Public Stats and What They Mean: Office of Generic Drug Policy

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Agenda

- Review FDA Reauthorization Act of 2017 (FDARA) Title VIII Sections 807 and 805 webpage
- Discuss trends seen in the data for the FDARA Sections 807 and 805 reports
- Review Competitive Generic Therapy (CGT) Approvals webpage

FDARA Title VIII Sections 807 and 805

FDARA Title VIII Sections 807 and 805

- The FDA Reauthorization Act of 2017 (FDARA)
  - Sections 805 and 807 included reporting requirements
- Sec. 807*
  - Status of ANDAs subject to priority review
  - Status of ANDAs with CGT designation
  - Approvals of ANDAs with CGT designation for which action taken pursuant to Section 506H(c)
- Sec. 805
  - Pending suitability petitions

*Sec 807(2) and Sec 807(3) are not covered in this presentation

FDARA Title VIII Sections 807 and 805

Activities Report of the Generic Drug Program | FDARA Title VIII Sections 807 and 805

Fiscal Year 2022

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Section 807 of the FDA Reauthorization Act of 2017 (FDARA) requires the FDA to report on certain abbreviated new drug applications (ANDAs) subject to priority review under

- URL: https://www.fda.gov/industry/generic-drug-user-fee-amendments/activities-report-generic-drug-program-fdara-title-viii-sections-807-and-805
- Webpage is updated quarterly
  - January, April, July, October
- Reports are based on the status of the application at the end of the reporting quarter
- Webpage has complete data for fiscal year (FY) 2018 to FY 2021, and data for the first two quarters of 2022

ANDAs Subject to Priority Review under Section 505(j)(11)

FY 2021 ANDAs Subject to Priority Review under Section 505(j)(11)* of the FD&C Act

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	October - December	January - March	April - June	July - September
ANDAs Awaiting FDA Action	54	58	59	56
ANDAs Awaiting Applicant Action	18	19	25	31
ANDAs Approved	6	10	4	9

- ANDAs subject to priority review
  - Section 505(j)(11)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)
    - Not more than three approved and no blocking patents or exclusivities
    - Drug product on the drug shortage list
  - FD&C Act section 505(j)(11)(D), other applications determined appropriate by the Secretary (see MAPP 5240.3)

ANDAs with a Competitive Generic Therapy Designation under Section 506H of the FD&C Act

FY 2021 ANDAs with a Competitive Generic Therapy Designation under Section 506H of the FD&C Act

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	October - December	January - March	April - June	July - September
ANDAs Awaiting FDA Action	114	129	132	146
ANDAs Awaiting Applicant Action	53	55	76	75
ANDAs Approved	14	15	10	14
Number of Presubmission Meetings Requested	0	0	0	1
Number of Presubmission Meetings Held	0	0	0	0
Number of Product Development Meetings Requested	4	4	6	7
Number of Product Development Meetings Held	7	5	5	7

- Awaiting action metric is for ANDAs granted CGT designation that have been filed
- Number of meetings metric is for ANDAs granted CGT designation
  - Includes pre-ANDA meetings requested in a quarter (even if request ultimately denied) and pre-ANDA meetings held in the quarter (meetings may not be held in the same quarter they are requested)
- Some overlap with prioritization reporting metric if CGT also subject to priority review

ANDAs with a CGT Designation for which the Secretary has taken action pursuant to Section 506H(c) of the FD&C Act

- Actions under 506H(c), including meetings with applicant prior to submission (pre-submission or product development meeting)
- five examples since passage of FDARA
  - Too few approvals to conclude what effect – if any – 506H(c) had on number of review cycles or length of time for approval
    - All approved after two review cycles with shorter time to approval than mean and median approval time for the quarter in which they were approved

Pending Suitability Petitions under Section 505(j)(2)(C)

FY 2021 Pending Suitability Petitions under Section 505(j)(2) (C) of the FD&C Act*

