enter the interstate marketplace to be sold for consumption by either livestock or pets. The Committee is concerned about the time associated with the ingredient review and approval process. To address these concerns, the Committee directs the Center for Veterinary Medicine to improve animal food ingredient reviews to enable innovation and address challenges and opportunities in the animal food industry.

Animal Product Terminology.—The Committee is concerned about the increase of products, which do not include meat or egg products, that are labeled and marketed using animal food product terminology and related iconography. The Committee directs the FDA to conduct a study to better understand consumers' attitudes, beliefs, motivations, and perceptions relative to product composition, health attributes, and labeling. The FDA shall assess consumer perceptions of different terms used on labeling of plant-based alternative products. No later than 1 year after the date of enactment of this act, FDA shall submit to the Committee, and make publicly available online, a report on the findings of this study.

Animal Testing for Cosmetics.—The Committee acknowledges the FDA's increased authority to regulate the safety substantiation of cosmetic products under Public Law 117–328 in the Modernization of Cosmetics Regulation Act of 2022. The Committee reiterates the sense of Congress that animal testing should not be used for the purposes of safety testing on cosmetic products and should be phased out. The Committee is encouraged by progress made to replace cosmetic animal testing with modern nonanimal approaches, and understand that many companies already substantiate cos-

metic safety without the use of animals. The Committee urges the FDA to continue supporting the development and testing of cosmetic products without the use of animal testing.

Antimicrobial Research.—The Committee maintains fiscal year 2023 levels for biofilms and the regulatory science of biofilms associated with FDA work on medical devices, drug delivery, and public health. The funding increase will help the FDA meet its objectives to reduce healthcare associated infections as described in the FDA CDRH Regulatory Science Priorities report, and support the domestic manufacture and use of medical devices, drugs, and biological products.

Autoantibody Qualification.—The appearance of certain islet autoantibodies in the serum of individuals increases the chance of developing type 1 diabetes at some point in the future. Therefore, the Committee encourages the FDA to continue working with the Type 1 diabetes community on the assessment of potential diabetes biomarkers related to islet autoimmunity, which might help inform the design of clinical studies.

Botanical Dietary Supplements.—The Committee encourages the FDA to further invest in the science base for regulatory decisions on botanical dietary supplements. Expanding outreach and broadening safety evaluations of botanical supplements will help further that work. Studies of the interactions between botanical supplements and prescription drugs would help further patient safety and help inform the FDA's scientific review of botanical dietary supplements.

Botanical Drugs and Drug Interactions.—The Committee encourages FDA to further invest in research to identify potential drug interactions with botanical drugs.

Cell Cultured Products.—The Committee is aware that FDA has completed its first pre-market consultation for a human food made from cultured animal cells, the first such action completed under the Formal Agreement Between the U.S. Department of Health and Human Services Food and Drug Administration and the U.S. Department of Agriculture Office of Food Safety (the "Formal Agreement") announced on March 7, 2019. The Committee is interested in the internal FDA protocols related to pre-market consultations for cell-cultured protein products, and specifically whether or not there are special or unique considerations made for these products in pre-market consultation processes under the Formal Agreement. The Commissioner is therefore directed to submit a report no later than 60 days following the enactment of this act to the Committee outlining the pre-market consultation process for cell-cultured protein products, noting any special accommodations made to comply with the Formal Agreement, and any Agency plans to coordinate with its counterparts at the Department of Agriculture on further action regarding the same products.

Cellular Immunity.—The Committee encourages FDA to better understand how the cellular components of the immune response contribute to the effectiveness, and duration of effectiveness, of vaccines, boosters, and therapeutics for COVID–19 and other diseases. FDA is encouraged to support collaborative research with NIH, universities, and industry comprehensively evaluate the immune response of clinical trial participants. FDA is further encouraged,

when relevant, the collection of cellular immunity data, in addition to serology data, in its evaluation of such medical products. FDA is directed to report on collaborative research within 1 year of the enactment of this act.

Center for Food Safety and Applied Nutrition Centers of Excellence.—The Committee is aware of the important contribution of the FDA CFSAN Centers of Excellence [COEs] program in supporting critical basic research as well as facilitating FSMA implementation. The Committee encourages the agency to continue to fully utilize the COEs to accomplish these goals and instructs that it enhance its level of support for FDA FSMA activities.

Center for Food Safety and Applied Nutrition [CFSAN] Petitions.—The Committee is concerned about CFSAN's delays in evaluating State and local petitions for exemption from preemption by the Federal Food, Drug, and Cosmetic Act's nutrition and menu labeling standards. The Committee directs the FDA to report to the Committee no later than 30 days after enactment of this act on the number of pending exemption petitions before the FDA and the length of time these petitions have been pending. The Committee further directs the Agency to update the Committee on FDA's efforts to explore strategies to improve the preemption exemption petition process.

Clinical Trial Operations.—The Committee recognizes that the COVID–19 pandemic further increased the staffing shortages already present at clinical research sites, exacerbating longstanding challenges to the timely collection and efficient reporting of clinical trial data in cancer research. The burden of data collection, entry, and verification is high and rests primarily with site staff, who most often input data manually. Meanwhile, the data fields requested for developing a given drug class have become increasingly numerous and may be complex. The Committee urges the FDA to provide guidance to cancer trial sites, sponsors, and contractors that both defines necessary data elements and streamlines data entry and verification processes. Such guidance will be foundational in maximizing clinical trial efficiency through a targeted reduction of the administrative burden currently placed upon research staff.

Cloud.—The Committee notes the increased adoption of cloud-based technologies by FDA-regulated companies, and appreciates FDA's interest in accelerating use of modern systems to facilitate innovation and improve patient care. To further cloud adoption, the Committee encourages FDA to finalize guidance to medical product sponsors, including drug and medical device sponsors, on the use of cloud to meet and exceed regulatory requirements. The Committee further encourages FDA to continue to explore mechanisms to support cloud adoption, including looking at critical areas such as record-keeping, data integrity, and other regulatory requirements. The agency should ensure the collection of robust public input, including from regulated companies and cloud technology vendors.

