DIA 2016

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The Pennsylvania Convention Center

Electronic Submissions Update

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A GATHERING OF GLOBAL PERSPECTIVES

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TOPICS COVERED

1. Important Submission Deadlines
2. Submission Metrics and Recent Milestones
3. Plans for FY2016-17

DEADLINES FOR REQUIRED ECTD SUBMISSION

- **May 5, 2017:** NDA, BLA, ANDA and DMFs must be in eCTD format

- **May 5, 2018:** Commercial INDs 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 Gateway for submissions 10GB and smaller – no more CD/DVDs
  - ✓Submissions larger than 10GB may come via the Gateway or USB drive
- ✓Must use Fillable Forms & Electronic Signatures within those forms
- ✓Must use correct Lifecycle operators
  - ✓Do not send the same study data over and over

DEADLINES FOR STANDARDIZED STUDY DATA

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

- For IND submissions, the date is December 17, 2017

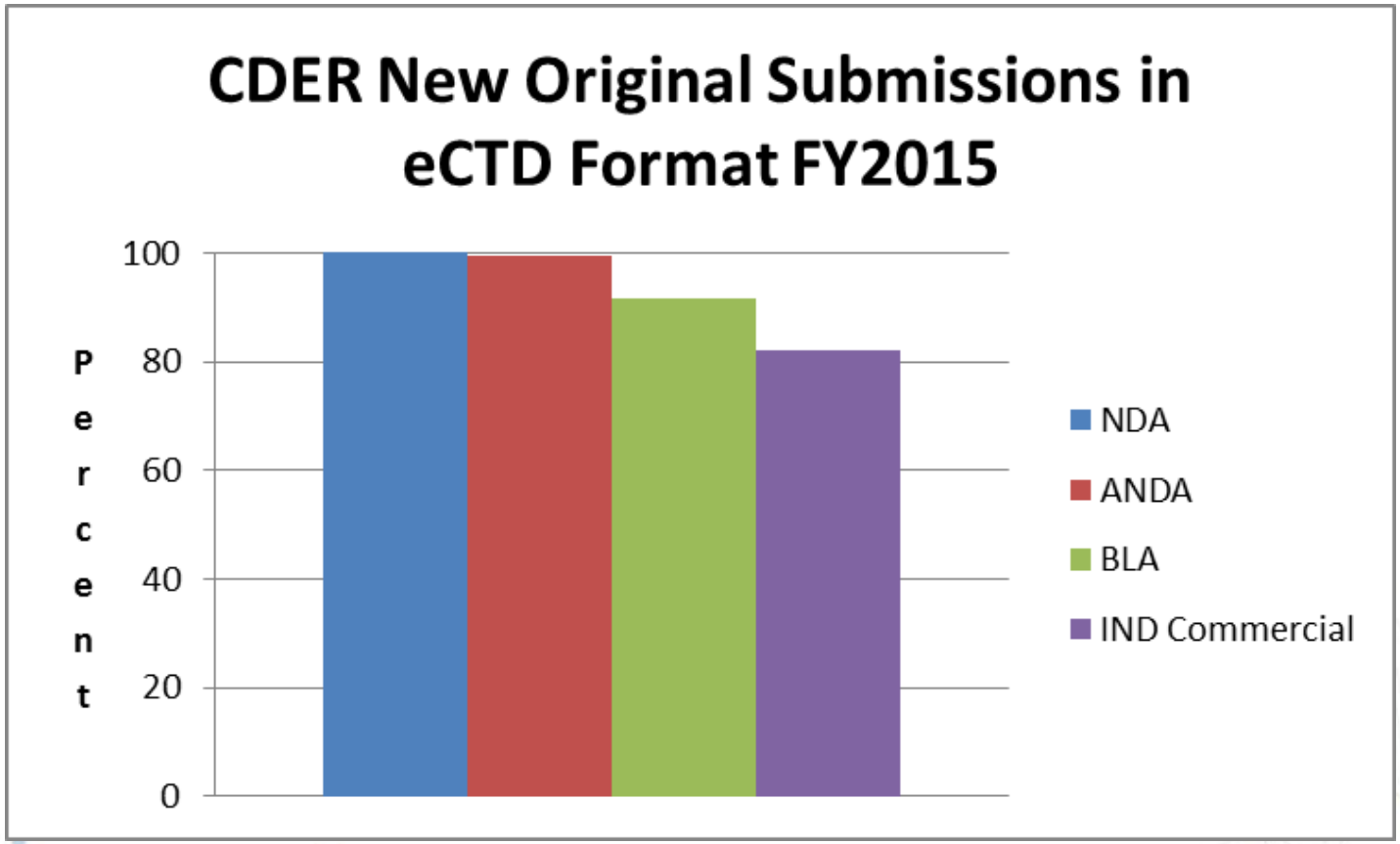
CDER FY2016 SUBMISSION METRICS (10/1/2015 – 6/24/2016)

