Public Stats:
What Are They and What Do They Mean

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Office of Generic Drugs
Center for Drug Evaluation and Research
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Agenda

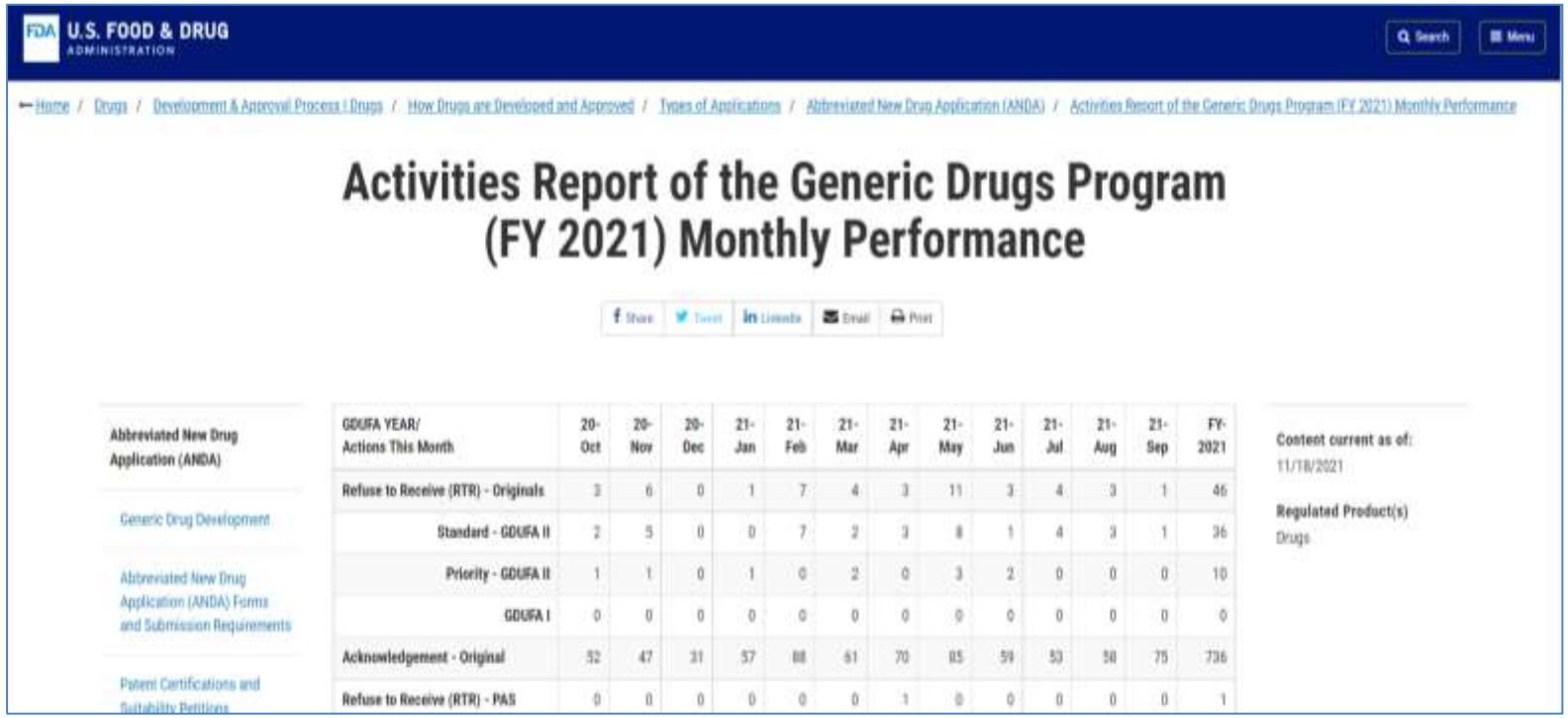
- Generic Drugs Program Activities Report - Monthly Performance
  - Bob Berger
- Activities Report of the Generic Drugs Program | GDUFA II Quarterly Performance
  - Dave Holovac
- CDER's Work to Meet User Fee Goals During the Pandemic
  - Russell Storms
- Performance Report To Congress for the Generic Drug User Fee Amendments
  - Ted Sherwood

Learning Objectives

- Understand what types of Generic Drug stats are posted for public viewing
- Know when and where the various types of Generic Drug stats are posted for public viewing
- Gain insight on what the Generic Drug stats mean

Generic Drugs Program Activities Report - Monthly Performance

Link: https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/generic-drugs-program-activities-report-monthly-performance



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Activities Report of the Generic Drugs Program (FY 2021) Monthly Performance