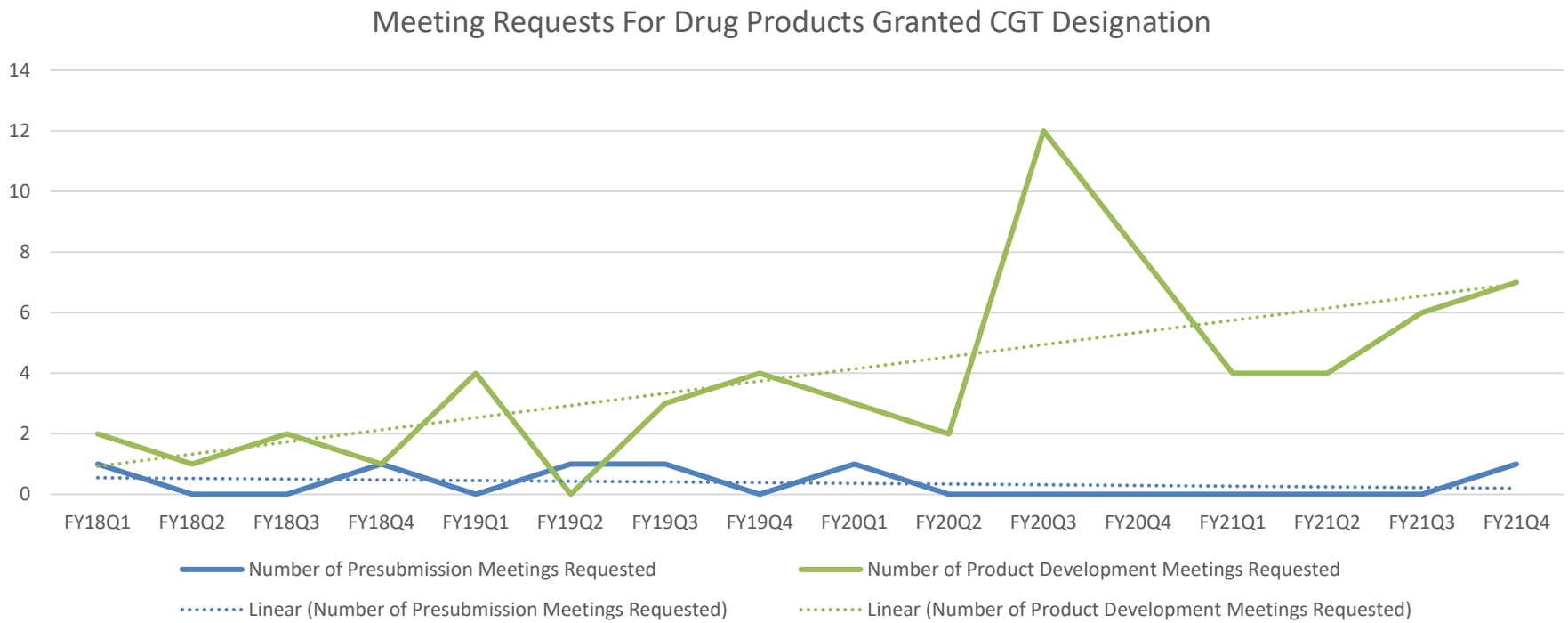
	FY 2021
Petitions Pending a Substantive FDA Response	199
Petitions Pending a Substantive FDA Response for More than 180 Days of Receipt	184

