FDA Disclaimer

The views and opinions presented here represent those of the speaker and should not be considered to represent advice or guidance on behalf of the U.S. Food and Drug Administration.

eCTD

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April 4, 2017

Poll Question

How would you characterize your ability to submit your ANDA in proper eCTD format?

Topics Covered

- Important Submission Deadlines
- Gateway Acknowledgements
- Where Submission Issues Occur

Deadlines for Required eCTD Submission

- **May 5, 2017:** ANDAs must be in eCTD format
- Do not send Paper and/or non-eCTD submissions after these deadlines!

Deadlines for Required eCTD Submission

- Exemptions are outlined in the guidance
- Submissions that do not adhere to the requirements stated in the eCTD Guidance will be **not be filed or received**
- Please see the eCTD web page www.fda.gov/ectd for further information

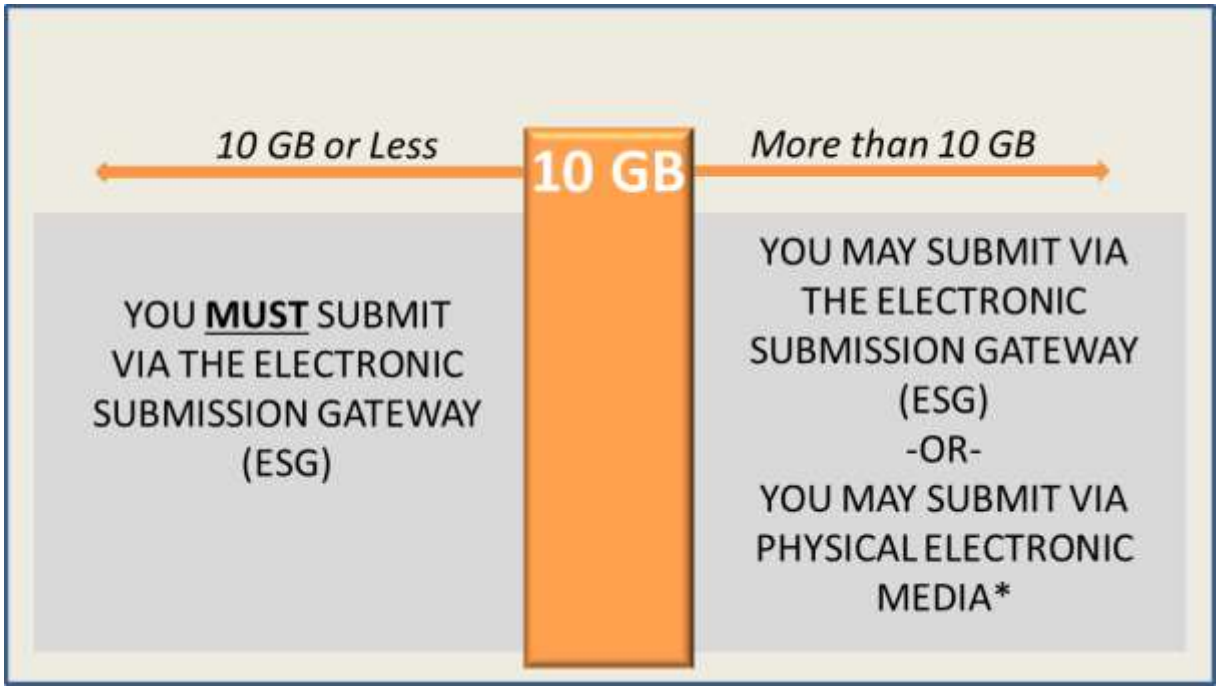
What Else?

- ✓Must use Fillable Forms & Electronic Signatures within those forms
- ✓Must use correct Lifecycle operators
  - Use the “Replace” lifecycle operator when updating content

What Else?

- ✓ Must use Gateway for submissions 10GB and smaller

  Submissions larger than 10GB may come via the Gateway or USB drive



*See Transmission Specification for additional details

Deadlines for Standardized Study data

- Studies that start after December 17, 2016 must be in standardized format for ANDA submissions

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Deadlines for Standardized Study Data

- **What** is the new requirement?
  - Studies that start after **December 17, 2016** must be in standardized format for ANDA submissions
  - See the Study Data Standards Resources page for more information

    http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm

- **How** will we enforce it?
  - Technical Rejection Criteria for Study Data
  - Specifications for eCTD Validation Criteria

    http://www.fda.gov/ectd

Deadlines for Standardized Study Data

- **When** will we starting enforcing it?

