CDER's Work to Meet User Fee Goals During the Pandemic

On January 31, 2020, the Secretary of Health and Human Services declared a public health emergency related to COVID-19, effective as of January 27, 2020. One of the challenges facing FDA during the public health emergency is how to ensure timely reviews of applications for drugs and biological products despite a surge in work volume and practical constraints, such as travel limitations, quarantine and social distancing requirements or lockdowns. Americans depend on the agency to review and, when they meet our high scientific standards, approve medical products that are important to patients and health care professionals.

A key way FDA meets its mandate is through user fee programs. These statutory programs authorize FDA to assess and collect fees from companies that produce certain medical products, including drugs and biological products. FDA has generally committed to reviewing 90% of applications for specified drug and biological products within the timeframes we have agreed to in user fee negotiations with industry. As we focus on fighting the pandemic on multiple fronts, we still prioritize meeting our user fee commitments while maintaining our high standards and responsibility to the public health and the safety of our staff.

Additional information on the user fee commitments and annual performance reports is available below:

- Prescription Drug User Fee Act (PDUFA)
- Generic Drug User Fee Amendments (GDUFA)
- Biosimilar User Fee Act (BsUFA)

The purpose of this webpage is to provide periodic updates on key metrics related to application review and the pre-approval process throughout the pandemic. The data presented below only reflects

CDER data and includes all actions due during the specified timeframe, regardless of receipt date. This differs from FDA's annual Congressional performance reports where performance is based on the fiscal year of receipt, and includes CDER and Center for Biologics Evaluation and Research (CBER) data.

CDER Inspections during COVID-19

As we evaluate and inspect manufacturing facilities, we maintain our rigorous review standards, while ensuring the health, safety and well-being of our investigators. We continue to conduct mission-critical inspections of domestic and foreign manufacturing facilities to help assure compliance with our high standards for quality. Similarly, for the Bioresearch Monitoring program, pre-approval and for-cause assignments deemed mission-critical are being considered for on-site inspection on a case-by-case basis.

While continuing to conduct mission-critical and prioritized inspections, due to practical constraints, such as travel limitations, quarantine and social distancing requirements or lockdowns, we have been increasingly relying on inspection alternatives including:

- Reviewing the compliance histories of facilities
- Using information shared by trusted foreign regulatory partners through mutual recognition and confidentiality agreements
- Requesting records directly from facilities in lieu of on-site drug and biological product inspections
- Sampling drugs at the border

The table below shows:

1. Percentage of applications acted on during the fiscal year by quarter, on or before their user fee goal date
2. Percentage of pre-approval inspections not conducted where other tools and approaches were used in lieu of an inspection
3. Number of abbreviated new drug application (ANDA) originals and ANDA, new drug application (NDA), and biologics license application (BLA) manufacturing supplements, approved for drugs and biologics used in the treatment of patients with COVID-19

Percentage of applications acted on during the fiscal year by quarter, on or before their user fee goal date[1]

Fiscal Year (FY) Quarter	FY20 Q3 (4/1/2020 - 6/30/2020)	FY20 Q4 (7/1/2020 - 9/30/2020)

Prescription Drug User Fee Act (PDUFA)		
Original Applications[2]	98%	94%
Efficacy Supplements[2]	100%	94%
Manufacturing Supplements	99%	97%
Generic Drug User Fee Amendments (GDUFA)		
Original Applications	94%	93%
Original Applications with Imminent Approval[3]	98%	96%
Prior Approval Supplements	99%	96%
PAS with Imminent Approval[3]	99%	97%
Biosimilar User Fee Act (BsUFA)		
Original Biosimilar Product Applications[2]	100%	75%
Supplements with Clinical Data[2]	100%	100%
Manufacturing Supplements	100%	95%

Percentage of pre-approval inspections not conducted where other tools and approaches were used in lieu of an inspection[4]

Fiscal Year Quarter	FY20 Q3 (4/1/2020 - 6/30/2020)	FY20 Q4 (7/1/2020 - 9/30/2020)
	48%	60%

Number of ANDA originals and ANDA/NDA/BLA manufacturing supplements, approved for drugs and biologics used in the treatment of patients with COVID-19[5]

Fiscal Year Quarter	FY20 Q3 (4/1/2020 - 6/30/2020)	FY20 Q4 (7/1/2020 - 9/30/2020)
ANDA Originals	17	14
Supplements	314	277

Resources

- Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID-19 Public Health Emergency Questions and Answers Guidance for Industry August 2020
- Coronavirus (COVID-19) Update: FDA prepares for resumption of domestic inspections with new risk assessment system

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1. This metric only contains CDER data and will not match the FDA Annual Performance Reports, which also include CBER data, and uses different methodology for data calculations.
2. Includes applications that were resubmitted.
3. Performance adjusted for imminent approval or tentative approval. Under the Generic Drug User Fee Amendments, FDA classifies an action as an imminent approval or tentative approval action if it is taken within 60 days of the original goal date.
4. Other tools and approaches are described in Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID-19 Public Health Emergency Questions and Answers: Guidance for Industry.
5. Drugs and biologics determined by the FDA to be regularly used in the treatment of patients with COVID-19, not necessarily treatments for COVID-19. Please visit COVID-19 Frequently Asked Questions for Information about medical products approved for the treatment of COVID-19.

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