- Numbers are updated annually at the end of the FY

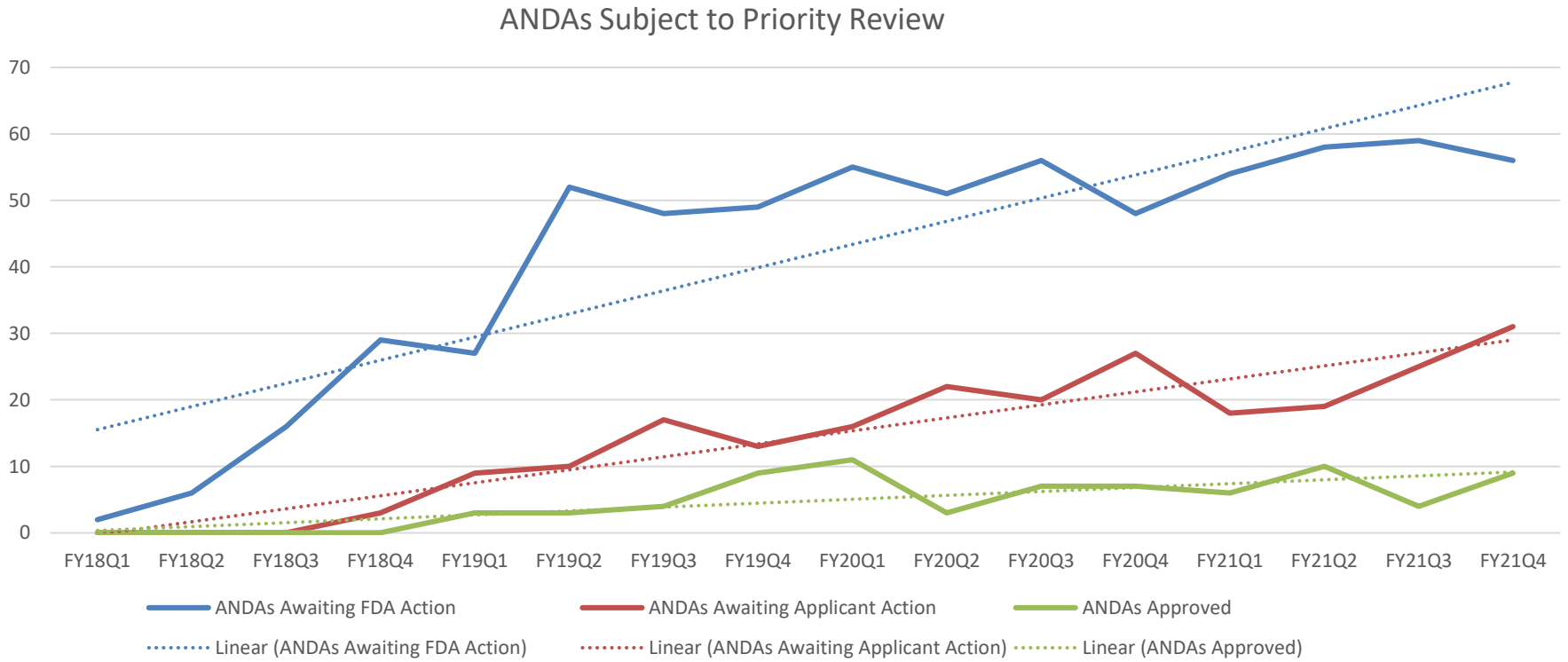
FDARA Title VIII Sections 807 and 805

- Data trends FY 2018 to FY 2021
  - Upward trend in:
    - Product development meetings for ANDAs granted CGT designation
    - ANDAs subject to priority review awaiting action
    - ANDAs granted CGT designation awaiting action