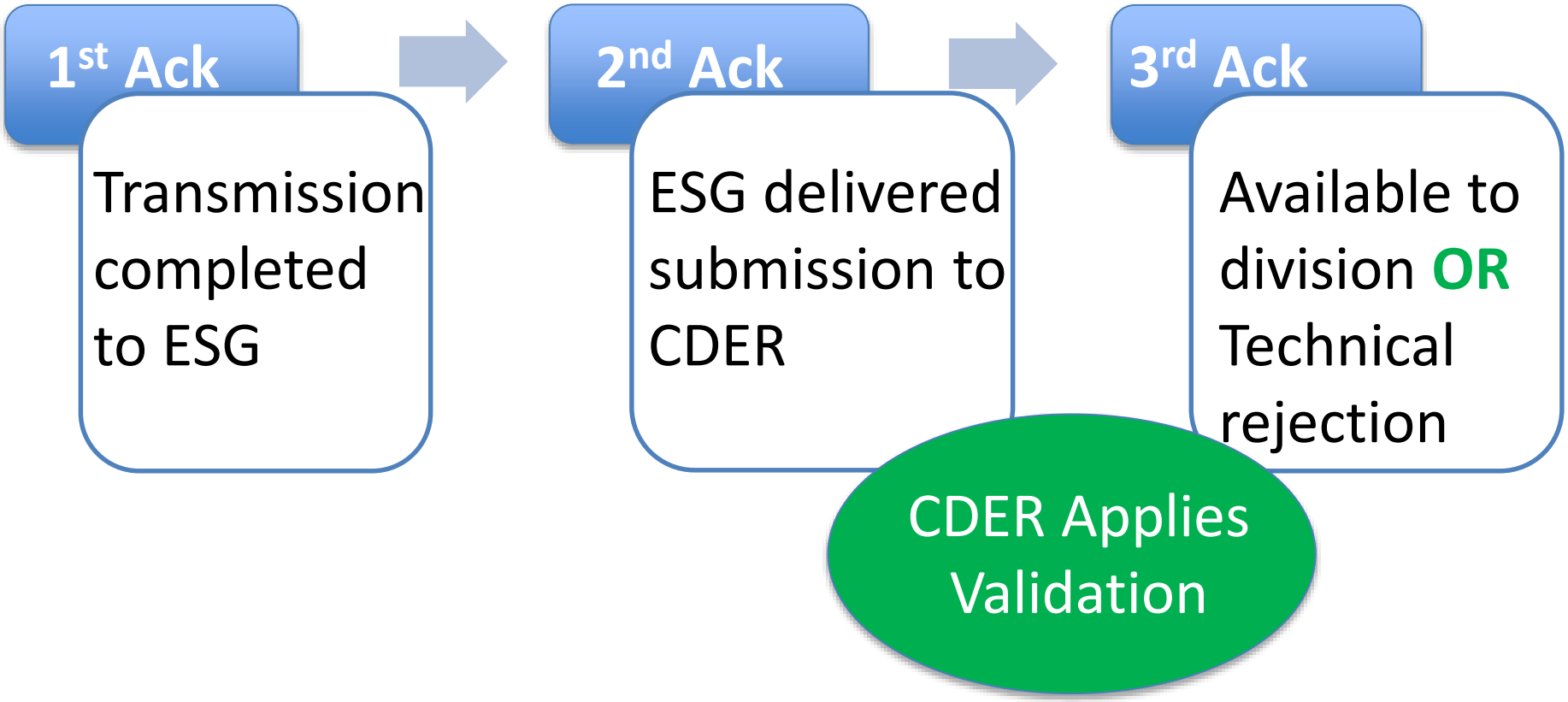
  CDER will start using the new validation criteria later this year

- **Where** can I find the guidance?

  https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM292334.pdf

- Have Questions? Contact eData@fda.hhs.gov

Gateway Acknowledgements



CDER Gateway Successful 3rd Acknowledgement

- Began May 31, 2016
- Applies only to NDA, ANDA, BLA, IND or DMF submissions
- Sent when the submission is validated and ready for division's review

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CDER Gateway Successful 3rd Acknowledgement

- This is in addition to the ESG Message Delivery Notification acknowledgement (first acknowledgement) and the Official Center acknowledgement (second acknowledgement)
- May be delayed if your submission fails validation and needs manual processing

Where Submission Issues Occur

- Transmission to ESG is unsuccessful – 1st Acknowledgement
- CDER runs technical validation on submission and it fails – after 2nd Acknowledgement
- Division of Filing Review finds issues with content of application – after 3rd Acknowledgement

Summary

- Important Submission Deadlines
  - **ANDAs Must be Submitted in eCTD Format May 5, 2017**
- Gateway Acknowledgements (three of them!)
  - **When** you receive them, **What** they mean
- Where Submission Issues Occur
  - **ESG Processing. CDER Processing. Division of Filing Review.**

Thank You

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