Data Systems.—The Committee is aware of a recent review of FDA's Human Foods Program that found, among other issues, a significant need to modernize data systems at FDA. Specifically, the report recommended that "FDA should consider the feasibility,

resource requirements, and potential benefits of connecting existing IT systems or developing a single system to receive, track and process information and ensure timely notification of appropriate personnel of potential signals of significant public health threats." This ability is critical to address safety and supply chain issues associated with regulated high-risk products. Currently, tracebacks are time and labor intensive and frequently limited by inadequate and disparate records and comingling of product in distribution.

The Committee notes the increased adoption of cloud-based technologies by FDA-regulated companies, and appreciates FDA's interest in accelerating use of modern systems to facilitate innovation and improve patient care. To further cloud adoption, The Committee encourages the Center for Food Safety and Applied Nutrition to implement an end-to-end system of data management and analytics designed to work in any cloud environment. This system should provide food safety regulators across the human foods program the analytical tools to more proactively identify or prevent threats to regulated product safety and quality; provide capability for FDA to receive information via a digital chain of trust systems for high-risk products; and support public health response activities.

Developing Products to Treat Rare Diseases.—The Committee is aware of the increasing number of therapeutics in development for rare disease patients, but there still remain significant gaps with 95 percent of rare diseases not having a FDA-approved treatment. As such, the Committee recognizes the importance of the Orphan Products Grant Program which supports development of products to treat orphan or rare diseases including the programs to support clinical trials, natural history studies, and the new authority to fund grants addressing regulatory science challenges. The Committee provides no less than the fiscal year 2023 level to reflect the critical need to support this program and the documented economic burden of all rare diseases.

Device Remanufacturing Safety and Awareness.—The Committee recognizes that FDA has authority over remanufacturing of devices but is concerned that the agency needs to increase public awareness of the requirements applicable to device remanufacturing, consistent with the agency's mission to protect and promote public health. The Committee recognizes that the agency plans to publish a final guidance document on the remanufacturing of devices in fiscal year 2023. Within 30 of the issuance of the final guidance document, the Committee directs the agency to provide a briefing to the Committee on the guidance and the agency's plans to promote public awareness of the applicable requirements and related compliance.

Drug Approvals.—The Committee asserts that FDA's authority to approve medications should be based on sound science and devoid of political or economic considerations.

Drug and Device Shortages.—The Committee remains concerned about continued reports of supply shortages for critical medications and devices, especially cancer drug shortages, which continue to pose a significant challenge, affecting patient access to vital treatments. The Committee provides an additional $3,750,000 and directs the FDA to leverage all available authorities to proactively

address this crisis and ensure a consistent supply of essential medications and devices for patients in need.

Enforcement of Nicotine Vapor Products.—The Committee is concerned that vapor use amongst youth is largely being driven by products that are not authorized or under review by the FDA in accordance with FDA's 2020 guidance. While the Committee is aware of recent enforcement action, the Committee strongly encourages the FDA to prioritize enforcement, including providing a public listing of vapor products that have been under review since 2020 so that distributors and retailers are aware of products that may be sold until FDA renders a decision on those applications; updating FDA's guidance to align disposal vapor products with pod-based vapor products; steps to improve the FDA's ability to identify unauthorized products on the market; and pursue all legally authorized remedies to ensure that all products being sold unlawfully are removed from the marketplace. The Committee directs the FDA to report back to the Committee in writing on a quarterly basis the enforcement actions the Agency has undertaken; the status of its review of vapor pre-market applications; and other steps the Agency has taken to ensure compliance with products that have not applied for pre-market review.

Essential Medicines.—The Committee is concerned about Americans' access to essential medicines, as defined by the FDA's October 2020 essential medicines and medical countermeasures list. As the agency in charge of approving prescription drugs, reporting drug shortages, and protecting public health, the Committee directs the FDA to coordinate with the Department of Health and Human Services [HHS] and report on current domestic manufacturing of drugs on HHS's Critical Drug List and dependence on international supply chains. The review may account for non-viability of certain components domestically.

FDA Advisory Committee Conflicts of Interest.—The Committee remains concerned with the Food and Drug Administration's conflict of interest rules as it pertains to advisory committees. The 2023 External Review of FDA Regulation of Opioid Analgesics Final Report noted the need for the FDA to address "concerns about inappropriate industry influence on agency decision-making". Current conflict of interest guidance is intended to show FDA's policies behind financial interests held by advisory committee membership and Government employees participating in advisory committee meetings. They do not specifically address industry influence, impact of this guidance on participation in meetings, or enforcement ability of conflict of interest guidance.

For this reason, the Committee directs the Government Accountability Office, to issue a report within 90 days of enactment of this Act detailing: how the FDA reviews and enforces conflicts of interest among invited speakers and advisory committee members; how the FDA discloses conflicts of interest to advisory committees, including but not limited to participation in the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials [IMMPACT] meetings; current FDA conflict of interest rules and transparency associated with communicating these rules to meeting participants and the general public; how the FDA choses invited speakers to advisory committee meetings, including their de-

cisions on expertise on the issues being considered; impact of conflict of interest rules on the FDA's ability to invite subject matter experts to advisory committee meetings; the FDA's ability to enforce conflict of interest rules and guidance and adherence to these policies.

FDA Study on Opioid Prescribing.—The Committee remains concerned with the ongoing opioid abuse epidemic, and effort to provide treatment for those impacted. As such, the Committee directs the FDA to review current opioid prescribing practices, including the total number of opioids prescribed in a calendar year. The purpose of the study is to show the number of opioids prescribed, excluding opioids prescribed for treatment of pain related to cancer or cancer treatment, patients participating in hospice, or a patient with respect to whom the prescriber of the applicable opioid determines that other non-opioid pain management treatments are inadequate or inappropriate.

Food Labeling Accuracy.—The Committee supports evaluating whether artificial intelligence [AI] driven audit tools can effectively assess food labeling accuracy and facilitate greater Federal labeling compliance. CFSAN is responsible for assuring that foods sold in the United States are safe and properly labeled. The Committee believes that AI-driven tools will accelerate CFSAN's goal of ensuring the accuracy of food labeling consistent with the Agency's obligation under the Federal Food, Drug and Cosmetic Act and the Fair Packaging and Labeling Act to monitor and ensure that food labels are truthful and not misleading. The Committee directs CFSAN to report to the Committee by on the status of its evaluation.

