GAIN Exclusivity

Katie Schumann
Deputy Director
Division of Regulatory Policy, Office of New Drug Policy
CDER | US FDA

Orange Book Conference – October 27 - 28, 2020

Disclaimer

- This presentation reflects the views of the author and should not be construed to represent FDA's views or policies
- This presentation is intended to provide a general description of GAIN exclusivity under section 505E of the Federal Food, Drug, and Cosmetic Act
- Refer to the relevant statutory provisions regarding GAIN exclusivity in order to make regulatory related decisions

Learning Objectives

- Describe the criteria for designating a drug product as a Qualified Infectious Disease Product (QIDP)
- List the types of exclusivity that may be extended by GAIN
- Explain the impact of the GAIN exclusivity extension on ANDAs and 505(b)(2) NDAs
- Recognize how the GAIN exclusivity extension is presented in the Orange Book

GAIN Act

- Generating Antibiotic Incentives Now (GAIN) signed into law in 2012 as Title VIII of FDASIA
- Created incentives to encourage development of antibacterial and antifungal drugs for serious infections
  - Fast track designation
  - Priority review for first application
  - 5-year exclusivity extension

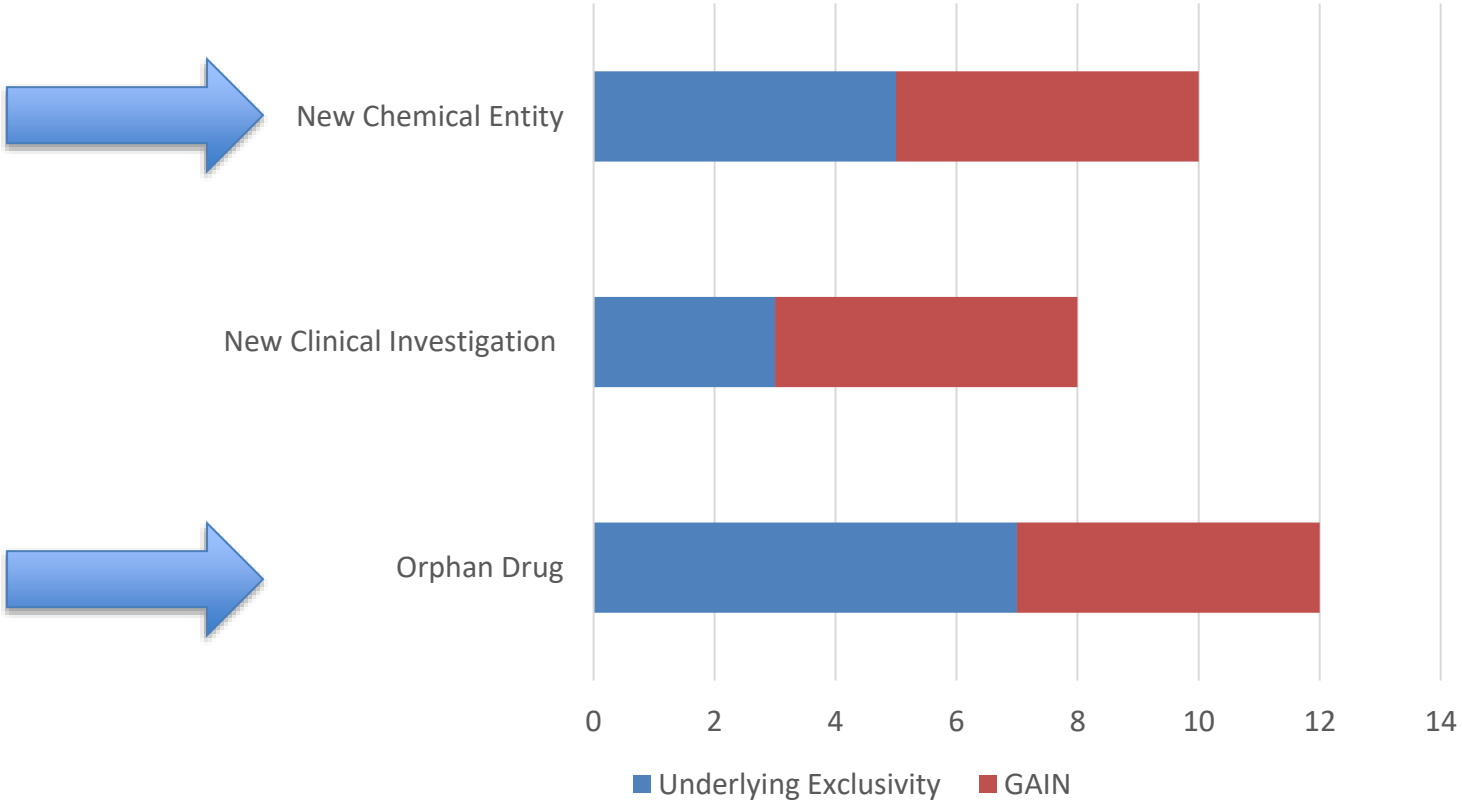
QIDP Designation

- GAIN incentives available for Qualified Infectious Disease Products (QIDPs)
- Section 505E(g) provides for designation of certain antimicrobial products as QIDPs:
  - Antibacterial or antifungal drug for human use
  - Intended to treat serious or life-threatening infections
- Applies to a specific drug product, from a specific sponsor, for a specific use for which it is being studied

