

Greetings From White Oak, MD: CDER's New "Home"



Prequel: Something Practical

Everything you need to know is on the Web at:

www.fda.gov

Hint:

If you are not happy with “sort by relevance”

Switch the search tool to

“sort by date.”

Prequel: Standards -- Merging the Visions and Doing the “Hard Stuff”

- CaBIG
- Critical Path
- CDISC Roadmap

Prequel: The “Hard Stuff”

- Taking the Right Next Steps

- Changing as we work
- Resources
- People
- Organization
- Politics – Internal/ External
- Personalities
- Motivations
- Priorities
- Policies
- Living with mistakes

“Supporting” Change at CDER: Taking a Next Step

Steve Wilson, Dr.P.H., CAPT USPHS

Deputy Director, Division of Biometrics II,

Acting Director, OBPS

CDER/FDA

CDISC Interchange 2005

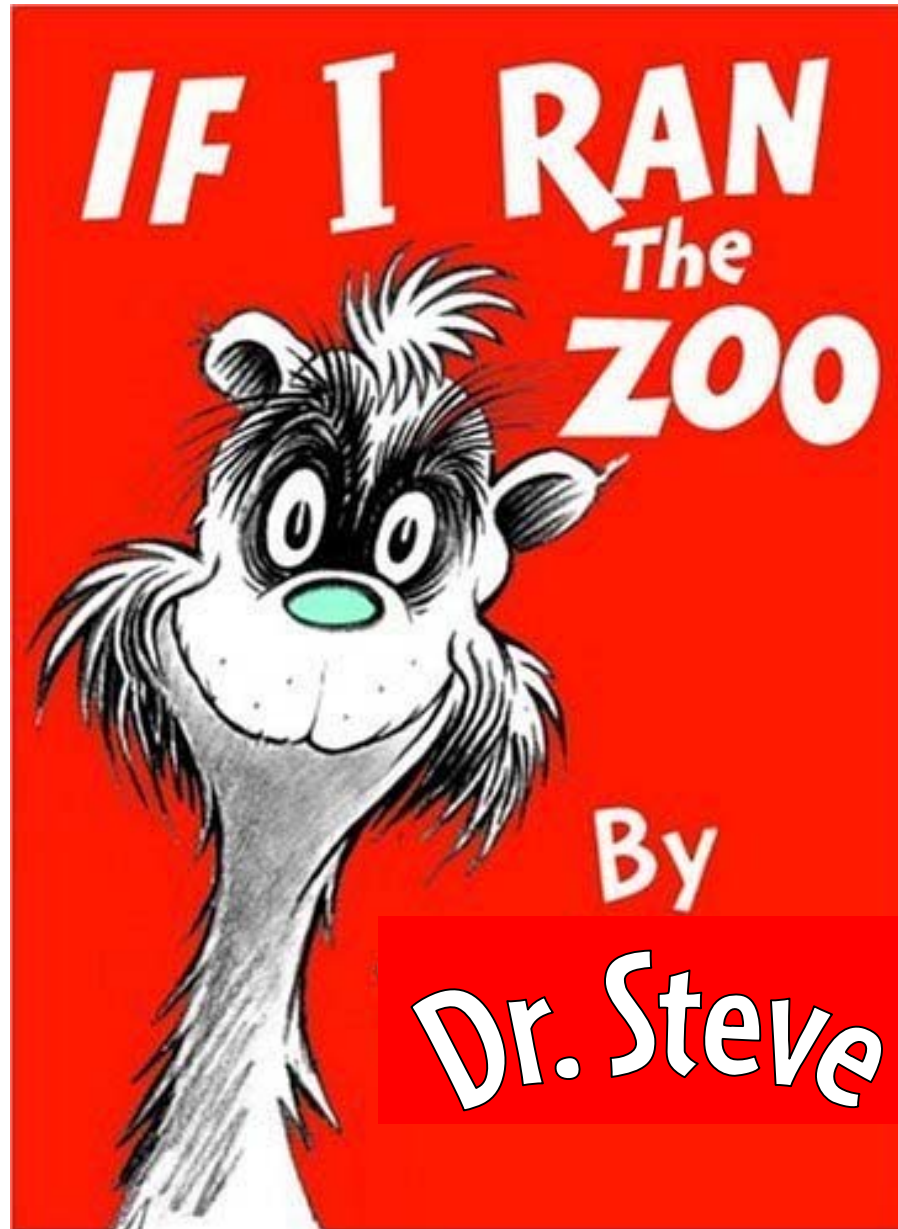
Bethesda Marriott, Washington, DC

September 21, 2005

Disclaimer

Views expressed in this presentation are those of the speaker and not, necessarily, of the Food and Drug Administration.