Food Safety Modernization Act Outreach to Small Farmers.—The Committee expects FDA to adequately fund its programs to provide outreach, training, and technical assistance to educate small farmers on compliance with the FSMA Produce Safety Rule and rules for agricultural water. The Committee expects CFSAN to continue support for the cooperative agreement established for this purpose. The Committee encourages FDA to support critical outreach and training services to small farmers until the Produce Safety Rule is fully implemented, including enforcement and compliance of Subpart E (agricultural water) and Subpart F (biological soil amendments of animal origin) for farms and businesses of all sizes.

Field Based Prevention Strategies.—The Committee directs the FDA Center for Excellence to continue to dedicate funds as necessary to develop field-based prevention strategies for the fresh produce industry.

Foreign Approved Drugs.—The Committee supports efforts to increase the tools available to FDA to ensure the timely approval of lifesaving drugs and encourages FDA to examine opportunities to facilitate submission of marketing applications by manufacturers of drugs with marketing authorization in countries listed in 21 USC 382, Federal, Food, Drug, and Cosmetic Act section 802(b), but which are not approved in the United States.

FSMA Clarification for Small Farms.—The Committee directs FDA to continue working with small farms to clarify requirements for compliance with the Food Safety Modernization Act, including information on the qualified exemptions available to small and very small farms and the actions required to achieve compliance under

these exemptions. The Committee urges FDA to communicate (including through appropriate guidance), offer technical assistance, and provide other resources to assist small farms with complicance.

Healthy Rule.—The Committee directs FDA to consider all data and information submitted during the open public comment period before publishing rules or regulations for updating the implied nutrient content claim healthy.

Heavy Metals in Baby Food.—The Committee is concerned that lead, arsenic, cadmium and mercury are often present in dangers quantities in foods intended for consumption by infants and toddlers and encourages the FDA to coordinate with the Department of Agriculture to ensure that a wide variety of healthy nutritious foods remain available to participants of Federal nutrition programs.

Homeopathy.—The Committee understands the importance of homeopathic medicines for millions of users. Consumers access and safety to these products are best ensured by implementing a legal pathway that includes homeopathic specific standards for the regulation of these medicines. The Committee understands FDA is limited to enforcing pharmaceutical specific standards when taking enforcement action against products labeled as homeopathic. The FDA's interpretation of the law that all homeopathic medicines are unapproved new drugs that are illegally marketed has created confusion both for the homeopathic community and enforcement officials. The Committee directs the FDA to work with the homeopathic community with regards to the regulation of these medicines.

Imported Shrimp Safety and Inspection Pilot Program.—The Committee commends and supports FDA's ongoing efforts to implement and increase its oversight and the regulation of the safety of shrimp products imported into the United States. The Committee maintains the fiscal year 2023 funding levels to implement the program. FDA's report to Congress emphasized the importance of increased sampling of import shipments, investment in laboratory capabilities, data analytics, and the establishment of regulatory partnership arrangements with the top three countries exporting shrimp to the U.S. The Committee encourages FDA to continue the full development and implementation of the shrimp pilot program including finalizing the establishment of regulatory partnership arrangements.

Infant Formula.—The 2023 CAA provided the FDA with additional authorities and requirements to protect infants and improve the U.S. formula supply, including the development of a national strategy on infant formula; annual inspections of each infant formula manufacturer; monitoring of supply disruptions; and a study from the National Academies on challenges in supply, market competition, and regulation of infant formula in the U.S. The Committee directs the FDA to work expeditiously to implement the infant formula provisions of the 2023 CAA, and directs the FDA to brief the Committee on such efforts on a semi-annual basis.

Innovative Glass Packaging.—The Committee directs the FDA to work with glass packaging suppliers and pharmaceutical manufacturers to evaluate and promote streamlined approval requirements designed to expedite the adoption and use of innovative glass pack-

aging technologies with the capacity to improve product quality, reduce product recalls, reduce drug shortages, and protect public health. Such streamlined approval requirements should address stability testing and other relevant types of data to be submitted in support of product approval.

International Mail Facilities.—The Committee remains concerned about the opioid epidemic that has taken the lives of thousands of Americans and support the FDA's continued investments in International Mail Facilities and Ports of Entry to prevent illicit drugs, including unapproved and counterfeit pharmaceuticals, from entering the United States.

Islet Therapies.—The agreement encourages FDA to engage with the diabetes community on potential cures for Type 1 and Type 2 diabetes, including islet therapies. The Committee remains concerned about ongoing delays in research and development to potential cures for diabetes, including islet therapies, and encourages FDA to engage with stakeholders, including advocates, researchers and manufacturers, on advancing transformative diabetes treatments and cures.

Listeria.—The Committee recognizes that developing the Compliance Policy Guide [CPG] for Listeria monocytogenes in ready-to-eat foods is a complex process, and directs the FDA to work with stakeholders to ensure that the CPG outlines a policy that is reflective of the current scientific evidence and is practical to implement.

Lupus.—The Committee is aware of barriers that have long affected the development of therapeutics for lupus, a disease that primarily targets women. A chronic and complex autoimmune disease, lupus can affect the joints, skin, brain, lungs, kidneys, and blood vessels, causing widespread inflammation and tissue damage in the affected organ. The Committee is pleased that FDA participated in an externally-led patient-focused drug development meeting with the lupus community and identified some of these barriers and that potential treatments are now in clinical trials. The Committee urges FDA to expedite its ongoing work with the lupus community to develop solutions to identified barriers that will accelerate development of new therapies.

Medical Foods.—The Committee recognizes the unique role medical foods play in the nutritional management of inborn errors of metabolism and encourages a flexible regulatory process that would enhance access to safe medical foods for individuals with serious or life-threatening inborn errors of metabolism. The Committees encourages the FDA to continue focusing on this issue.

