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Status of Food and Drug Administration Programs and Activities During the Current Government Shutdown

Agency-Wide	
Activity	**Description**

General	• FDA can perform activities necessary to address imminent threats to the safety of human life and activities funded by carryover funds, including, but not limited to, user fees and carryover balances for 21st Century Cures and opioids funding (these balances will only be spent on activities for which the funds were authorized). **FDA cannot accept 2019 user fees without an appropriations bill for FY19.**
	• **User-Fee Activities:** FDA can only undertake user-fee activities from FY18 carryover funds. These funds allow the Agency to continue working on existing user-fee related applications, including those applications for which user fees were paid prior to Dec. 22, 2018. These funds also allow the Agency to conduct post-market drug safety surveillance, develop guidance and advance policies that further FDA's regulatory oversight of medical products and animal drugs.
	• FDA will continue to maintain core functions to handle and respond to emergencies, and will perform the following functions:
	  • Monitoring for and quickly responding to outbreaks related to foodborne illness and the flu.
	  • Supporting high-risk food and medical product recalls when products endanger consumers and patients.
	  • Pursuing civil investigations when FDA believes the public health is imminently at risk.
	  • Pursuing criminal investigations.
	  • Reviewing food, drug and medical device imports.
	  • Continuing surveillance of adverse events for drugs, medical devices and other medical products.
	  • Drug shortages mitigation for life-sustaining drugs.

Inspections	• FDA has paused routine establishment inspections.
	• FDA will continue to perform the following activities:
	  • Inspecting facilities when FDA believes there is an imminent threat to health and life.
	  • Performing entry review of **all products** to determine the potential risk to health (e.g., whether the product poses an imminent threat to health/life).
	  • Conducting inspections at airport international-mail facilities to examine potentially violative products attempting to enter US commerce.
	  • Examining, including sampling, products that may pose a high risk to health.
	  • Detaining product, including products subject to detention without physical examination, if the product may pose a high risk to health.

CDER/CBER Drugs and Biologics	
Activity	**Description**
Product Development	• FDA will use carryover user fees to support product development. This includes participating in pre-approval discussions with sponsors seeking guidance on how to proceed with clinical research and other ongoing discussions to help advance development programs. • Work on certain guidance documents can proceed if user-fee related, but work on other guidance documents is on hold.
Drug Safety Surveillance	• As of Jan. 8, 2019, FDA is assessing its portfolio to focus allocating FDA resources to key consumer protection functions. FDA plans to reallocate user-fee funds from certain premarket drug review work to post-market drug safety surveillance.
Medical Product Applications	• FDA is continuing to work on existing user-fee related applications using FY18 carryover fees. Due to the planned reallocation of funds, work on certain premarket drug review activities may slow down or be suspended. • FDA can accept regulatory submissions for FY19 if user-fee program related, and the submission does not require the payment of a user fee (e.g., submissions that fall within the fee exemption for previously filed applications, applications for which FDA has waived the application fee (small business waiver), and NDAs or BLAs that only have orphan designated indications). • FDA cannot accept any regulatory submissions for FY19 for new drugs that require a fee payment and that are submitted during the shutdown, unless the required user fee was paid before Dec. 22, 2018. This applies to products covered by the Prescription Drug User Fee Amendments (PDUFA), the Biosimilar User Fee Amendments (BSUFA) and the Generic Drug User Fee Amendments (GDUFA). • FDA will review new emergency INDs and IND amendments that relate to the safety of individuals who are participating in clinical trials, even for products that are not covered by a user-fee program. PDUFA-Specific Guidance • FDA has approximately one month of FY18 carryover PDUFA funding remaining. • FDA will accept new regulatory submissions for which no fee is required, including INDs, annual reports, supplements to NDAs and BLAs, submissions that fall within fee exemptions, and general correspondence. • PDUFA-covered products include those that would be approved under an NDA, including a 505(b)(2) application, a 351(a) BLA, OTC products approved under NDAs, and medical gases that have been deemed to have NDAs through the medical gas certification process outlined in sections 575 and 576 of the FD&C Act. Generic Drug-Specific Guidance • FDA has approximately one month of FY18 carryover GDUFA funding remaining. • FDA will not accept generic drug submissions that require payment of a fee (e.g., Abbreviated New Drug Applications (ANDAs)). • FDA will accept generic drug submissions for which no fee is required if the product is within the scope of the GDUFA program. This includes Changes Being Effected (CBE) supplements and prior approval supplements (PAS) to approved ANDAs, amendments, annual reports, and applications for PET drugs.

