Using the Appropriate Business Operation(s) and Business Qualifier(s)

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Agenda

- Business Operation
- Operation Qualifier
- Appropriate Combinations
- Definitions
- Challenge Questions

Learning Objectives

- Upon completion of this presentation:
- Describe the relationship between Business Operation and Operation Qualifier
- Define the appropriate combinations
- Identify your establishment Business Operations and Qualifiers

Business Operation(s)

- Registration SPLs:
  - A registration data element which describes best the type of manufacturing activity performed at a facility
  - Facilities performing multiple operations should list **all** operations in the SPL
  - Business operations must accurately reflect what functions the facility performs
    - Used to assess certain statutory fees
    - Used for inspection planning
    - Used to access drug volume reporting requirements and compliance
    - Used for automated validations

Business Operation(s)

- Labeler Code SPLs:
  - A labeler code data element which describes best the type of distribution activity for the labeler
  - Labelers performing multiple operations including distribution, should list **all** operations in the SPL
  - Business operations must accurately reflect what functions the labeler performs:
    - Used to access assignment or rejection of labeler code requests to FDA
    - Used for automated validations

Business Operation(s)

SPL Acceptable Term	Code
ANALYSIS	C25391
API/FDF ANALYTICAL TESTING	C101509
API MANUFACTURE	C82401
CLINICAL BIOEQUIVALENCE OR BIOAVAILABILITY STUDY	C101511
DISTRIBUTES DRUG PRODUCTS UNDER OWN PRIVATE LABEL	C73608
FDF MANUFACTURE	C101510
HUMAN DRUG COMPOUNDING OUTSOURCING FACILITY	C112113
IMPORT	C73599
IN VITRO BIOEQUIVALENCE OR BIOANALYTICAL TESTING	C101512
LABEL	C84732
MANUFACTURE	C43360
MEDICATED ANIMAL FEED	C84635
MANUFACTUREhttps://www.fda.gov/industry/structured-product-labeling-resources/business-operation	
OUTSOURCING ANIMAL DRUG COMPOUNDING	C122061
PACK	C84731
PARTICLE SIZE REDUCTION	C84386
POSITRON EMISSION TOMOGRAPHY DRUG PRODUCTION	C91403
RELABEL	C73607
REPACK	C73606
SALVAGE	C70827
SIP FOREIGN SELLER	C175317
STERILIZE	C84382
THIRD-PARTY LOGISTICS PROVIDER	C118412
TRANSFILL	C125710
UNITED STATES AGENT	C73330
WHOLESALE DRUG DISTRIBUTOR	C118411

https://www.fda.gov/industry/structured-product-labeling-resources/business-operation

Business Operation Qualifier(s)

- A data element used in conjunction with each business operation
- The operation qualifier describes in detail the business operation (product type)
- Must be provided for all registration and labeler code SPLs

Business Operation Qualifier(s)

SPL Acceptable Term	Code
Compounding from bulk ingredient	C112092
Compounding sterile products	C112094
Contract manufacturing	C132491
Contract manufacturing for human over-the-counter drug products produced under a monograph	C170729
Distributes human prescription drug products	C111077
Distributes human over-the-counter drug products	C111078
Intent to compound 506E (drug shortage) drugs	C112087
Manufactures animal prescription drug products	C114889
Manufactures animal over-the-counter drug products	C114891
Manufactures animal over-the-counter Type A medicated article drug products	C114892
Manufactures human over-the-counter drug products neither produced under an approved drug application nor under a monograph	C131710
Manufactures human over-the-counter drug products produced under a monograph	C131708
Manufactures human over-the-counter drug products produced under an approved drug application	C131709
Manufactures human prescription drug products	C106643
Manufactures Non-Generics	C101886
Manufactures veterinary feed directive Type A medicated article drug products	C114890
No intent to compound 506E (drug shortage) drugs	C112091
Not compounding from bulk ingredient	C112093
Not compounding sterile products	C112095
Transfills Medical Gas	C126091
Warehouses human prescription drug products	C123274

https://www.fda.gov/industry/structured-product-labeling-resources/business-operation-qualifier

Appropriate Combinations

- Not all business operations or operation qualifiers are appropriate for establishment registration and drug listing under Section 510 of the FD&C Act.
- Available options depends on the submission tool, but in CDER Direct, you will only have the applicable list in the dropdown.
- Choosing the incorrect business operation or operation qualifier can lead to an automated validation error:
  - Example: Distributes Drug Products Under Own Private Label BO with Manufacture Human Prescription Drug Products