Medical Gas.—The Committee is concerned that healthcare providers, consumers, and medical gas manufacturers have been waiting for 45 years for the FDA to follow through on its commitment to issue separate regulations for medical gases since it first committed to doing so in the 1978 final rulemaking on current good manufacturing practices. The Committee is encouraged that FDA recently issued proposed regulations in response to the statutory deadlines for medical gas rulemaking required in section 1112 of Food and Drug Administration Safety and Innovation Act (Public Law 112–144) and section 756 of the Fiscal Year 2017 Consolidated Appropriations Act (Public Law 115–31). However, the Committee is significantly concerned that despite its directive in the Joint Ex-

planatory Statement accompanying the 2023 Consolidated Appropriations Act (Public Law 117–328) that final regulations on medical gases be issued by March 31, 2023 the agency has indicated a projected delay of 19 months for publication to October 2024. The Committee directs the FDA to issue the final separate regulations required by the Fiscal Year 2017 Consolidated Appropriations Act (Public Law 115–31) as soon as possible. Should the FDA not issue final regulations by September 30, 2023, the agency shall submit a written report to Committee every 30 days thereafter with an accompanying in-person briefing, including explaining the status of the rulemaking and reasons for delay.

Menthol Cigarettes.—The Committee commends the FDA for issuing proposed rules to set product standards prohibiting the use of characterizing menthol flavors in cigarettes and all non-tobacco characterizing flavors in cigars. These actions hold the potential to dramatically reduce smoking rates, mortality, and healthcare spending in current and future generations. The Committee notes that despite the clear science and recommendations from its own Advisory Committees, the FDA has failed to finalize such regulations to date despite several opportunities. The Committee directs FDA to expeditiously complete the rulemaking processes regarding product standards that ban characterizing menthol flavors in cigarettes and all non-tobacco characterizing flavors in cigars in order to protect public health.

Metastatic Cancer.—The Committee recognizes FDA for ongoing efforts to gather input and patient-focused feedback from the metastatic cancer community. The Committee notes the ongoing challenge identified by patients of needing access to multiple therapeutic option and various sites of care due to the fact that patients with metastatic cancer often progress through multiple therapies, and encourages FDA to continue working to ensure multiple safe and effective therapeutic options with varying delivery mechanisms are available.

Minimal (or Measurable) Residual Disease.—To expedite the development and safe patient access to new therapeutics, FDA is encouraged to support collaborative research with the National Institutes of Health, universities, and industry, regarding the utilization of Minimal (or Measurable) Residual Disease [MRD] testing to assess response to therapy and predict patient outcomes in its evaluation of therapeutic products. The Committee directs FDA to report within 1 year of the enactment of this act on advances in the science and development of products directed to the determination of MRD, that might soon enable the utilization of MRD to serve as an exploratory endpoint for clinical trial evaluations.

Neuroscience.—The Committee is encouraged by the Agency's plants to hire additional staff with neurological expertise to the expand the Agency's efforts to address regulatory challenges in neurodegenerative drug development. As previously mentioned, the Committee provides an additional $3,000,000 for the Agency's Medical Product Centers to build on current efforts to advance our scientific knowledge of neurological diseases.

New Alternative Methods Program.—The Committee directs FDA to efficiently and expeditiously utilize existing funds to reduce animal testing and advance alternative methods in a measurable and

impactful way. The Committee requests a report within 90 days of enactment that provides details on the status of forming the New Alternative Methods Program in the Commissioner's office, including but not limited to a description of program goals and staffing levels by position classification; FDA's priority areas for reducing animal use and advancing alternatives, including goals, timelines and funding associated with each of these identified priorities; the metrics the agency will use to measure impact; and how the agency will communicate information regarding acceptance of alternative methods to the regulated community.

New Era of Smarter Food Safety.—The Committee supports the FDA's efforts to bring together data from several agencies to identify and predict vulnerabilities in the Nation's food supply chain and enable the FDA to take a proactive approach to ensure food safety and supply chain continuity to prevent and respond to crises, such as the recent infant formula shortage. The Committee provides no less than the fiscal year 2023 level to continue this initiative.

New Prior Knowledge.—The Committee is aware of certain issues with domestic drug manufacturing supply chains, and that the FDA has been previously encouraged to improve generic drug development, manufacturing, and quality of generic drugs domestically. The Committee urges FDA to establish a pilot program that will apply new tools to improve generic drug development, manufacturing, and quality. The program must be in collaboration with academic institutions that offer strengths in assessing and improving the generic drug supply chain to ensure the utilization of evidence-based best practices.

Niemann-Pick Type C [NPC].—The Committee encourages FDA to increase its understanding and focus on NPC, a rare progressive and universally fatal disease that impact children and young adults. The Committee encourages FDA to use its existing authorities and pathways to meet the urgent unmet medical need of the current generation of NPC patients, including preserving access to existing experimental therapies already in use. The Committee further encourages FDA to maximize the use of existing natural history data and real world evidence contributed by this small patient population through existing and past clinical studies and to continue to work with patients, scientists, and industry partners to bring to full fruition the work that is being accomplished through patient organizations, scientists, researchers, and other to fully benefit this generation of NPC patients.

Office of Therapeutic Products.—The Committee recognizes the FDA's efforts with regard to rare disease and oncology pilot programs and other positive initiatives, as well as recent increases to support staffing, especially within the Center for Biologics Evaluation and Research and the Office of Therapeutic Products [OTP]. However, the Committee is concerned about the ability to consistently achieve the desired level of review timeliness and quality, and encourages the FDA to implement and apply modern approaches to keep pace with the science. Specifically, the Committee encourages OTP to facilitate reviewers' understanding of the current scientific consensus and disease-specific considerations for current and future programs through consultation with subject matter

experts, both internal and external to FDA. The Committee is also concerned about insufficient patient and expert input when weighing benefits and risks of potentially life changing or lifesaving new treatments. Further, the Committee is concerned that despite Congress recently reinforcing FDA's flexibilities and toolkit related to rare disease and unmet need, OTP is not fully utilizing these flexibilities and tools as Congress intended. The Committee notes the importance of use of these flexibilities and tools, as appropriate, and expects a report to the Committee on interim measures of progress within 1 year of enactment.