My New Disclaimer



Acknowledgements

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- ADaM / SDS / Protocol / eSDI /
Nomenclature / Define.xml / ODM /
Workgroups

Outline

- Regulation 101
- Re-Visiting the 2005 FDA Town Meeting
- Office of Business Process Support (OBPS)
- The Good Review Management Guidance: An Opportunity Disguised as a Problem?
- Time for Change
 - Pre-NDA eSub “Encounter”
 - Meta-Data Standards for Analysis
 - More Statistical Guidance

The World We Live In -- Regulation 101



Pre-Test: Communicating with FDA

- DSI
- ICH
- ADaM
- MaPP
- CRADA
- E3
- NDA
- CDRH
- BLA
- FDAMA
- GCP
- PDUFA
- DX
- CVM
- GSDB
- CFSAN
- FD&C
- CLIA
- CFR
- E9
- IND
- E10
- 21 CFR 11
- FR
- HL7
- PMA
- OB
- IDE
- CODB
- 510k
- COB
- GSB
- INAD
- AC
- ORA
- NDA

Regulation 101

- Law – FDAMA, PDUFA
- Regulations – 21 CFR 11, NDA
- Guidance – Electronic Submission, Safety Review
- Draft Guidance --
- Specifications – eCTD backbone,
- MaPP (Manual of Policies and Procedures) – a CDER SOP
- Federal Register
- SGEs, Advisory Committees & Town Meetings
- CRADA – Cooperative Research and Development Agreement

Regulation



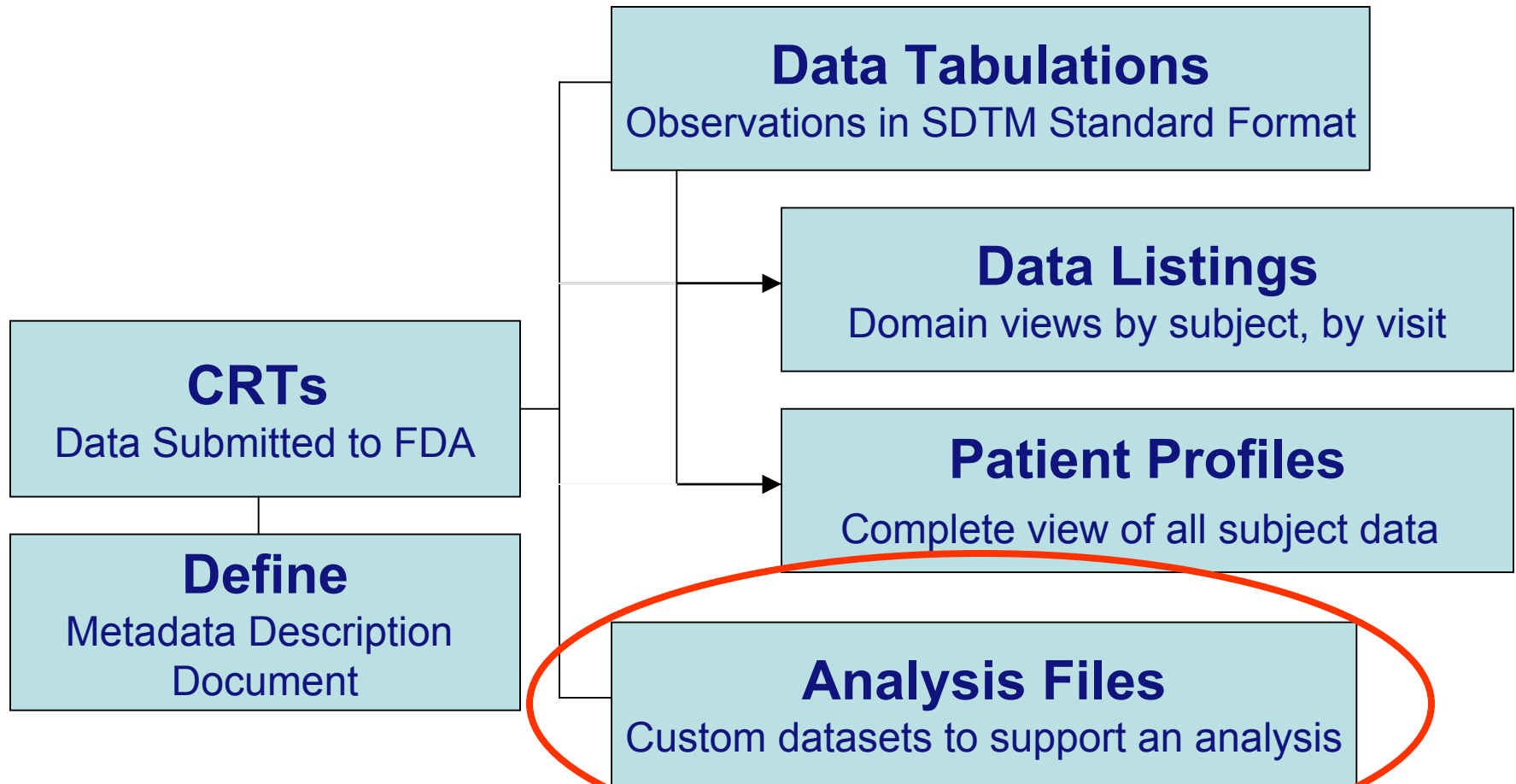
Guidance



Adapted from S. Woollen

Re-Visiting the 2005 FDA Town Meeting

Submission Files



Office of Business Process Support (OBPS)