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Abbreviated New Drug Application (ANDA)

Generic Drug Development

Abbreviated New Drug Application (ANDA) Forms and Submission Requirements

Patent Certifications and Suitability Petitions

GDUFA YEAR/ Actions This Month	20-Oct	20-Nov	20-Dec	21-Jan	21-Feb	21-Mar	21-Apr	21-May	21-Jun	21-Jul	21-Aug	21-Sep	FY-2021
Refuse to Receive (RTR) - Originals	3	6	0	1	7	4	3	11	3	4	3	1	46
Standard - GDUFA II	2	5	0	0	7	2	3	8	1	4	3	1	36
Priority - GDUFA II	1	1	0	1	0	2	0	3	2	0	0	0	10
GDUFA I	0	0	0	0	0	0	0	0	0	0	0	0	0
Acknowledgement - Original	52	47	31	57	88	61	70	85	59	53	58	75	736
Refuse to Receive (RTR) - PAS	0	0	0	0	0	0	1	0	0	0	0	0	1

Content current as of: 11/18/2021

Regulated Product(s) Drugs

Generic Drugs Program Activities Report - Monthly Performance (cont.)

- What is contained: Wide-range of metrics covering GDUFA era
- Update Schedule:
  - Key metrics posted 1 week after month
  - Full metrics posted 5 weeks after month
- Value: monitor on a monthly basis
- Caution: fluctuations expected (e.g., natural ebb and flow, key application dates, end of fiscal years)

Generic Drugs Program Activities Report - Monthly Performance (cont.)

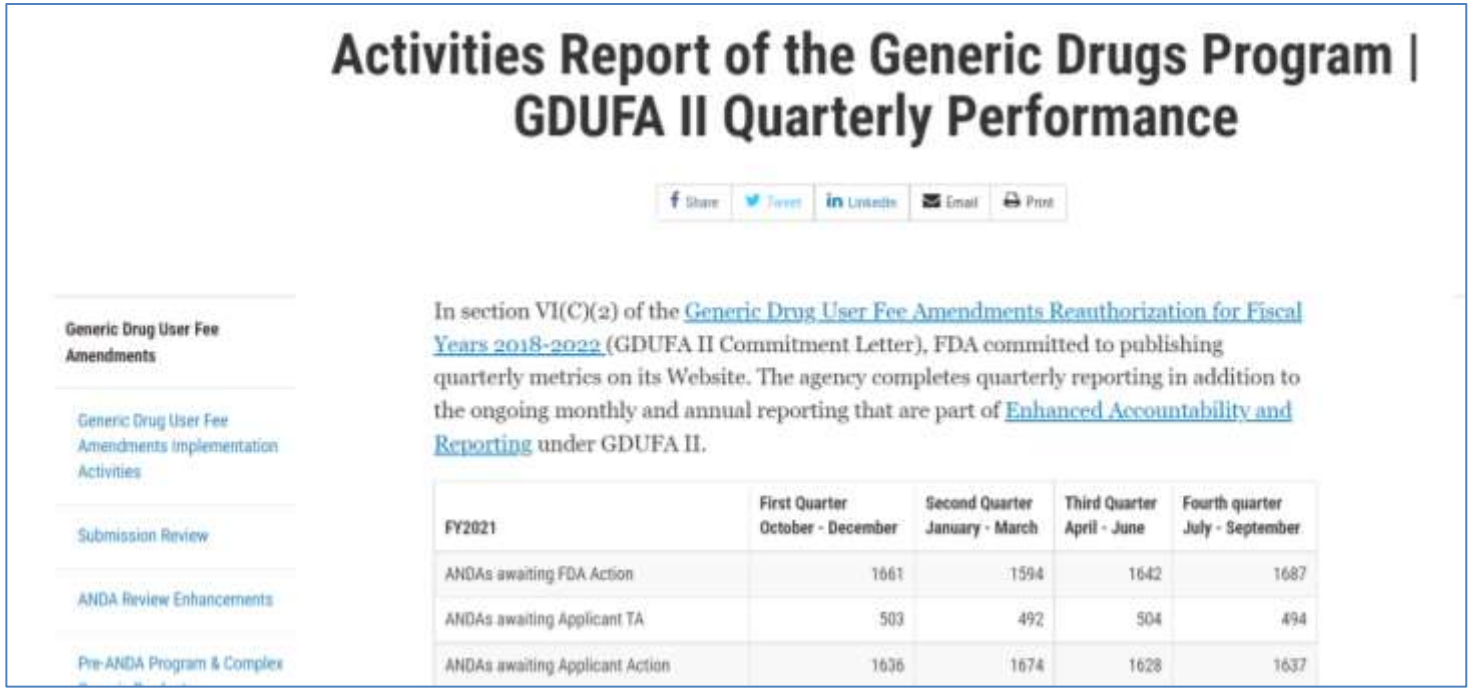
- Tips:
  - Correlation between inputs (receipts) and outputs (actions)
  - Refuse to Receive (RTRs) are at GDUFA low
    - Published filing check list
    - Industry quality control
    - Expanded use of Filing Information Requests

Generic Drugs Program Activities Report - Monthly Performance (cont.)

