



U.S. FOOD & DRUG
ADMINISTRATION

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Director

Division of User Fee Management and
Budget Formulation
Office of Management | CDER

SBIA Generic Drugs Forum
April 4, 2019

Today's Discussion

A blue speech bubble with a white border and a drop shadow.

Connect the
Dots

A green speech bubble with a white border and a drop shadow.

Program Fee
Portal

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Facilities

A blue speech bubble with a white border and a drop shadow.

Payments

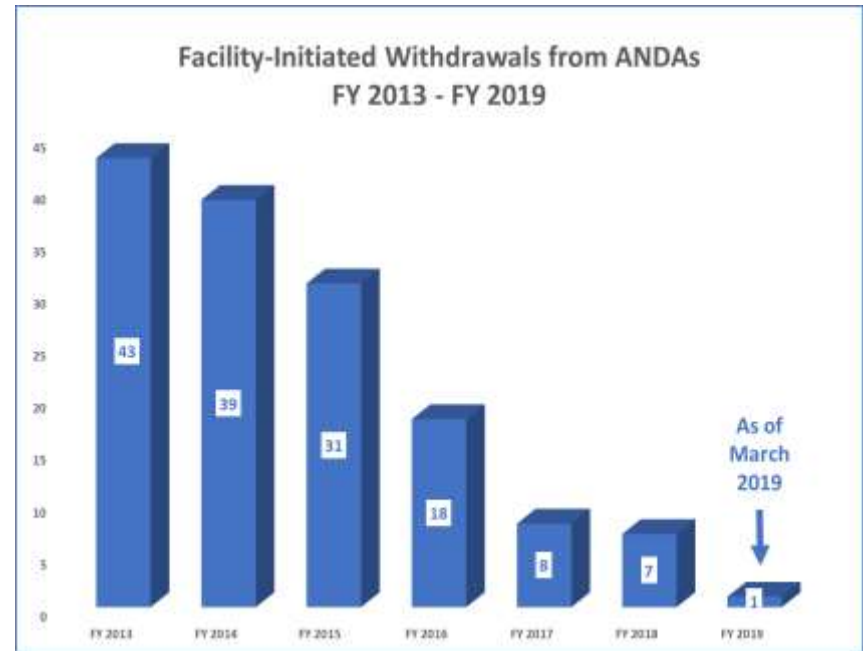
Withdrawing a Facility Reference

<u>Preferred</u> Method	Alternative Method
Amendment or post-approval notification	Self-withdrawal (for user fee purposes only)



Withdrawing a Facility Reference (con't)

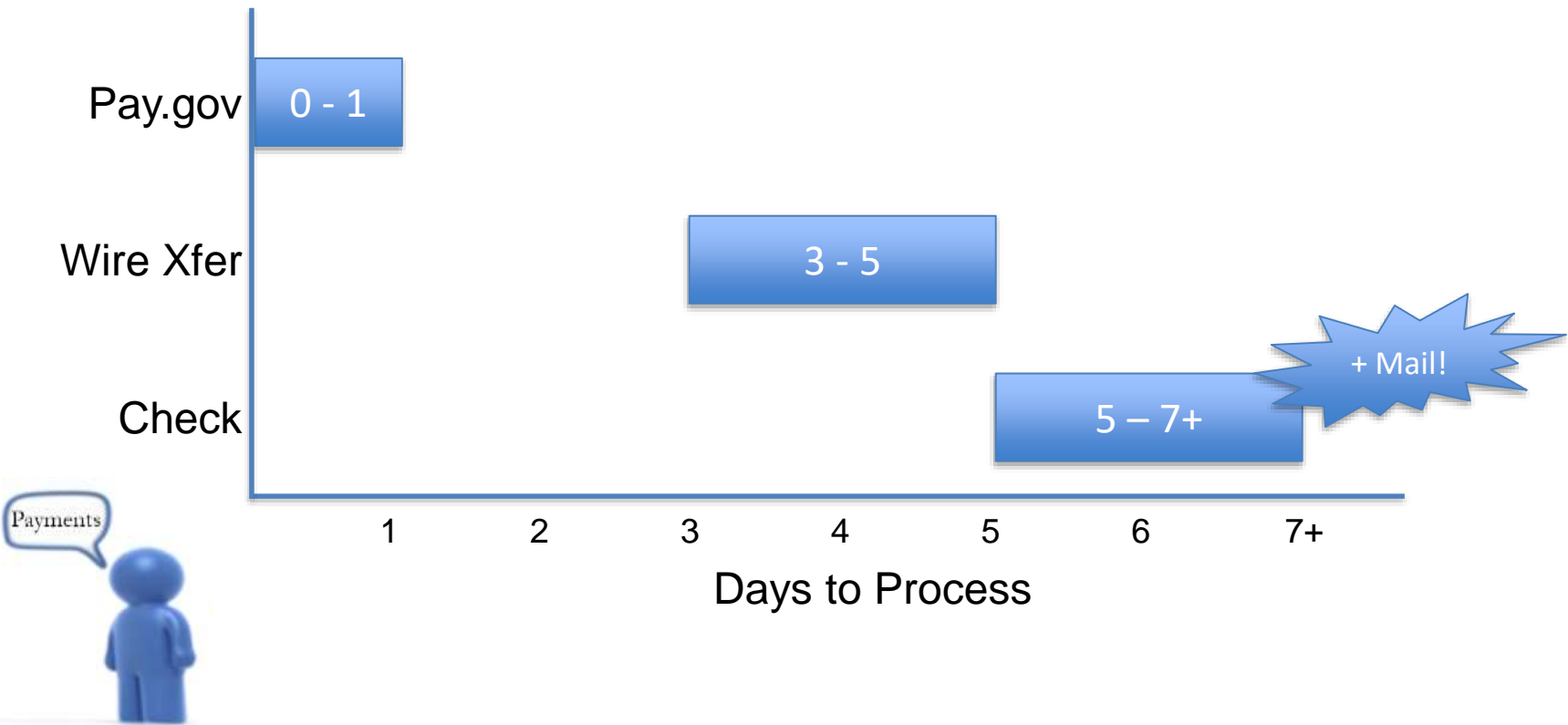
- Formerly “Q 38”
- Revised draft guidance to issue soon
- New deadline of July 1st each year



Facilities – Tracking Correctly on 356h

- Problems for sponsor
 - RTR if facility on arrears list
- Problems for facility
 - GDUFA facility fee incurred

Submitting Payments



Guessing Games



- Complete information helps us connect the dots
 - Cover sheet numbers on payments
 - Manual reconciliation process
 - May not be able to apply timely
 - Similar names can cause confusion
- Pay for someone else's location?



Connect the dots



Program Fee Portal

- Background
- Vision for Portal
- Implementation Status
 - CDER Direct NextGen Portal is live:
<https://edm.fda.gov/>



Program Fee Portal (con't)


- Known issues
 - Data inconsistencies
 - Missing parent companies
 - Un-withdrawn ANDAs
- Next steps



Reference Materials

 www.fda.gov/gdufa

 CDERCollections@fda.hhs.gov

 301.796.7900