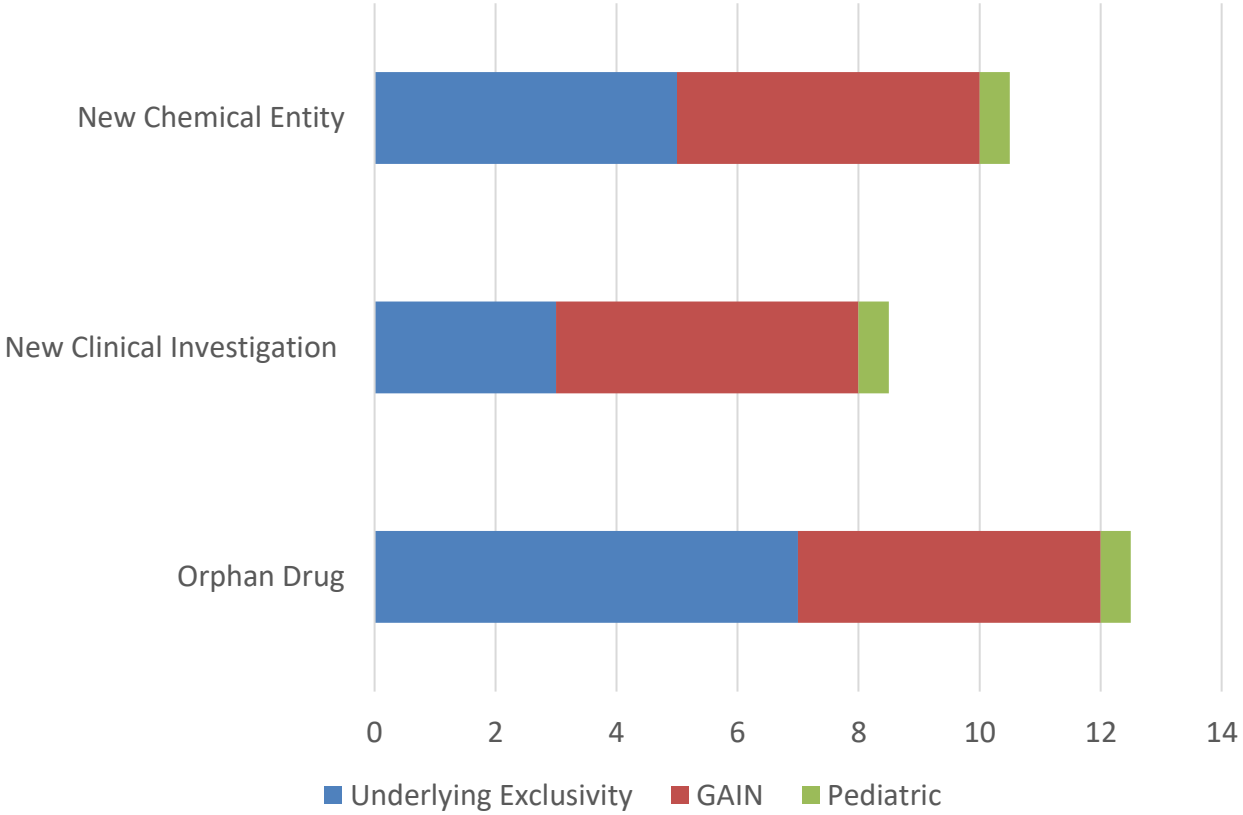
GAIN Exclusivity Extension

- A 5-year extension of any exclusivity for which an application for a QIDP qualifies for upon approval
  - New Chemical Entity (NCE) Exclusivity (5 years)
  - New Clinical Investigation Exclusivity (3 years)
  - Orphan Drug Exclusivity (ODE) (7 years)
- Assumes the scope of underlying exclusivity
- Subject to limitations described in section 505E(g)

GAIN Exclusivity Extension



GAIN Exclusivity Extension + Pediatric



GAIN Extension in the Orange Book

- Example: NDA 207500; ISAVUCONAZONIUM SULFATE (CRESEMBA) CAPSULE, 186MG

Exclusivity Data

Product No	Exclusivity Code	Exclusivity Expiration
001	NCE	03/06/2020
001	ODE-305	03/06/2022
001	ODE-90	03/06/2022
001	NCE *GAIN	03/06/2025
001	ODE-305 *GAIN	03/06/2027
001	ODE-90 *GAIN	03/06/2027

Challenge Question #1

Which of the following types of exclusivity cannot be extended by GAIN exclusivity?

A. 5-year New Chemical Entity (NCE) Exclusivity

B. 3-year New Clinical Investigation Exclusivity

C. 180-day Exclusivity

D. Orphan Drug Exclusivity (ODE)

Challenge Question #2

What is the total period for orphan drug exclusivity with a GAIN extension?

A. 8 years

B. 10 years

C. 11 years

D. 12 years

Resources

- Federal Food, Drug and Cosmetic Act – Section 505E
- Draft Guidance for Industry: Qualified Infectious Disease Product Designation — Questions and Answers
- February 2018 HHS Report to Congress on GAIN

Questions?

Katie Schumann
Deputy Director
Division of Regulatory Policy, Office of New Drug Policy
CDER | US FDA