FDARA Title VIII Sections 807 and 805, Data Trends



FDARA Title VIII Sections 807 and 805, Data Trends



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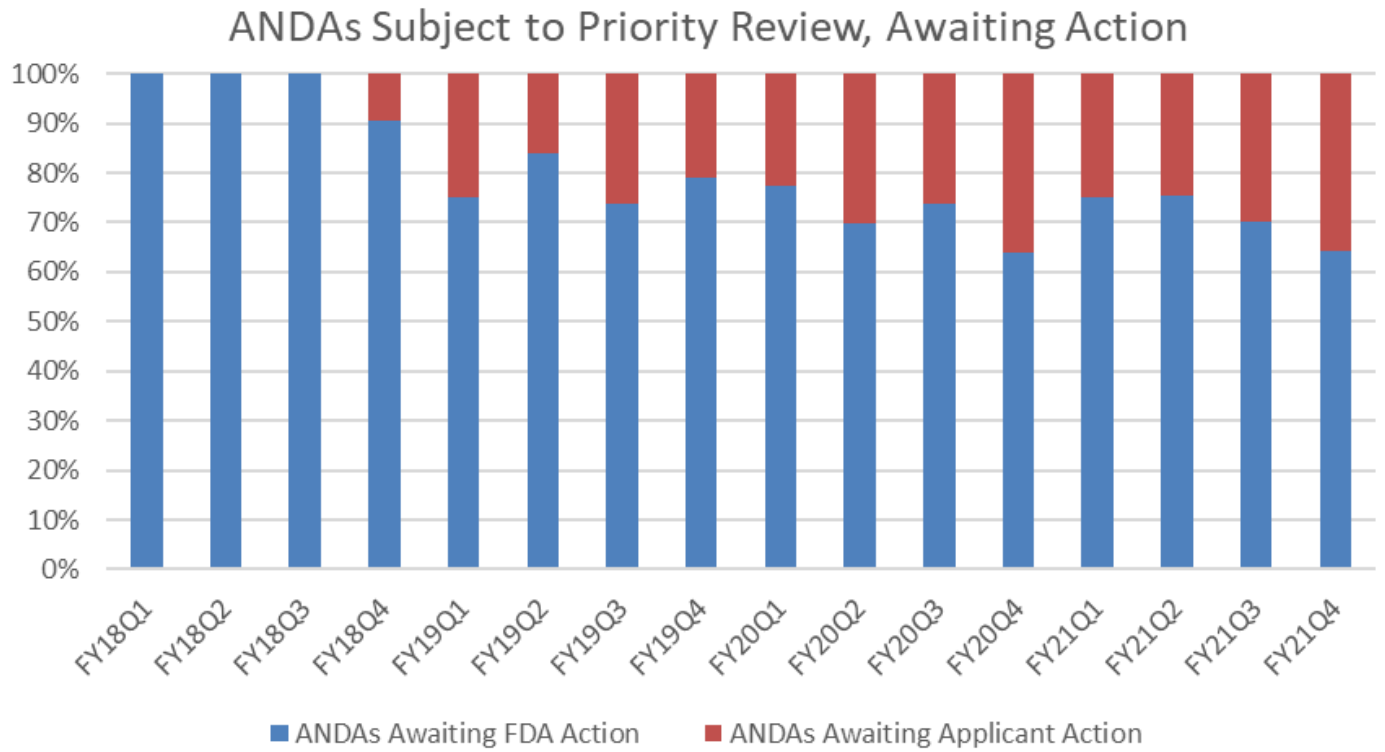