Opioids.—The Committee remains concerned with the FDA use of enriched enrollment, randomized, withdrawal [EERW] clinical trial designs. Whereas the FDA Anesthetic and Analgesic Drug Products Advisory Committee [AADPAC] held a meeting reviewing EERW on extended release/long acting [ER/LA] opioids on the efficacy of EERW on showing efficacy, while no vote was held, the AADPAC noted perceived flaws in the clinical trial design. As such the Committee directs the FDA to immediately conduct its study on the EERW methodology for its use on new prescription opioid approvals, and review EERWs use in approving opioids currently on the market. The study should be completed within 90 days of the enactment of this Act. In addition, the FDA should carefully consider the broader public health effect of opioid analgesic drugs in making its approval decisions and in monitoring/considering new information about approved drugs, including the risks related to misuse, abuse, opioid use disorder, accidental exposure, and overdose, for both patients and others, as well as any properties of a drug expected to mitigate these risks.

The Committee applauds FDA for its ongoing efforts to combat opioid abuse and for prioritizing Agency actions to expand access to non-addictive treatments and encourages FDA to collaborate with DEA in situations where descheduling could be helpful to improving access to such non-addictive treatments, particularly for populations that have a high prevalence of insomnia and other high risk conditions that impact veterans, military service members and front line workers. Within 180 days, the Committee requests that FDA brief the committee on the status of any scientific and medical evaluation that may be in progress under the provisions of 21 U.S.C. 811.

Opioid Packaging.—The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act granted FDA new authority to require special packaging for opioids and other drugs that pose a risk of abuse or overdose. The Committee is pleased FDA issued a request for information on requiring fixed-quantity blister packaging for certain opioids and strongly urges the agency to finalize this requirement to promote safe opioid handling and reduce the risk of unintentional ingestion. Additionally, the Committee encourages FDA to consider expanding the scope of this requirement beyond immediate-release, commonly-prescribed opioid analgesics to cover all solid, oral dosage form opioids.

Oversight Activities.—The Committee provides $1,500,000 for the HHS Office of Inspector General specifically for oversight of FDA activities.

Pasteurized Orange Juice.—The Committee is concerned that pests, disease and hurricanes are having a devastating impact on Florida's citrus growers and processors. These circumstances have resulted in a natural decline in the Brix level for Florida's mature oranges, with no known adverse health consequences for consumers. The Committee believes it is necessary to provide for analytical deviation in the minimum Brix level for pasteurized orange juice to account for these naturally occurring growing conditions. The Committee strongly encourages both USDA and FDA to expedite work with Florida's citrus growers and processors, and other stakeholders as necessary, to consider additional flexibility by modernizing requirements for pasteurized orange juice that better account for naturally-occurring Brix variation.

Pathogen Reduction.—The Committee supports FDA's efforts to recommend an individual risk assessment for blood donor eligibility. The Committee encourages FDA to continue studying how to improve existing blood donation policies to advance a safe and adequate supply of blood and reduce stigma. Further, FDA must prioritize further investments in pathogen reduction technologies to reduce the risk of transfusion-transmitted infections and safeguard the blood supply.

Patient Experience Data.—The Committee supports the development of patient experience data to inform clinical research design and regulatory reviews under the patient-focused drug development process. Critical patient perspective insights have been generated by the Duchenne Muscular Dystrophy and other patient communities to ensure FDA has the benefit of this information for critical decisions including on potential gene therapies for this serious condition. The Committee encourages FDA to make every effort to incorporate all relevant patient experience data, including from patient advocacy organizations, across its regulatory obligations.

Pediatric Device Consortia Grants.—Pediatric Device Consortia grants provide funding to assist innovators in developing medical and surgical devices designed for the unique needs of children, needs that often go unmet by devices currently available on the market. The Committee is pleased that the FDA-funded Pediatric Device Consortia have assisted in advancing the development of more than 2,500 proposed pediatric medical device projects since 2009. The Committee encourages FDA to fund Pediatric Device Consortia grants at the authorized level in fiscal year 2024.

PFAS in Cosmetics.—The Committee is concerned about the presence of perfluoroalkyl or polyfluoroalkyl [PFAS] substances in cosmetics. The Committee directs the FDA to develop a plan outlining research needed to inform regulatory decisionmaking, including potential development of a proposed rule to ban intentionally added PFAS substances in cosmetics. Not later than 90 days after enactment, FDA will brief the committee on the research plan, potential regulatory options, and discuss considerations and anticipated challenges with issuing such a proposed rule.

Pharmaceutical Marketing.—The Committee is aware of promotional activities by pharmaceutical companies to physicians and acknowledges this practice can help inform providers of new treatments. The Committee notes that this can also lead to an increase in prescribing rates of newer, and potentially more expensive

brand-name medications. The Committee urges FDA to clarify the obligation of prescription drug and biological product sponsors with respect to promotional activities.

Plant Based Alternatives.—The Committee is concerned that the current labeling practices of some plant-based alternatives to animal-derived foods have the potential to cause consumer confusion. The Committee directs FDA to conduct a study to 1) better understand consumers' perceptions and motivations relative to product composition, health attributes, and other confusing labeling and marketing practices, and 2) assess consumer perceptions of different terms used on labeling of plant-based alternative products. No later than 1 year after the date of enactment of this act, FDA shall submit to Congress, and make publicly available online, a report on the findings of this study.

Plant Based Product Labeling.—The Committee supports FDA's case-by-case approach to evaluating product labels considering terms and representations used within the context of the entire label, including qualification of any statements or names with additional terms or information. The Committee urges FDA to apply this same approach to labeling in pending guidance on plant-based foods.

Polycystic Ovary Syndrome [PCOS].—The Committee recognizes that there have been no FDA-approved treatments specific to PCOS and commends the FDA for supporting the Externally-Led Patient-Focused Drug Development (EL–PFDD] meeting on PCOS. The Committee further encourages the FDA, based on the findings of the EL–PFDD meeting, to work with investigators, industry, patients, practitioners, and researchers to advance the development of safe new evidence-based therapies, diagnostics, devices, and that address the identified needs and treatment priorities of PCOS patients.

