Overview of Orange Book Exclusivity

Truong Quach, PharmD
OGD/DLRS/Orange Book
CDER | U.S. FDA

Celebrating 40 Years: An In-Depth Examination of the FDA Orange Book
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Learning Objectives

At the conclusion of this presentation, you should be able to:

- Describe the different types of exclusivity available to NDA and ANDA applicants
- Identify how the Orange Book lists information on exclusivity

What is Exclusivity for a Drug Product?

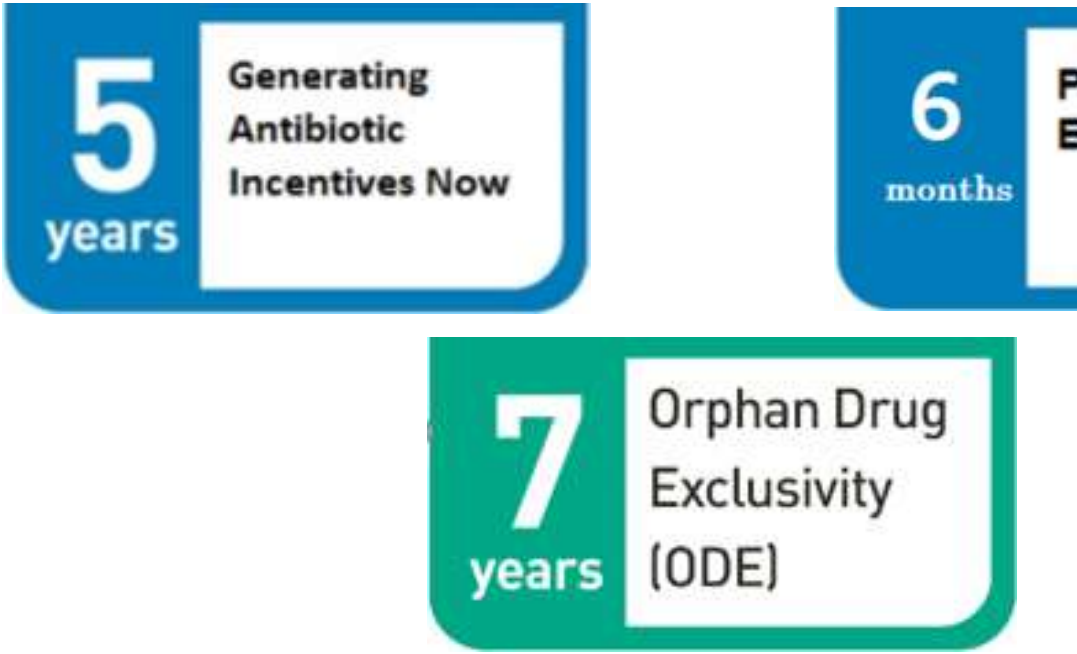
- FDA can grant periods of exclusive marketing rights to a New Drug Application (NDA) or supplemental NDA
- Exclusivity serves to delay the submission or final approval of generic or 505(b)(2) applications
- Part of the balance between new drug innovation and marketing competition
- Several types of exclusivity may be granted to an application upon approval

‡*See 21 CFR 314.108, 316.31, 316.34 and sections 505A, 505E, and 505(j)(5)(B)(iv) of the FD&C Act*

Exclusivities for New Drugs

[‡]*See 21 CFR 314.108*

Exclusivities for New Drugs



‡*See 21 CFR 314.108, Orphan Drug Act and 21 CFR 316.31*

Examples of Exclusivities in the Electronic Orange Book

Exclusivity Code	Exclusivity Expiration
NPP	09/28/2020
NCE	11/05/2020
I-812	10/03/2022
ODE-284	09/28/2024
ODE-285	09/28/2024

‡See Online Orange Book Exclusivity

Exclusivities for Generics

- Patent Challenge (PC)
- Competitive Generic Therapy (CGT)