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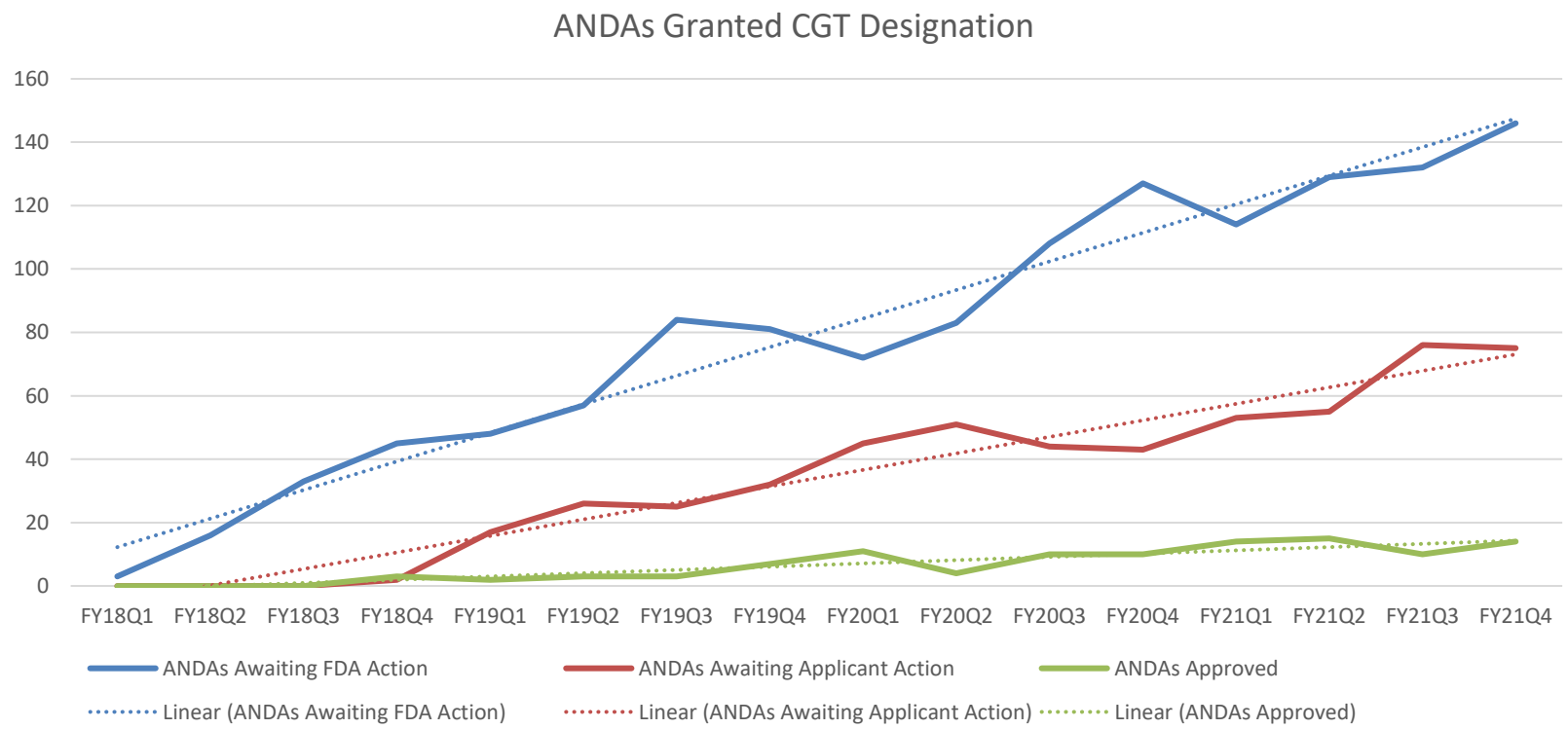

Competitive Generic Therapy Approvals

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Competitive Generic Therapy Approvals

	RLD Name and NDA Number	ANDA Number	ANDA Applicant	Active Ingredient Name, Dosage Form, Strength	Date of Approval	Eligible for CGT Exclusivity	CGT Exclusivity Forfeiture	Date of First Commercial Marketing of CGT with Exclusivity
129	Apokyn Injection NDA 021264	212025	Sage Chemical, Inc.	Apomorphine Hydrochloride Injection, 30 mg/3 mL (10 mg/mL), Single-Patient-Use Glass Cartridge	2/23/2022	Yes		
128	Veltin Gel, NDA 050803	212845	Solaris Pharma Corporation	Clindamycin Phosphate and Tretinoin Gel, 1.2%/0.025%	2/10/2022	Yes		

- URL: https://www.fda.gov/drugs/generic-drugs/competitive-generic-therapy-approvals
- Contains all approved ANDAs for products that received CGT designation
- Updated every 2 weeks
- 100+ CGT approvals since passage of FDARA

Competitive Generic Therapy Approvals

- Includes all applicants granted CGT designation, not just ‘first approved’ (or those eligible for CGT exclusivity)
- Lets you know if an ANDA has been approved with CGT designation for a drug product
- Webpage provides information on CGT exclusivity, including the date it is triggered by first commercial marketing or whether it has been forfeited

Summary

- Webpages improve transparency about the status of priority ANDAs and those granted CGT designation
- Trends since passage of FDARA show increase in number of ANDAs subject to priority review and ANDAs with CGT designation, as well as utilization of product development meetings

U.S. FOOD & DRUG ADMINISTRATION

Questions?

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