Number and Percent of Submissions by Delivery Description and Application Type

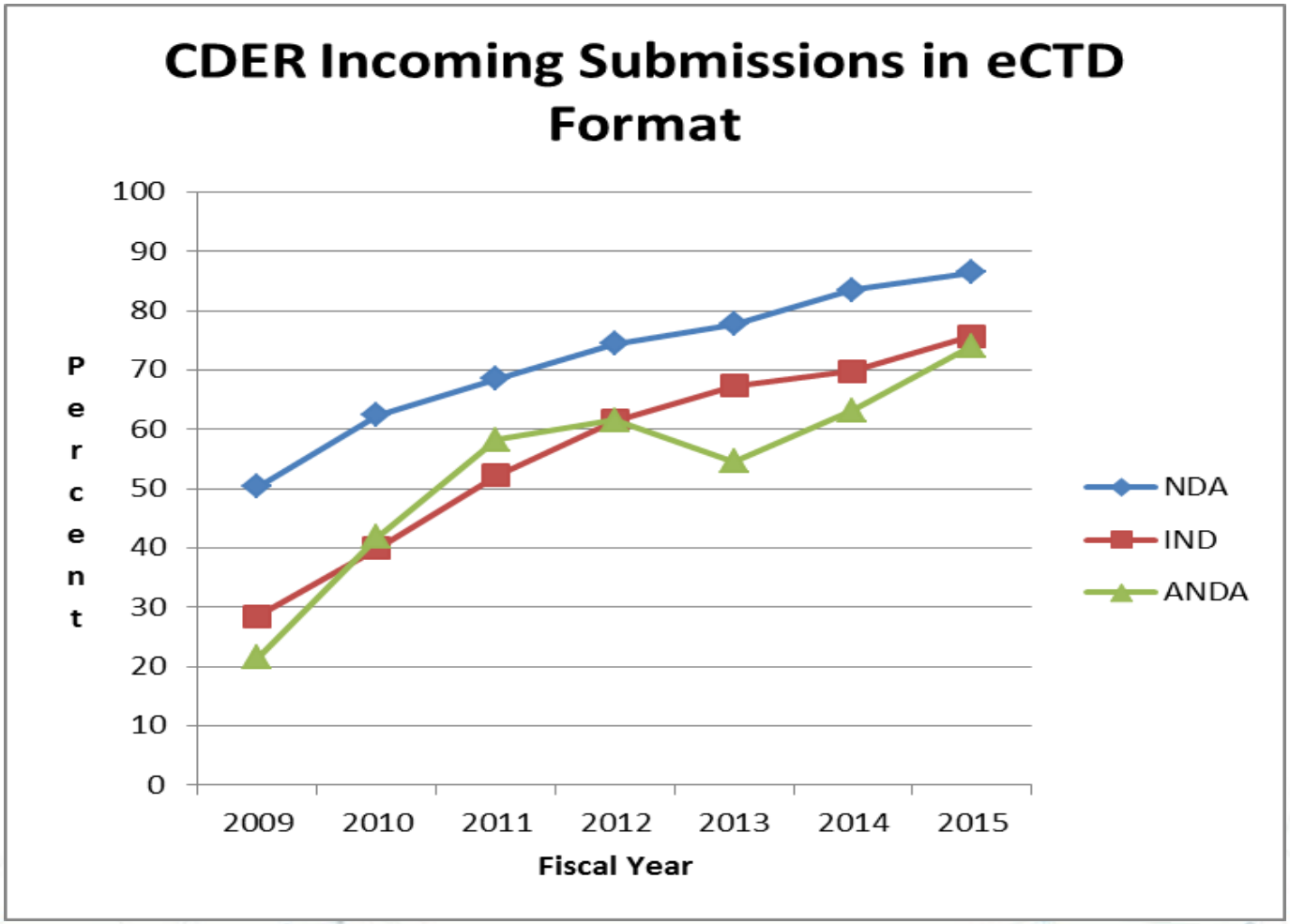
	FY2016										#	%
	ANDA		BLA		IND		MF		NDA			
Document Delivery Description Derived	#	%	#	%	#	%	#	%	#	%		
Electronic Only	356	1.0%	8	0.3%	832	1.1%	156	0.8%	199	1.2%	**1,551**	**1.0%**
Gateway	34,246	92.4%	2,650	97.8%	60,810	77.0%	5,250	26.7%	15,922	92.5%	**118,878**	**76.3%**
Mixed	438	1.2%	8	0.3%	2,125	2.7%	37	0.2%	180	1.0%	**2,788**	**1.8%**
Paper Only	2,025	5.5%	43	1.6%	15,249	19.3%	14,251	72.4%	918	5.3%	**32,486**	**20.9%**
Grand Total	**37,065**	**100.0%**	**2,709**	**100.0%**	**79,016**	**100.0%**	**19,694**	**100.0%**	**17,219**	**100.0%**	**155,703**	**100.0%**

EXCLUDES PROMOTIONAL ADVERTISING & LABELING SUBMISSIONS

SUBMISSION METRICS & MILESTONES



SUBMISSION METRICS & MILESTONES



STUDY DATA METRICS & MILESTONES

As of FY2016, 2nd Quarter:

- 88% of **study data** submitted in support of NEW NDAs are coming in standardized format
- 75% of **study data** submitted within all NDA submissions are coming in standardized format

CDER GATEWAY THIRD ACKNOWLEDGEMENT

- Began May 31, 2016
- Applies only to NDA, ANDA, BLA, IND or DMF submissions
- Sent to you when your submission has successfully completed validation and processing, and is available to the assigned review division

NEW: CDER GATEWAY THIRD ACKNOWLEDGEMENT

TEST PURPOSE ONLY

Your submission was successfully processed into the CDER Electronic Document Room, and is available to the assigned review division.