- Tips (cont.):
  - Underappreciated stats:
    - Hundreds of Controlled Correspondence - interest in future
    - Hundreds of Information Requests and Discipline Review Letters
      - Considerable communication with applicants beyond Complete Response Letters
      - Much of it is gratuitous
    - Hundreds of supplements: work does not stop with approval

Activities Report of the Generic Drugs Program | GDUFA II Quarterly Performance

Link: https://www.fda.gov/industry/generic-drug-user-fee-amendments/activities-report-generic-drugs-program-gdufa-ii-quarterly-performance



Activities Report of the Generic Drugs Program | GDUFA II Quarterly Performance

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Generic Drug User Fee Amendments

Generic Drug User Fee Amendments Implementation Activities

Submission Review

ANDA Review Enhancements

Pre-ANDA Program & Complex

In section VI(C)(2) of the Generic Drug User Fee Amendments Reauthorization for Fiscal Years 2018-2022 (GDUFA II Commitment Letter), FDA committed to publishing quarterly metrics on its Website. The agency completes quarterly reporting in addition to the ongoing monthly and annual reporting that are part of Enhanced Accountability and Reporting under GDUFA II.

FY2021	First Quarter October - December	Second Quarter January - March	Third Quarter April - June	Fourth quarter July - September
ANDAs awaiting FDA Action	1661	1594	1642	1687
ANDAs awaiting Applicant TA	503	492	504	494
ANDAs awaiting Applicant Action	1636	1674	1628	1637

Activities Report of the Generic Drugs Program | GDUFA II Quarterly Performance (cont.)

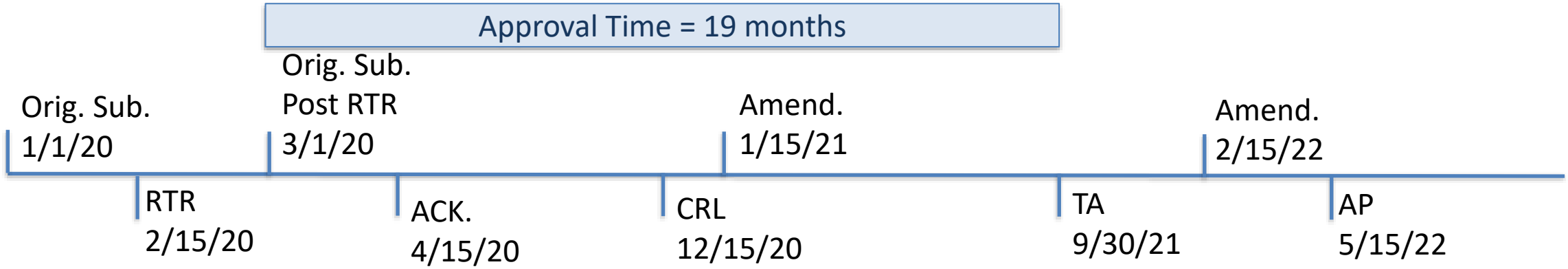
- What is contained: program level application status and approval times
- Update Schedule: 5 weeks after the quarter
- Value:
  - Monitor flow of applications
  - Approval time vs 30 months…

Activities Report of the Generic Drugs Program | GDUFA II Quarterly Performance (cont.)

- Caution:
  - Fluctuations expected (e.g., end of fiscal years and old ANDA approvals)
  - Approval time not reflective of a quality application submitted today

Activities Report of the Generic Drugs Program | GDUFA II Quarterly Performance (cont.)

- Tips:
  - ANDAs awaiting FDA Action: GDUFA low <1600 with peak at >3600
  - Approval time is calculated from the original submission that is filed/Acknowledged by the Division of Filing Review and the first Approval or Tentative Approval action taken



Challenge Question #1

One value of the Activities Report of the Generic Drugs Program | GDUFA II Quarterly Performance is:

A. Helps keep track of when seasons change
B. Monitor flow of applications
C. Provides stats on New Drug activities
D. None of the above

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

Link: https://www.fda.gov/industry/fda-user-fee-programs/cders-work-meet-user-fee-goals-during-pandemic

CDER's Work to Meet User Fee Goals During the Pandemic (cont.)

