Additional eCTD instructions for former NDAs that were deemed to be BLAs on March 23, 2020

On March 23, 2020, the Biologics Price Competition and Innovation Act of 2009 required that an approved application for a "biological product" under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) be deemed to be a license for the biological product (i.e., an approved Biologics License Application (BLA)) under section 351 of the Public Health Service Act (PHS Act).

We are providing the additional instructions below to facilitate the initial eCTD submissions to such deemed BLAs on or after March 23, 2020.

Transitioning from NDA eCTD to BLA eCTD using us-regional v2.01

When transitioning from NDA eCTD to BLA eCTD, the initial BLA eCTD submission should be coded according to its corresponding current regulatory activity. For example, if the current regulatory activity of the initial BLA eCTD submission relates to a supplement or annual report (including either an amendment to an existing supplement/annual report or a new supplement/annual report), code the initial BLA eCTD submission as the appropriate supplement type (e.g., labeling supplement) or as annual report.

Example: BLA 123456 was former NDA 123456, which had a Labeling Supplement that was pending at the time the former NDA was deemed to be a BLA. How should the Application holder submit an amendment to the pending supplement?

If this is the first BLA eCTD submission made to the pending supplement, use the following eCTD submission type:

eCTD Application number = the same application number as the former NDA
eCTD Application Type = "BLA"
eCTD submission type = "labeling-supplement"
eCTD sequence number = continue sequence numbering used from the last eCTD submission to the former NDA (if last sequence number under the former NDA was 0300, then use 0301 here)
NOTE: Sponsor will still select "amendment" on the 356h Fillable Form

Once the initial eCTD submission is made to the BLA Supplement, future eCTD submissions to that Supplement would use:

eCTD submission type = "amendment"
eCTD sequence number = next available (i.e. 0302)
If eCTD Publishing Software asks for a related sequence number, then 0301 would be populated.

Transitioning from NDA eCTD to BLA eCTD using us-regional v3.3

The initial BLA eCTD submission utilizing us-regional v3.3 should be coded according to its corresponding current regulatory activity. The submission-id for the initial BLA eCTD submission should match its sequence number. For the initial BLA eCTD submission the submission type and subtype should be coded according to its corresponding current regulatory activity. For example, if the current regulatory

activity of the initial BLA eCTD submission relates to a supplement or annual report (either existing or new), the submission type and subtype should be coded with the appropriate supplement type (e.g., submission-type = labeling supplement/ submission-subtype = application) or as an annual report (e.g., submission-type = annual report / submission-subtype = report).

Example: BLA 123456 was former NDA 123456, which had a Labeling Supplement that was pending at the time the former NDA was deemed to be a BLA. How should the Sponsor submit an amendment to the pending supplement ?

If this is the first BLA eCTD submission made to the pending supplement, use the following eCTD submission type.
eCTD Application number = the same application number as the former NDA
eCTD Application Type = "BLA"
eCTD submission type = "Labeling Supplement"
eCTD submission subtype = "Application"
eCTD sequence number = continue sequence numbering used from the last NDA eCTD submission to the former NDA (if last sequence number under the former NDA was 0300, then use 0301 here)
eCTD submission-id number = same as sequence number (0301 in this example)
NOTE: Sponsor will still select "amendment" on the 356h Fillable Form

Once the initial eCTD submission is made to the BLA Supplement, future eCTD submissions to that Supplement would use:
eCTD submission type = "Labeling Supplement"
eCTD submission subtype = "Amendment"
eCTD submission-id number = sequence number that started this BLA eCTD Supplement (0301 in this example)
eCTD sequence number = next available (i.e. 0302)