BACKGROUND

Beginning on December 22, 2018, the Food and Drug Administration (FDA) entered into a “lapse period” in which no congressional appropriation exists to fund the agency. The lapse period will continue until the date of enactment of an FY19 appropriation or a Continuing Resolution. During this period there are limited activities in which the FDA can engage. Those activities that the agency can perform include: (1) activities necessary to address imminent threats to the safety of human life and (2) activities funded by carryover funds, notably but not exclusively, user fees.

This toolkit is intended to be a central resource for the media and for members of the Alliance for a Stronger FDA to understand the impact on FDA of the lapse in appropriated funding.

RESOURCES DIRECTLY FROM THE FDA

The government has provided a number of resources to the public to explain the impact on the FDA:

- **Short statement from the FDA:** “FDA 2018 Lapse in Funding Information.”
- **HHS statement on contingency staffing plan:** FY 2019 HHS Contingency Staffing Plan for Operations in the Absence of Enacted Annual Agriculture and Interior Appropriations.
- **FDA lapse in funding information for employees:** Information for Employees.
- **Direct Communications from FDA Commissioner Scott Gottlieb:**
  - On Friday, December 21, Commissioner Gottlieb sent a note to all FDA employees, indicating that each employee would be receiving an informal notice of their employment status later that afternoon if a lapse in appropriations were to occur. The commissioner’s communication is available here.
  - Later that day, FDA issued a further communication about continuation of salary and benefits for exempt and non-exempt FDA employees here.
  - Throughout the shutdown, Commissioner Gottlieb has continued to tweet updated information from his Twitter account.

CONCERN FROM THE ALLIANCE FOR A STRONGER FDA

“The FDA regulates products that make up twenty percent of consumer spending. Despite that, forty percent of FDA’s workforce has been shut down because of an unrelated issue in an appropriations bill that doesn’t involve FDA. The Alliance will now redouble our efforts to make sure that policymakers and the public understand that FDA provides public health services that are core
functions of government. When FDA is unable to perform them, the public is at unnecessary risk,” said Wayne Pines, Vice President of the Alliance for a Stronger FDA.

Ladd Wiley, Executive Director of the Alliance for a Stronger FDA, stated: “While the most critical FDA functions will be handled during this shutdown, and many user fee-funded activities will continue for a time, we hope that the Congress and the President will move swiftly to break the impasse or, at least, pass the Agriculture/FDA appropriations bill to enable FDA to resume its essential consumer-protection activities.”

Alliance staff are available to talk directly with the media and Alliance members, and can be reached at: Steven Grossman (sgrossman@strengthenfda.org) or Ladd Wiley (lwiley@ofwlaw.com).

OVERVIEW FROM FDA

“…[B]eginning on December 22, 2018 and continuing until the date of enactment of an FY 2019 appropriation or Continuing Resolution ("lapse period"), agency operations continue to the extent permitted by law…The FDA plays a critical public health role. Our work protects the food that families feed their children and pets and ensures the effectiveness of the medicine they need, all of which contribute to improving the health and welfare of Americans. All our work is important, but only some of our work is permitted to continue during a lapse in funding…”

“[P]ublic health activities that will continue include, among other things maintaining core functions to handle and respond to emergencies – such as:

- 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 we believe public health is imminently at risk and
- pursuing criminal investigations,
- screening the food and medical products that are imported to the U.S. to protect consumers and patients from harmful products, and
- addressing other critical public health issues that involve imminent threats to the safety of human life.

Mission critical surveillance for significant safety concerns with medical devices and other medical products will also continue.” [re-formatted for clarity]

HOW THE SHUTDOWN IS IMPACTING THE FDA

How many FDA employees have been furloughed? Of FDA’s 17,397 employees, 41% (7,053) will be furloughed, according to HHS documents (available here). Some of those employees who are furloughed were with the agency for the first day or two of the shut-down, but only to carry-out the orderly shutdown of activities funded by appropriated monies. Among the furloughed, some employees are subject to being called back to work in the case of an urgent public health situation.