Predictive Toxicology Roadmap Guideline Studies.—The Committee supports activities to implement goals set in the Predictive Toxicology Roadmap. However, the Committee is concerned that funding intended to advance New Approach Methodologies [NAMs] and reduce animal testing for product development will be used to conduct new animal tests for comparative guideline studies. While it is important to ensure that novel methods can be relied upon for product development and regulatory decision-making, the Committee encourages FDA to first consider the use of human data or existing animal study data in this comparative assessment, when feasible, to remain aligned with the intentions of the Roadmap and animal testing reduction, refinement, and replacement goals. The Committee directs NCTR to prioritize use of existing human data, or existing data from animal tests conducted prior to enactment of this act when scientifically appropriate, when collaborating with other FDA Centers and the National Toxicology Program data if appropriate.

Promoting Domestic Manufacturing.—The Committee supports the Agency's work to promote the domestic manufacturing of drugs and biological products to help bolster supply chain resiliency, including consistent with Executive Order 13944. The Committee encourages the FDA to increase its efforts to encourage the pharmaceutical industry to expand and relocate drug manufacturing to the

United States. The Committee encourages FDA continue programs and policies that would encourage the pharmaceutical industry to adopt advanced manufacturing technologies, which could help prompt industry to relocated foreign manufacturing to the United States or expand current domestic manufacturing. The Committee encourages the FDA to use any additional resources to collaborate with academic institutions to support the advancement, development, and implementation of advanced and continuous pharmaceutical manufacturing.

Seafood Product Labeling.—The Committee continues to hear concerns with the labeling of certain foods as a fish or seafood product when the products are highly-processed plant-based foods rather than derived from actual fish or seafood, and the labeling of these products are misleading, deceptive, and confusing to consumers. The Committee is concerned the terms "plant-based" and "vegan" exempt the producer from describing the actual plant source as part of the product name, in opposition to other FDA guidance. The Committee directs the FDA to provide clarity around the labeling of these foods using seafood terminology to ensure they are held to the same standards as actual seafood products to avoid consumer confusion, and aligns with the structure it has applied to the draft guidance for the labeling of plant-based milk alternatives.

Sodium.—As the agency considers next steps in finalizing short-term sodium reduction guidance, the Committee urges FDA to monitor progress towards the short-term targets and engage with industry stakeholders on implementation of the guidance. The Committee acknowledges the investment and technology challenges that exist for food manufacturers in reaching the proposed long-term reduction targets, including those that jeopardize food safety and integrity of food products, and believes it is critical that FDA demonstrate the feasibility and effectiveness of the long-term targets before moving forward.

Sponsor Communication.—The Committee is concerned with FDA's reliance on "Written Response Only" communication, in lieu of live interactions when responding to meeting requests from sponsors. While written response can be a useful tool, there are times where meaningful scientific exchanges between sponsors and FDA is required. The Committee urges FDA to offer face to face or teleconference meetings when the topic of the meeting requires face to face or teleconference interface, as discussed in FDA guidance documents.

Sunscreen.—The Committee is aware that FDA has issued a proposed sunscreen order in accordance with the procedures set forth by the Sunscreen Innovation Act and the CARES Act. The Committee encourages FDA to work with stakeholders to issue a final order that clarifies the status of currently marketed sunscreen ingredients, recognizing the benefit of currently marketed sunscreens as a proven preventative tool against skin cancer, the most common cancer in the United States. The Committee urges FDA to utilize its authorities provided under the CARES Act to evaluate new sunscreen ingredients already approved for use around the world and to educate stakeholders about the administrative order process to encourage research and development of new sunscreen technology.

Synthetic Nicotine Products.—The Committee is concerned that thousands of unauthorized non-tobacco nicotine products remain on the market despite provisions in the Consolidated Appropriations Act, 2022 (Public Law 117–103) that require these products to undergo premarket review by the FDA. Enforcement of this requirement is critical to address unauthorized nicotine products that appeal to youth, including flavored e-cigarettes. The Committee urges FDA to clearly communicate to manufacturers, distributors, and retailers which products can be lawfully sold; improve its ability to identify unauthorized products on the market; and pursue all legally authorized remedies to ensure that all products being sold unlawfully are removed from the marketplace. The Committee directs the FDA to report back on the status of its review of premarket applications for non-tobacco nicotine products, the enforcement actions it has taken against unauthorized non-tobacco nicotine products, and other steps the agency has taken to ensure compliance with the premarket review requirement.

Tart Cherries.—The FDA published a proposed rule, titled Food Labeling: Nutrient Content Claims; Definition of Term "Healthy" (Docket No. FDA–2016–D-2335), that, if implemented as proposed, would prevent tart cherries from utilizing the term "healthy" due to restrictive added sugar content limits. These limits fail to recognize that tart cherries require added sugars to meet consumer expectations for palatability and would place tart cherries at a competitive disadvantage to similarly situated fruit products that qualify as "healthy" despite those products containing higher levels of natural sugars. Therefore, the agency shall carefully consider all comments received on the proposed rule related to tart fruits, including tart cherries, and continue to engage with the tart fruit industry about their concerns with the proposed added sugar limits for the "healthy" nutrient content claim.

Temporomandibular Disorder.—The Committee encourages FDA to support the development and implementation of a Patient-Centered Coordinated Registry Network [CRN] for Temporomandibular Joint Disorder [TMD]. This Registry will be a critical component in the transformation of temporomandibular disorder research across other Government Agencies. The Committee supports collaborations among medical product centers related to the development of treatments for TMD and urges FDA to support implementing of a Temporomandibular Joint [TMJ] CRN, continuing the developmental work of the TMJ Patient-led RoundTable and its partners in successfully developing the Registry as an important tool in ongoing efforts to improve the treatment and management of TMD patients.

Tobacco Issues.—The Committee remains deeply concerned about data from the National Youth Tobacco Survey showing that more than two million youth use e-cigarettes and urges FDA to use its full authority to address this serious public health problem. The Committee urges FDA to promptly complete its required premarket review of e-cigarettes and other deemed tobacco products that remain on the market and to deny authorization for any product that does not meet the statutory standard for "appropriate for the protection of the public health". The Committee also urges FDA to take enforcement action against all products that failed to file a

premarket tobacco product application or received a negative action on a submitted application, including marketing denial order.