Activity	Description

	• Sponsors who have not paid GDUFA facility fees for FY19 should not remit payment during the shutdown because FDA cannot accept the fees.
	• Drug Master Files (DMFs): FDA will accept DMFs, including Type II Active Pharmaceutical Ingredient (API) DMFs intended to be referenced in generic applications.
	  ◦ Type II API DMF fees should not be submitted during the shutdown because FDA cannot accept the fees. Fees that are due during the shutdown may be paid as soon as it ends.
	  ◦ FDA will not conduct initial completeness assessments on Type II API DMFs for which the fee has not been paid and these new DMFs will not be placed on the Available for Reference List.
	  ◦ If a generic drug application references, for the first time after Dec. 22, 2018, a Type II API DMF for which the fee has not been paid, then FDA will notify the applicant that the fee must be paid within 20 calendar days.
	  ▪ If the fee is not paid within 20 days of that notice, FDA will not receive the application. FDA has not determined what approach it will take if the 20-calendar-day period expires during the shutdown.
	Medical Products Outside the Scope of User-Fee Programs
	• Certain limited categories of medical products regulated by CDER and CBER are not within the scope of any of FDA's user-fee programs. As such, user-fee funding is not available to carry out activities with respect to those products.
	  ◦ For example, within CDER, carryover user-fee funding is not available for OTC monograph drug activities.
	  ◦ Within CBER, work on whole blood, blood components for transfusion, allergenic extract products, and human cells, tissues, and tissue-based products regulated solely under Section 361 of the Public Health Service Act cannot be conducted with carryover user-fee funding.
	• FDA will not perform any activities with respect to these medical products except for emergency work involving the safety of human life or the protection of property.
	  ◦ For example, FDA will continue to conduct surveillance for adverse events to determine the potential risk to health from such products and conduct recalls or take other critical actions to protect the safety of human life.
	• Additionally, for medical products in these categories subject to premarket approval, FDA will suspend review of any pending regulatory submissions unless the submission is an emergency IND or an IND amendment related to the safety of human subjects (e.g., an IND safety report).
	  ◦ If a sponsor sends FDA a non-emergency IND during the shutdown for a medical product not covered by a user fee, the 30-day review clock will not start until the shutdown is over.

Expanded Access	• FDA is continuing to quickly review and respond to requests for expanded access or compassionate use of an investigational medical product outside of a clinical trial.

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CDER/CBER Medical Devices	
Activity	**Description**
Applications	• FDA is continuing to work on existing user-fee related applications using FY18 carryover fees. FDA has approximately two to three months of FY18 carryover Medical Device User Fee Amendments (MDUFA) funding remaining. • FDA cannot accept any regulatory submissions for FY19 that require a fee payment and that are submitted during the shutdown, unless the required user fee was paid before Dec. 22, 2018. This applies to products covered by MDUFA. • If the user fee has been paid, but was not fully processed prior to the shutdown, then the application will be placed on user-fee hold until the shutdown ends, and the payment can be fully processed. • Processing of Investigational Device Exemptions should continue.

CVM Veterinary Products	
Activity	**Description**
Applications	• FDA is continuing to work on existing user-fee related applications using FY18 carryover fees. • FDA cannot accept any regulatory submissions for FY19 that require a fee payment and that are submitted during the shutdown, unless the required user fee was paid before Dec. 22, 2018. This applies to new submissions for which payment of a FY19 fee is required under the Animal Drug User Fee Amendments (ADUFA) or the Animal Generic Drug user Fee Amendments (AGDUFA)

CTP Tobacco Products	
Activity	**Description**
General	• FDA is continuing to oversee manufacturing, distribution and marketing of tobacco products; efforts to educate about their dangers; efforts to combat the epidemic of youth e-cigarette use and access to all tobacco products; and will continue carrying out the Tobacco Control Act.

CFSAN Foods, Dietary Supplements, Cosmetics	
Activity	**Description**

General	• FDA is continuing to inspect foreign manufacturers, manage high-risk food recalls, manage outbreaks related to foodborne illness, inspect import entries to determine potential risks to public health, and conduct inspections where inspectors suspect a problem may exist.
	• FDA has suspended all routine inspections of domestic food-processing facilities. 2013 legal guidance instructed the Agency that it could not perform regular food inspections during a funding shortfall.
	  • FDA is currently working on a plan to bring back inspectors to resume inspections of high-risk facilities. Having cancelled more than 50 high-risk inspections, Dr. Gottlieb has obtained new guidance that he believes will allow him to recall ~150 furloughed inspectors to focus on high-risk facilities.
	  • A facility's risk is assessed based on a comprehensive, cross-cutting profile. The primary factors contributing to a facility's risk profile include: the type of food, the manufacturing process and the facility's compliance history.
	  • High-risk commodities include, but are not limited to: modified atmosphere packaged products; acidified and low-acid canned foods; seafood; custard-filled bakery products; dairy products, including soft, semi-soft, soft ripened cheese and cheese products; unpasteurized juices; sprouts ready-to-eat; fresh and processed fruits and vegetables; shell eggs; sandwiches; prepared salads; infant formula; and medical foods.
	  • To provide a sense of the volume of activities suspended, FDA typically conducts about 160 routine food inspections per week in the US. Of FDA's weekly domestic inspections, 31 percent are considered high risk.
	• FDA has also paused activities pertaining to cosmetics, dietary supplements, food additive petitions, and nutrition programs unless there is an emergency situation, as well as guidance development, and (likely) training and technical assistance programs.