Also, depending on the duration of the shutdown and the availability and amount of FY 18 carryover funding from user fee accounts, some employees working on user-fee funded activities at the beginning of the lapse period are at risk to be furloughed as the shutdown continues and user-fee funds are depleted.
Who will be working at FDA?

- As noted and sourced above, 59% (10,344) of FDA employees were retained at the beginning of the lapse period.
- At the beginning of the lapse period, approximately 6,900 employees were retained based on the availability of user fees. About 900 of them are at the Tobacco Center because it is fully-funded by user fees and presumably 100% will be working.
- FDA can only undertake user fee activities from FY18 carryover funds. Depending on the duration of the shutdown, account balances and burn rates, there may reach a point where funds to carry out user fee-funded activities are not available and employees are furloughed. This eventual phase-down will be different for each of the separate user fee programs.
- Members of the U.S. Public Health Service Commissioned Corps are not subject to the furlough and will be working. This is about 1,100 FDA employees, who are spread throughout the agency.
- Also unaffected would be individuals working in areas where their absence would constitute a threat to public health and safety or property. For example:
  - Emergency inspections would be staffed, but not routine ones.
  - Criminal enforcement work and civil investigations related to imminent threats to human health or life will be staffed.
  - The FDA will be staffed to continue to address existing critical public health challenges, including drug shortages. In an emergency, additional staff can be called back from their furloughed status, but only for as long as they are needed to address the immediate issue.
- FDA has also announced that it has limited carryover balances for 21st Century Cures and opioids funding. These balances will only be spent on activities for which the funds are authorized.

Who is not working at FDA?

- 41% (7,053) of the agency employees are furloughed.
- Most individuals involved in the development of regulations or the conduct of administrative or policy work are furloughed. We understand there may be a small number of exceptions for guidance development that can be paid for with user fees.
- FDA has specifically said that the OTC monograph process will not be operating unless there is an emergency situation. Our understanding is the same for cosmetics, dietary supplements, food additive petitions, and nutrition programs, among others.
- Food programs (nearly 5,000 employees of CFSAN and CVM) are thinly-staffed, apart from import inspectors, individuals working on recalls, and other front-line employees needed to address essential duties that protect human and animal health and safety.
- Along with those furloughed, we expect that contract employees and contractor firms, to the extent they are paid with appropriated monies, will mostly be on “stop work” orders. While there is a reasonable expectation that FDA employees will eventually be paid their salaries for the shutdown period, there is no such expectation for contractors.

Will user fee-funded activities continue through the entire shutdown period, regardless of its duration? No. The FDA can only use user fee carryover balances from FY 18. Depending on how much money is available in each of the user fee accounts and depending on the burn rates for
the activities they fund, FDA will eventually run out of money (here). Dr. Gottlieb has promised to release information on the account balances, burn rate and approximately how long activities can continue under carryover balances.

Even still, stakeholders should not expect precision in the numbers that are released. To make funds last as long as possible and assure that funds are spent on the highest priority activities, we expect FDA will triage programs and closely manage spend-downs of cash. Of necessity, this will be a fluid process and it is likely that staff initially paid for with user fees at the beginning of the lapse period will eventually be furloughed as cash flow is managed. This suggests that ongoing activities and staff levels performing user fee activities will grow smaller in stages. Thus, Dr. Gottlieb’s statement that carry-over PDUFA funds would likely run out in a month might be implemented in such a way that some individuals working on PDUFA-funded activities may be furloughed sooner and those working on a few very-high priority programs may continue later.

**How much of the drug and device product review programs will continue during a shutdown?** As noted, medical product review programs will generally continue, but subject to triage of priorities, judicious management of available funds, and programs shrinking in phases.

We estimate that, right from the beginning, drug and device review programs will not be fully staffed. For example, about 30% of the drug review process is paid for by appropriations. Those appropriated dollars will not be available during the shutdown. Therefore, logically, some part of the drug review process will not continue during a shutdown, despite user fees. The same would be true of devices, except that we believe a larger percentage of the costs are paid from appropriated funds.

