LICENSED NON-BLOOD
BIOLOGICAL PRODUCT DEVIATION CODES
FY16

CBER enters the fourth level detail code (e.g., A, B, C) into the database as standardized remarks to further describe some of the codes, in particular miscellaneous codes. These codes are not included on the BPD report form.

IM-**-** INCOMING MATERIAL SPECIFICATIONS

IM-10-** Miscellaneous
- IM-10-01 Other

IM-12-** Container
- IM-12-01 Specifications not met
- IM-12-02 Defective

IM-13-** Closures
- IM-13-01 Specifications not met
- IM-13-02 Defective

IM-14-** Source or raw material does not meet specifications or otherwise found to be unsuitable
- IM-14-01 Other
  - A - Source material collected from donor who traveled to vCJD risk area
  - B - Source material collected from donor who was diagnosed with CJD
  - C - Source material collected from donor who was at risk for vCJD - family history
  - D - Source material collected from donor who tested positive for a viral marker
- IM-14-02 Contains precipitate/particle
- IM-14-03 Contaminated with microorganism
- IM-14-04 Contaminated with mold
- IM-14-05 Impurities exceed specification
- IM-14-06 Testing deviation
- IM-14-07 Stored or shipped at incorrect temperature or lack of controlled temperature

PC-**-** PROCESS CONTROLS

PC-20-** Miscellaneous
- PC-20-01 Other

PC-21-** Manufacturing or processing performed using incorrect parameters
- PC-21-01 Other
- PC-21-02 Incorrect temperature
- PC-21-03 Filling not performed according to specifications
- PC-21-04 Aseptic processing not performed according to procedures

PC-22-** Process/Procedure

PC-22-01 Other
PC-22-02 Interruption of process
PC-22-03 Environmental monitoring excursions; environmental monitoring not performed or performed incorrectly
PC-22-04 Equipment not performing properly
PC-22-05 Sanitization procedures not performed or performed incorrectly
PC-22-06 Media fill failure or media fill performed incorrectly

PC-23-** Process Water - specification not met
PC-23-01 Other
PC-23-02 Water for injection
PC-23-03 Purified water

PC-24-** Bulk or intermediate material does not meet specifications or otherwise found to be unsuitable
PC-24-01 Other
PC-24-02 Contains precipitate/particle
PC-24-03 Contaminated with microorganism
PC-24-04 Contaminated with mold
PC-24-05 Impurities exceed specification
PC-24-06 Stored at incorrect temperature
PC-24-07 Stored for an excessive hold time

TE--** TESTING**
TE-30-** Miscellaneous
TE-30-01 Other

TE-31-** Safety
TE-31-01 Performed incorrectly
TE-31-02 Not performed or not documented

TE-32-** Purity
TE-32-01 Performed incorrectly
TE-32-02 Not performed or not documented

TE-33-** Potency
TE-33-01 Performed incorrectly
TE-33-02 Not performed or not documented

TE-34-** Sterility
TE-34-01 Performed incorrectly
TE-34-02 Not performed or not documented

TE-35-** Identity
TE-35-01 Performed incorrectly
TE-35-02 Not performed or not documented

TE-36-** Stability
TE-36-01 Performed incorrectly
TE-36-02 Not performed or not documented

LA--** LABELING**

LA-40-** Miscellaneous
LA-40-01 Other

LA-41-** Package insert
LA-41-01 Incorrect/illegible
LA-41-02 Missing
LA-41-03 Not current or approved

LA-42-** Product label
LA-42-01 Incorrect/illegible
A – Recipient identification
LA-42-02 Missing

LA-43-** Carton label
LA-43-01 Incorrect/illegible
LA-43-02 Missing

LA-44-** Expiration date
LA-44-01 Extended/illegible
LA-44-02 Missing

LA-45-** Lot number
LA-45-01 Incorrect/illegible
LA-45-02 Missing

LA-46-** Storage temperature
LA-46-01 Incorrect/illegible
LA-46-02 Missing

LA-47-** Administration route
LA-47-01 Incorrect/illegible
LA-47-02 Missing

LA-48-** Concentration or volume
LA-48-01 Incorrect/illegible
LA-48-02 Missing

LA-49-** Multiple information *{e.g., lot number and expiration date}*
LA-49-01 Incorrect/illegible
LA-49-02 Missing

A - Expiration date and lot number

PS--** PRODUCT SPECIFICATIONS**

PS-50-** Miscellaneous
PS-50-01 Other

PS-51-** Product specification not met
PS-51-01 Other
PS-51-02 Contains precipitate
PS-51-03 Contaminated with microorganism
PS-51-04 Contaminated with mold
PS-51-05 Impurity levels
PS-51-06 Moisture
PS-51-07 Preservative content
PS-51-08 Potency
PS-51-09 Appearance
A - Cloudy
B - Hemolyzed
C - Foreign object/particle
PS-51-10 Fill volume
PS-51-11 Container closure not secure or damaged *{includes reports of complaints of leaking vials due to loose cap; missing stoppers; damaged or incomplete seals that may be associated with manufacturing}*
PS-51-12 Unexpected positive, negative, or weak reactions in testing

PS-52-**Component packaged with final product did not meet specifications
PS-52-01 Other
PS-52-02 Contains precipitate/particle
PS-52-03 Contaminated with microorganism
PS-52-04 Contaminated with mold
PS-52-05 Fill volume
PS-52-06 Broken/cracked vial

PS-53-** Stability testing failed
PS-53-01 Other
PS-53-02 Potency
PS-53-03 Preservative
PS-53-04 Container closure integrity
PS-53-05 Chemical analysis/purity
PS-53-06 Moisture
PS-53-07 pH
PS-53-08 Appearance

PS-54-** Administration set (packaged with product) incorrect or incomplete
PS-54-01 Other
PS-54-02 Incorrect or missing label

PS-54-03 Defective
PS-54-04 Expired

QC--** QUALITY CONTROL AND DISTRIBUTION**

QC-60-** Miscellaneous
QC-60-01 Other

QC-61-** Product distributed inappropriately
QC-61-01 Other
QC-61-02 Product distributed prior to completion of required testing
QC-61-03 Product distributed prior to CBER approval of a PAS
QC-61-04 Product distributed less than 30 days after submission of CBE-30 or prior to submission of CBE-30
QC-61-05 Product distributed prior to validation of process
QC-61-06 Outdated product distributed
QC-61-07 Product distributed prior to release by the quality control unit

QC-62-** Shipping and storage
QC-62-01 Other
QC-62-02 Product shipped at incorrect temperature
QC-62-03 Product stored at incorrect temperature
QC-62-04 No documentation product was shipped or stored at appropriate temperature

QC-63-** Product identified as unacceptable, and not quarantined
QC-63-01 Other

QC-64-** Packing
QC-64-01 Other
QC-64-02 Vial missing
QC-64-03 Packaged incorrectly
QC-64-04 Broken or cracked vial/syringe
QC-64-05 Improper orientation (e.g., sideways)

MI--** MISCELLANEOUS**

MI-70-** Miscellaneous
MI-70-01 Other
MI-70-02 Leaking vial/container; not confirmed or cause of leak cannot be determined *{includes complaints that are not confirmed or cause of leak cannot be determined}*