- What is contained: GDUFA goal compliance
- Update Schedule: 2 months after the quarter
- Value:
  - Impact of travel restriction
  - Shows impact of imminent approval

CDER's Work to Meet User Fee Goals During the Pandemic (cont.)

- Caution:
  - Imminent approval data lags a quarter
  - Some supplement data includes Prior Approval Supplements (PAS) and Changes Being Effected (CBE) supplements
  - Other data is PAS only
- Tips:
  - Best data on the impact of travel restrictions on issuance of a true Complete Response Letter
  - Best data on the impact of imminent approvals

Performance Report To Congress for the Generic Drug User Fee Amendments

[Link: https://www.fda.gov/about-fda/user-fee-performance-reports/gdufa-performance-reports](https://www.fda.gov/about-fda/user-fee-performance-reports/gdufa-performance-reports)

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GDUFA Performance Reports

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User Fee Performance Reports

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- GDUFA Performance Reports
- MDUFA Performance Reports
- PDUFA Performance Reports

Performance Reports

GDUFA was enacted into law on July 9, 2012, as part of the Food and Drug Administration Safety and Innovation Act (FDASIA). GDUFA was based on an agreement between FDA and the human generic drug industry, codified by Congress, to accelerate the delivery of high-quality, lower-cost human generic drugs. FDASIA authorized GDUFA for a 5-year period from October 1, 2012, through September 30, 2017. Each iteration of GDUFA has covered a five-year period. On August 18, 2017, the President signed into law the FDA Reauthorization Act of 2017 (FDARA) which included the Generic Drug User Fee Amendments of 2017 (GDUFA II).

GDUFA I (2012 to 2017)

GDUFA I enabled FDA to administer critical and measurable enhancements to the performance of the human generic drugs program and bring greater predictability and timeliness to the review of human generic drug applications. A critical component of GDUFA I was to expedite the review and approval of human generic drugs. It also established equivalency between domestic and foreign manufacturers providing human generic products to American consumers by ensuring that all facilities, located anywhere in the world, are inspected with comparable depth and rigor using risk-based approaches.

GDUFA II (2018 – 2022)

Performance Report To Congress for the Generic Drug User Fee Amendments (cont.)

GDUFA Performance Reports

Performance reports for previous years are ava

- FY 2021 GDUFA Performance Report
- FY 2020 GDUFA Performance Report
- FY 2019 GDUFA Performance Report
- FY 2018 GDUFA Performance Report
- FY 2017 GDUFA Performance Report
- FY 2016 GDUFA Performance Report
- FY 2015 GDUFA Performance Report

Performance Report To Congress for the Generic Drug User Fee Amendments (cont.)

- What is contained:
  - Achievements: stats and other activities (e.g., workshops)
  - Wide-range of stats covering GDUFA activities of all types
  - “Updated” information on prior year
  - “Preliminary” information on the recently closed year
- Update Schedule: posted several months after the fiscal year

Performance Report To Congress for the Generic Drug User Fee Amendments (cont.)

- Value:
  - Program level, yearly trend monitoring
  - Imminent approval impact

GDUFA FY 2020 Updated Review Goals by Submission Type	Review and Act on 90 % Within	Actions Complete*	Percent on Time†	Potential Range‡	On Time Imminent Approval	Imminent Approval Potential Range
Original ANDA Review						
Standard Original ANDA Submissions	10 months	667 of 684	95%	94% to 95%	97%	95% to 97%
Priority Original ANDA Submissions (if applicant meets requirements of a PFC)	8 months	31 of 31	97%	97% to 97%	97%	97% to 97%
Priority Original ANDA Submissions (if applicant does not meet requirements of a PFC)	10 months	127 of 133	97%	92% to 97%	97%	92% to 97%

Performance Report To Congress for the Generic Drug User Fee Amendments (cont.)

- Caution:
  - Fluctuations expected (e.g., natural ebb and flow)
  - Report year/recently closed year data is preliminary as many goals extend into the next fiscal year
  - Data may not always match other reports

Performance Report To Congress for the Generic Drug User Fee Amendments (cont.)

- Tips:
  - Data reflects the cohort of receipt
    - Other reports capture the cohort of action data
    - Cohort of receipts is the best indicator of what you can expect for a submission sent today
  - Common causes and trends impacting ability to meet goals

Challenge Question #2

Generic Drug stats are posted how often:

A. Monthly
B. Quarterly
C. Annually
D. All the above

Thank you!


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