There are also some products not covered by user fees. Staff working on them will have been furloughed. FDA has said: CBER will pause non-emergency work on whole blood, blood components for transfusion, allergic extracts and HCT/Ps regulated solely under section 361 of the PHSA. FDA has also said that: “products that would be approved under an ANDA or 351(k) biosimilar BLA are not PDUFA-covered products. Nor are OTC monograph drugs, although OTC products approved under NDAs are PDUFA-covered.”

FDA has also said: “If a sponsor sends a non-emergency IND during the lapse period for a medical product in one of these [non-user fee] categories, the 30-day review clock will not start until the lapse period is over. The only new INDS and IND amendments for these products that FDA will consider “received” (and proceed to review) during the lapse period are: new emergency INDS; and new IND amendments that relate to the safety of human subjects.”

On December 21, 2018, in anticipation of the shutdown, FDA described a major exception to the continuation of user fee activity (available here): “…FDA will not be able to accept any regulatory submissions for FY 2019 that require a fee payment and that are submitted during the lapse period.” The fee programs involved are: PDUFA (drugs), GDUFA (generic drugs), BsUFA (biosimilars), MDUFA (medical devices), and ADUFA and AGDUFA (animal drugs and animal generic drugs).

FDA has offered the following additional information: “during the shutdown, for PDUFA products, FDA will accept new regulatory submissions for which no fee is required. This includes submissions that fall within the fee exemption for previously filed applications.” When Dr. Gottlieb, via twitter, was asked for further clarification, he said: “It also includes applications for which FDA has waived the application fee (e.g., small business waiver) and NDAs or BLAs that only have orphan designated indications.”
Those companies that have filed and paid the product user fee at the time of a regulatory filing and prior to the shutdown, can expect FDA to continue the agency’s review. Based on this (and relying in part on 2013 guidance available here), we believe that:

- while reviews will continue, there is a risk that agency timeframes may slip because review teams are smaller and some ancillary services may be missing.
- while we can think of no specific examples, it is possible that a product review could require some activity or input that is unavailable in the absence of appropriated resources.
- products on which user fees have already been paid (e.g. NDAs) are more likely to have robust staffing than earlier stage activities.

Our understanding from past shutdown threats is that user fee monies will be prioritized to later stage projects—closer to benefitting patients—and then on to earlier stage products. The exception, as noted above, is that the agency will not, after December 21, be able to accept regulatory filings that require a product user fee.

We do not know where the precise lines are being drawn in every instance and cannot provide assurance that any given user-fee funded activity will be fully continued (or partly continued or not continued) during a shutdown.

**What happens to Food Safety?** We know that food safety will be particularly hard-hit, including the furloughing of workers in charge of routine inspections, guidance development and, also, we assume, those staffing training and technical assistance programs (e.g. assistance to industry in complying with FSMA requirements). These functions are almost exclusively funded by appropriations. FDA will be staffed to manage outbreaks related to foodborne illness. FDA will be staffed to manage high-risk recalls. The FDA will review import entries to determine potential risks to health.

**Agency Websites.** Most agency websites will not be updated during a shutdown. Some portals may be open and accessible electronically, but personnel who routinely respond to inquiries about those portals may not be available.

**Does it matter to FDA that most non-FDA components of HHS are already funded?** Most of the rest of HHS (except the Indian Health Service) are funded through either the Labor-H appropriations bill or mandatory funding. That other parts of HHS are working does not materially impact FDA.

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**ABOUT THE ALLIANCE**

The Alliance for a Stronger FDA is a multi-stakeholder coalition that educates and advocates for increased appropriated funding for FDA. The Alliance was founded more than 10 years ago and has been successful in changing the views of policymakers as to the FDA’s vital public mission.

For more information, contact Steven Grossman (sgrossman@strengthenfda.org) or Ladd Wiley (lwiley@ofwlaw.com)