Traceability Rule.—The Committee notes the expanded scope and complexity for implementation of FDA's final rule entitled "Requirements for Additional Traceability Records for Certain Foods" (21 CFR Part 1, Subpart S). The Committee recognizes that the FDA needs to develop a list of each commodity grouping subject to the rule; to make available educational materials for providers thatare interested in developing cost-effective technology for purposes of rule implementation; and to publish a protocol detailing consistent investigation practices the agency will use to respond to foodborne illness and outbreak investigations.

Traceback.—The Committee recognizes that the ability to prevent, identify, and trace back contaminated products is critical to containing food safety outbreaks but that challenges associatedwith tracing these products consistently from the end-consumer through the supply chain continue to persist. To achieve this, the Committee recognizes the need to modernize data systems to receive, track, and process information and ensure timely notification of significant public health threats. This ability is critical to address safety and supply chain issues associated with regulated high-risk products to more proactively identify or prevent threats to regulated product safety and quality.

Usher Syndrome.—The Committee requests that the FDA immediately consider new technology and innovative measurements to determine effective treatments for rare ophthalmic diseases. Acceptable endpoint measurements must better reflect the slow progression and rare nature of Usher syndrome if potential treatments are ever going to be available to patients.

Valley Fever.—The Committee is encouraged by progress made toward producing a Valley Fever vaccine and recommends that FDA consult with the public and obtain input on the state of the science related to vaccines to prevent Valley Fever. The Committee further recommends that FDA draft and issue industry guidance for entities seeking approval under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or licensure under section 351 of the Public Health Service Act (42 U.S.C. 262) of antifungal therapies to treat Valley Fever.

Vibrio.—The Committee is aware of the public health challenge related to the naturally occurring bacteria called Vibrio parahaemolyticus that can accumulate in shellfish and believes that more scientific research is necessary to develop proper controls that will reduce the risk to consumers and sustain a healthy domestic shellfish industry. The Committee encourages the FDA to increase funding for research into Vibrio illnesses associated with the consumption of raw molluscan shellfish, improve risk assessment models, and develop improved rapid detection methods for virulent Vibrio strains.

Women in Clinical Research.—Following recommendations by the Task Force on Research Specific to Pregnant Women and Lactating Women, the Committee urges the agency to issue final regulations relating to the protection of human subjects, including parts 50 and 56 of title 21, Code of Federal Regulations, with the latest regulations of the Department of Health and Human Services relating to

the inclusion of pregnant women as subjects in clinical research. The agency should consider further guidance about ethical issues to be considered and strategies for designing ethical studies, to inform the inclusion of pregnant women and lactating women in a clinical trial and facilitate their participation.

BUILDINGS AND FACILITIES

Appropriations, 2023	$12,788,000
Budget estimate, 2024	18,788,000
Committee recommendation	12,788,000

FDA maintains offices and staff in 49 States and in the District of Columbia and Puerto Rico, including field laboratories and specialized facilities, as well as the National Center for Toxicological Research complex. Repairs, modifications, improvements, and construction to FDA headquarters and field facilities must be made to preserve the properties, ensure employee safety, meet changing program requirements, and permit the agency to keep its laboratory methods up to date.

COMMITTEE RECOMMENDATIONS

The Committee recommends an appropriation of $12,788,000 for FDA buildings and facilities.

This funding shall be used to upgrade FDA facilities and laboratories which are currently below public safety standards and incapable of performing agency requirements. The Committee is aware that several FDA-owned facilities need significant renovations and repairs. The Committee understands that high-quality, reliable buildings are a necessity to support the FDA's mission-critical work.

FDA INNOVATION ACCOUNT, CURES ACT

(INCLUDING TRANSFER OF FUNDS)

Appropriations, 2023	$50,000,000
Budget estimate, 2024	50,000,000
Committee recommendation	50,000,000

The Committee recommends $50,000,000 for the FDA as authorized in the 21st Century Cures Act (Public Law 114–255).

INDEPENDENT AGENCY

FARM CREDIT ADMINISTRATION

LIMITATION ON ADMINISTRATIVE EXPENSES

Limitation, 2023	$88,500,000
Budget estimate, 2024	94,300,000
Committee recommendation	94,300,000

The Farm Credit Administration [FCA] is the independent agency in the executive branch of the Government responsible for the examination and regulation of the banks, associations, and other institutions of the Farm Credit System.

Activities of FCA include the planning and execution of examinations of Farm Credit System institutions and the preparation of examination reports. FCA also promulgates regulations, establishes

Total, title IV, Domestic Food Programs	189,057,589	188,715,813	161,160,930	−27,896,659	−27,554,883
TITLE V—FOREIGN ASSISTANCE AND RELATED PROGRAMS					
Office of the Under Secretary for Trade and Foreign Agricultural Affairs	932	1,035	932	.....	−103
Office of Codex Alimentarius	4,922	5,009	4,922	.....	−87
Foreign Agricultural Service					
Salaries and expenses	237,330	256,149	237,330	.....	−18,819
(By transfer from export loans)	(6,063)	(6,063)	(6,063)	.....	.....
Food for Peace Title II Grants:					
Expenses	1,750,000	1,800,000	1,800,000	+50,000	.....
McGovern-Dole International Food for Education and Child Nutrition program grants	243,331	243,331	248,331	+5,000	+5,000
Commodity Credit Corporation Export (Loans):					
Credit Guarantee Program Account	6,063	6,063	6,063	.....	.....
Foreign Agriculture Service, Salaries and expenses (transfer out)	(−6,063)	(−6,063)	(−6,063)	.....	.....
Total, title V, Foreign Assistance and Related Programs	2,242,578	2,311,587	2,297,578	+55,000	−14,009
(By transfer)	(6,063)	(6,063)	(6,063)	.....	.....
(Transfer out)	(−6,063)	(−6,063)	(−6,063)	.....	.....
TITLE VI—RELATED AGENCIES AND FOOD AND DRUG ADMINISTRATION					
DEPARTMENT OF HEALTH AND HUMAN SERVICES					
Food and Drug Administration					
Salaries and expenses					
Direct appropriation	3,530,150	3,896,028	3,550,150	+20,000	−345,878
Transfer to OIG (transfer out)	(−1,500)	(−1,500)	(−1,500)	.....	.....
Spending from appropriated user fees:					
Prescription drug user fees	1,310,319	1,336,525	1,336,525	+26,206	.....
Medical device user fees	324,777	331,273	331,273	+6,496	.....
Human generic drug user fees	582,500	594,150	594,150	+11,650	.....
Biosimilar biological products user fees	41,600	42,432	42,432	+832	.....
Animal drug user fees	32,144	33,500	33,500	+1,356	.....
Animal generic drug user fees	29,303	25,000	25,000	−4,303	.....
Tobacco product user fees	712,000	712,000	712,000	.....	.....