Exclusivity Code	Exclusivity Expiration
PC	02/27/2021

Exclusivity Code	Exclusivity Expiration
CGT	04/04/2021

Exclusivity Codes with Definitions

Code	Definition
CGT	COMPETITIVE GENERIC THERAPY
D	NEW DOSING SCHEDULE (SEE INDIVIDUAL REFERENCES)
GAIN	GENERATING ANTIBIOTIC INCENTIVES NOW
I	NEW INDICATION (SEE INDIVIDUAL REFERENCES)
M	MISCELLANEOUS EXCLUSIVITY CODES (SEE INDIVIDUAL REFERENCES)
NC	NEW COMBINATION
NCE	NEW CHEMICAL ENTITY
NCE*	NEW CHEMICAL ENTITY (AN ENANTIOMER OF PREVIOUSLY APPROVED RACEMIC MIXTURE. SEE SECTION 505(U) OF THE FEDERAL FOOD AND DRUG COSMETIC ACT)
NDF	NEW DOSAGE FORM
NE	NEW ESTER OR SALT OF AN ACTIVE INGREDIENT
NP	NEW PRODUCT
NP*	NEW PRODUCT (MINT FLAVORED)
NPP	NEW PATIENT POPULATION
NR	NEW ROUTE
NS	NEW STRENGTH
ODE	ORPHAN DRUG EXCLUSIVITY
PC	PATENT CHALLENGE
PED	PEDIATRIC EXCLUSIVITY

‡See Orange Book Exclusivity Codes and Definitions

Challenge Question #1

The Orange Book uses exclusivity codes to denote the type of exclusivity being granted to an application. Which of the following is <u>not</u> an Orange Book code?

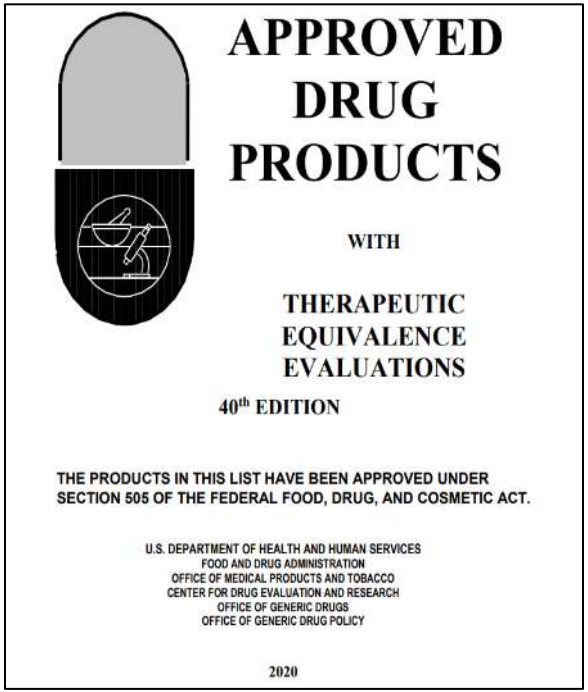
A. New Product (NP)

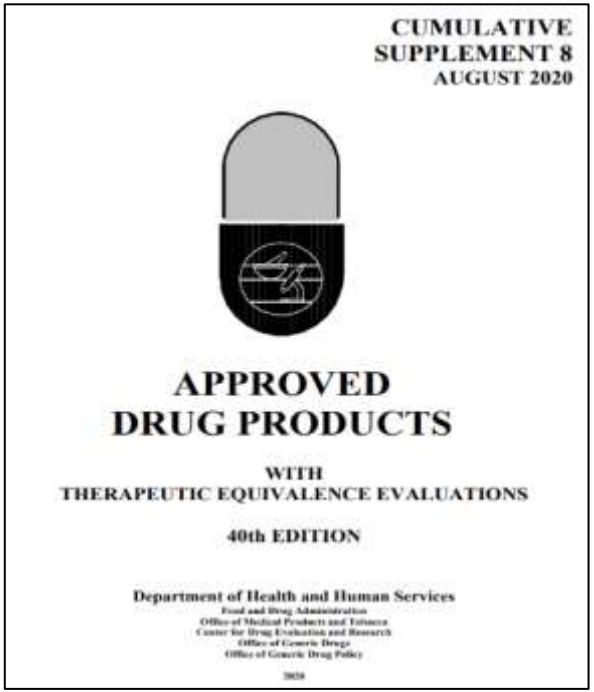
B. New Pediatric Population (NPP)

C. New Indication (I)

D. New Chemical Entity (NCE)

Orange Book Publications





[ǂSee Orange Book Publications]

Challenge Question #2

Name the types of exclusivity that may be added on to any other types of exclusivity for that application?

A. Pediatric Exclusivity

B. Orphan Drug Exclusivity

C. New Chemical Entity

D. Generating Antibiotic Incentive Now

E. A and D

Summary

- Exclusivity is a period of time when new drug product are protected from generic drug competition
- In general, exclusivity is designed to promote a balance between new drug innovation and generic drug competition
- There are different exclusivities for different situations and exclusivities are officially listed in the Orange Book

Exclusivity Questions?

Electronic Orange Book

www.fda.gov/orangebook

General Exclusivity questions can be emailed to the Orange Book mailbox

ORANGEBOOK@FDA.HHS.GOV