Definitions

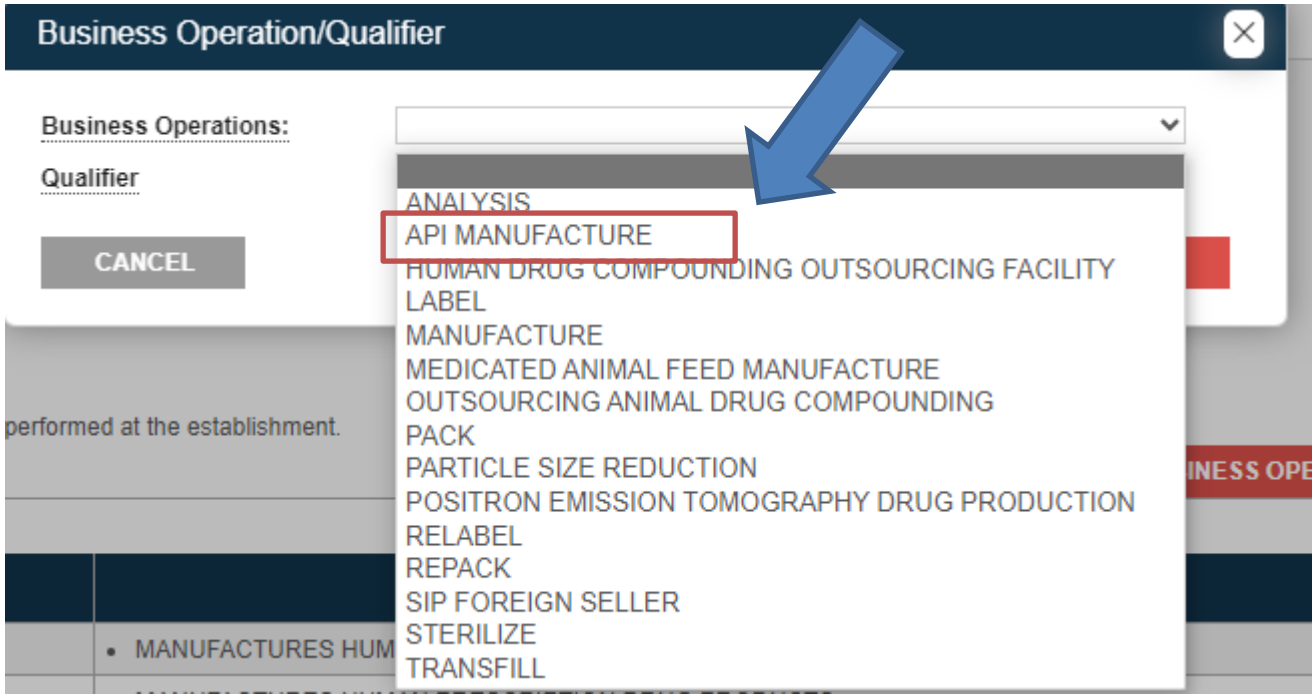
- Certain terms are defined under Section 510 of the FD&C Act and Part 207 of 21 Code of Federal Regulations.
- Some definitions are included in NCI Thesaurus.
- Terms “Pack” and “Label” were created for entities that perform the packaging and labeling part of the manufacturing process under contract.

Challenge Question

A foreign establishment has registered in CDER Direct as an API manufacture. The establishment develops human prescription drugs.

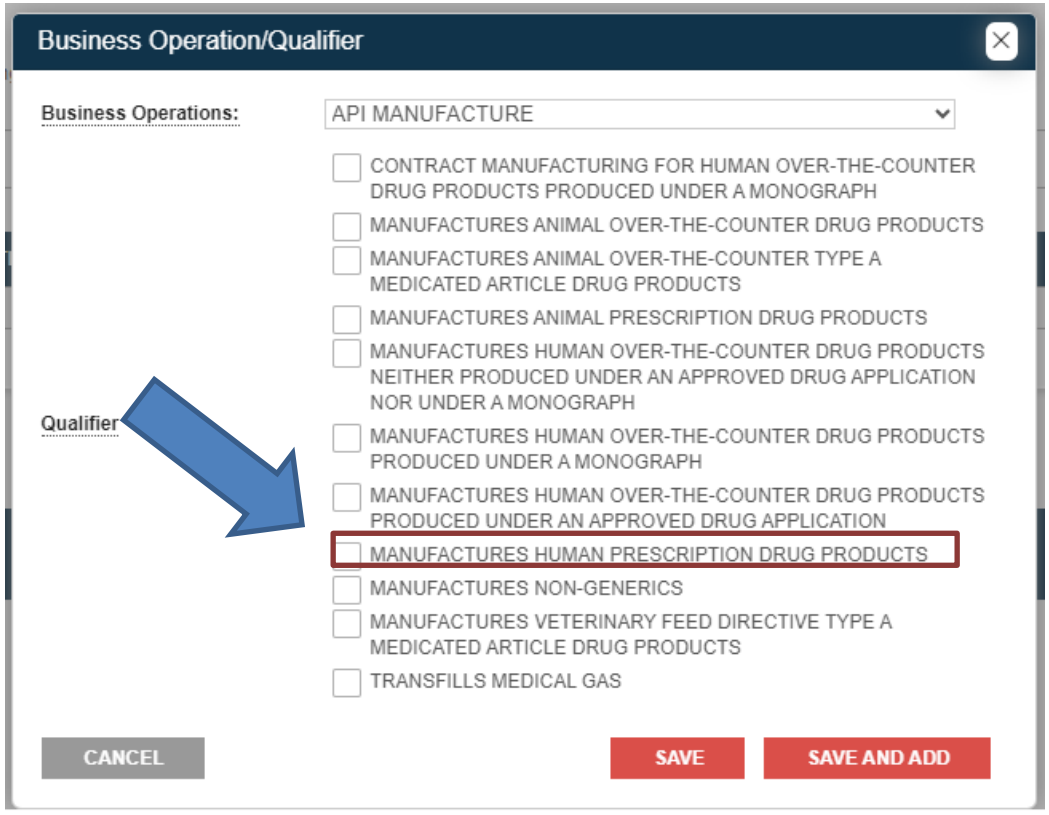
What will the business operation be?

Challenge Question



Challenge Question

The Business Operation Qualifier will be…



Challenge Question

Business operations must accurately reflect what functions the facility performs such as:

A) Asses certain statutory fees
B) Inspection planning
C) Access drug volume reporting requirements and compliance
D) Automated validations
E) All of the above

Questions?

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