COMPARATIVE STATEMENT OF NEW BUDGET (OBLIGATIONAL) AUTHORITY FOR FISCAL YEAR 2023 AND BUDGET ESTIMATES AND AMOUNTS RECOMMENDED IN THE BILL FOR FISCAL YEAR 2024—Continued

[In thousands of dollars]

Item	2023 appropriation	Budget estimate	Committee recommendation	Senate Committee recommendation compared with (+ or −)	
				2023 appropriation	Budget estimate
Subtotal, user fees (appropriated)	3,032,643	3,074,880	3,074,880	+42,237	
Subtotal (including appropriated user fees)	6,562,793	6,970,908	6,625,030	+62,237	−345,878
Mammography user fees	19,371	19,758	19,758	+387	
Export user fees	5,083	5,185	5,185	+102	
Color certification user fees	10,891	11,109	11,109	+218	
Food and Feed Recall user fees	1,552	1,584	1,584	+32	
Food Reinspection fees	6,942	7,079	7,079	+137	
Voluntary qualified importer program fees	5,737	5,852	5,852	+115	
Pharmacy compounding fees	1,646	1,679	1,679	+33	
Priority review vouchers (PRV) pediatric disease	8,320	8,486	8,486	+166	
Priority review vouchers (PRV) tropical disease	2,660	2,713	2,713	+53	
Priority review vouchers (PRV) medical countermeasures	2,660	2,713	2,713	+53	
Third party auditor	771	787	787	+16	
Over-the-Counter Monograph fees	30,356	31,800	31,800	+1,444	
Increased export certification fees (leg proposal)		5,000			−5,000
Expand tobacco products fees (leg proposal)		100,000			−100,000
Subtotal, spending from FDA user fees	3,128,632	3,278,625	3,173,625	+44,993	−105,000
Total, Salaries and expenses (including user fees)	6,657,282	7,173,153	6,722,275	+64,993	−450,878
HHS Office of Inspector General (by transfer)	(1,500)	(1,500)	(1,500)		
Buildings and facilities	12,788	18,788	12,788		−6,000
FDA Innovation account, Cures Act	50,000	50,000	50,000		
Offset of appropriation pursuant to Section 1002 (b)(3)(B) of the 21st Century Cures Act (PL 114–255)	−50,000	−50,000	−50,000		
Spending of FDA innovation account (transfer)	(50,000)	(50,000)	(50,000)		
Total, FDA (w/user fees, including proposals)	6,671,570	7,193,441	6,736,563	+64,993	−456,878

Total, FDA (w/enacted user fees only)	6,671,570	7,088,441	6,736,563	+64,993	−351,878
FDA user fees	−3,128,632	−3,278,625	−3,173,625	−44,993	+105,000
Total, Food and Drug Administration (excluding user fees)	3,542,938	3,914,816	3,562,938	+20,000	−351,878
INDEPENDENT AGENCIES					
Farm Credit Administration (limitation on administrative expenses)	(88,500)	(94,300)	(94,300)	(+5,800)	.....
Total, title VI, Related Agencies and Food and Drug Administration	3,542,938	3,914,816	3,562,938	+20,000	−351,878
TITLE VII—GENERAL PROVISIONS					
Richard B Russell National School Lunch Act (Sec 732)	.....	12,000	.....	.....	−12,000
NIFA Military Veteran Grants	5,000	.....	3,000	−2,000	+3,000
Rural Hospital Technical Assistance	2,000	.....	.....	−2,000	.....
Protecting Animals with Shelter Grants	3,000	.....	.....	−3,000	.....
International Agricultural Education Fellowship	1,000	.....	.....	−1,000	.....
Healthy Fluid Milk	4,000	.....	.....	−4,000	.....
Pollinator Research Coordinator	400	.....	.....	−400	.....
Farm Opportunities Training and Outreach	4,000	.....	.....	−4,000	.....
Water Bank program	4,000	.....	2,000	−2,000	+2,000
Maturing mortgage pilot	2,000	.....	2,000	.....	+2,000
WIC (rescission)	−315,000	.....	.....	+315,000	.....
Mitigation banking	5,000	5,000	2,000	−3,000	−3,000
NOAA working group	500	.....	500	.....	+500
Institute for Rural Partnership	15,000	.....	9,000	−6,000	+9,000
Bison Inspection Waiver	.....	.....	700	+700	+700
Bison Marketing Pilot	.....	.....	3,000	+3,000	+3,000
NAS Study	1,300	.....	.....	−1,300	.....
Farm Loan balances (rescission)	−73,000	.....	.....	+73,000	.....
PFAS	5,000	.....	.....	−5,000	.....
Cotton Classing Office Upgrades	4,000	.....	.....	−4,000	.....
RMA A&O	25,000	.....	.....	−25,000	.....
Nonrecurring Expenses Fund (rescission)	−150,000	.....	.....	+150,000	.....
Summer EBT (rescission)	−80,000	.....	.....	+80,000	.....
Institute of Child Nutrition	.....	2,000	.....	.....	−2,000
Broadband Treasury Rate Loan Program (rescission)	.....	−9,156	−9,156	−9,156	.....
Maturing Mortgage Pilot Program (rescission)	.....	−3,000	.....	.....	+3,000