Application Type/Number: IND123456
eCTD Sequence Number: 0001
CoreID: ci1441927177074.54973@fdsul08620_te2

Your official receipt date is calculated in accordance with the following final Guidance for Industry:
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072385.pdf

Contact Information:

For technical assistance only: eSUB@fda.hhs.gov

For all other questions regarding your submission, contact your review division.

Thank you,

Electronic Document Room
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

CDER GATEWAY THIRD 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 (e.g., Mismatch between your form and your eCTD XML)

CDER GATEWAY THIRD ACKNOWLEDGEMENT

- Note: A rejection is also a third acknowledgement, and separate from this acknowledgement

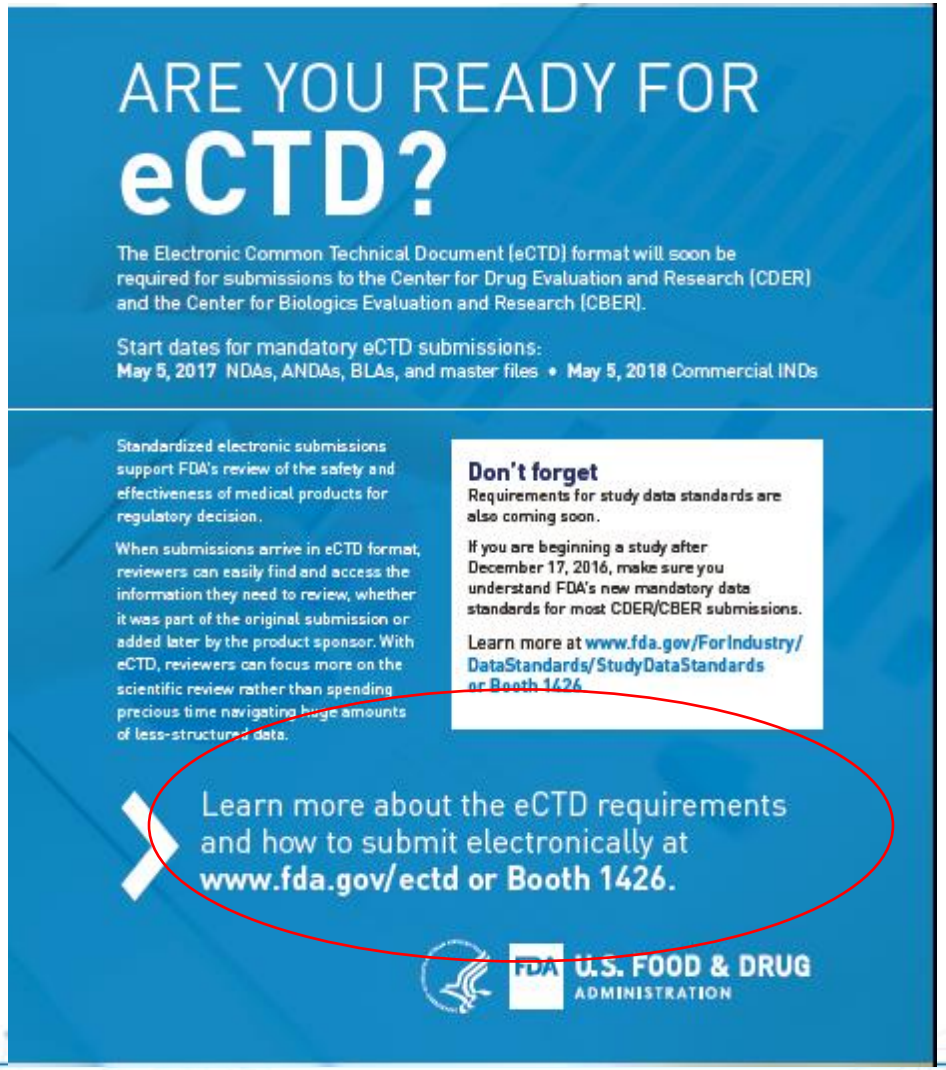
NEW: AUTO REJECTIONS

- Duplicate Submissions
  - You send the same submission sequence more than once
- Single File Submissions
  - Not allowed
- Empty Submissions
  - You send nothing inside your folders

COMING SOON…

- More information added to 2nd (Center) Gateway Acknowledgement
- 1st Update to Technical Conformance Guide
- Updates to validation criteria
  - Rejection criteria for study data & more
- Planning for eCTD v4.0 implementation

WE ARE IN THE EXHIBIT HALL



Thank You

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