- The Office *formerly known* as the Office of Information Management

A focal point for:

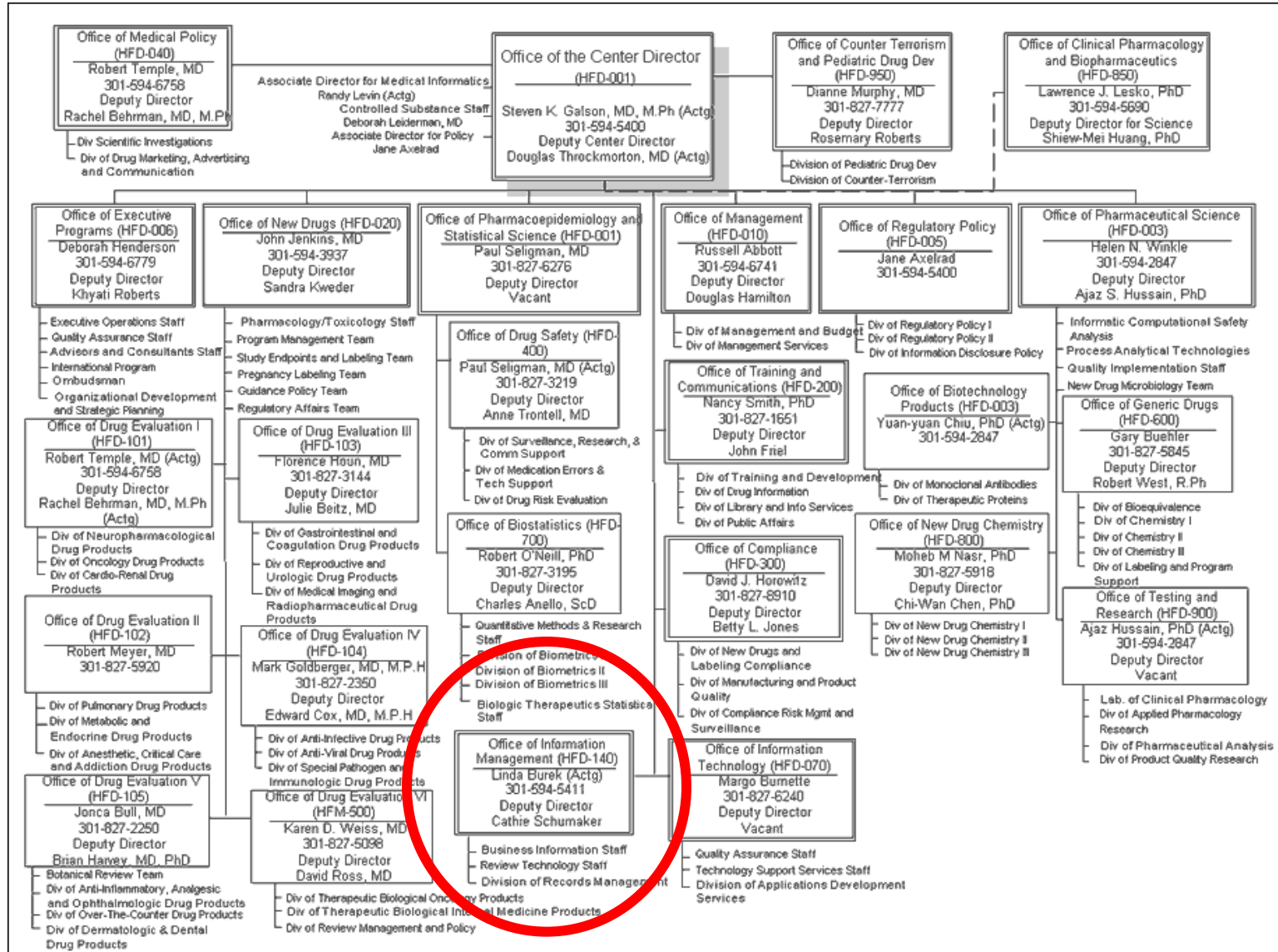
- Establishing standards for regulatory and health data standards; standards for paper and electronic submissions
- Training for use of review tools
- Coordination of systems development projects with the Office of Information Technology
- Reports and analysis of drug review information
- Oversight of CDER databases

OBPS Organization

- Office of the Director
- Division of Records Management
- Business Information Staff
- Review Technology Staff

The CDER

<http://www.fda.gov/cder/>



The Good Review Management Guidance (GRMP)

Guidance for Review Staff and Industry

Good Review Management Principles and Practices for PDUFA Products

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

April 2005
Procedural

GRMP: Fundamental Values

- Quality
- Efficiency
- Clarity
- Transparency
- Consistency
- Mom
- Apple Pie
- No Surprises

Guidance for Good Review Management Principles for PDUFA Products

Application Receipt
CDR assigns NDA/BLA no.

EOP2 Mtg. Pre-NDA Mtg.

Filing

Presubmission

Fileability Evaluation

Encourage Regular Mtgs.

Acknowledgement Letter

Request Consults

Scientific & Reg. Advice

Assignment of Review Team, Review Priority,
Signature Authority

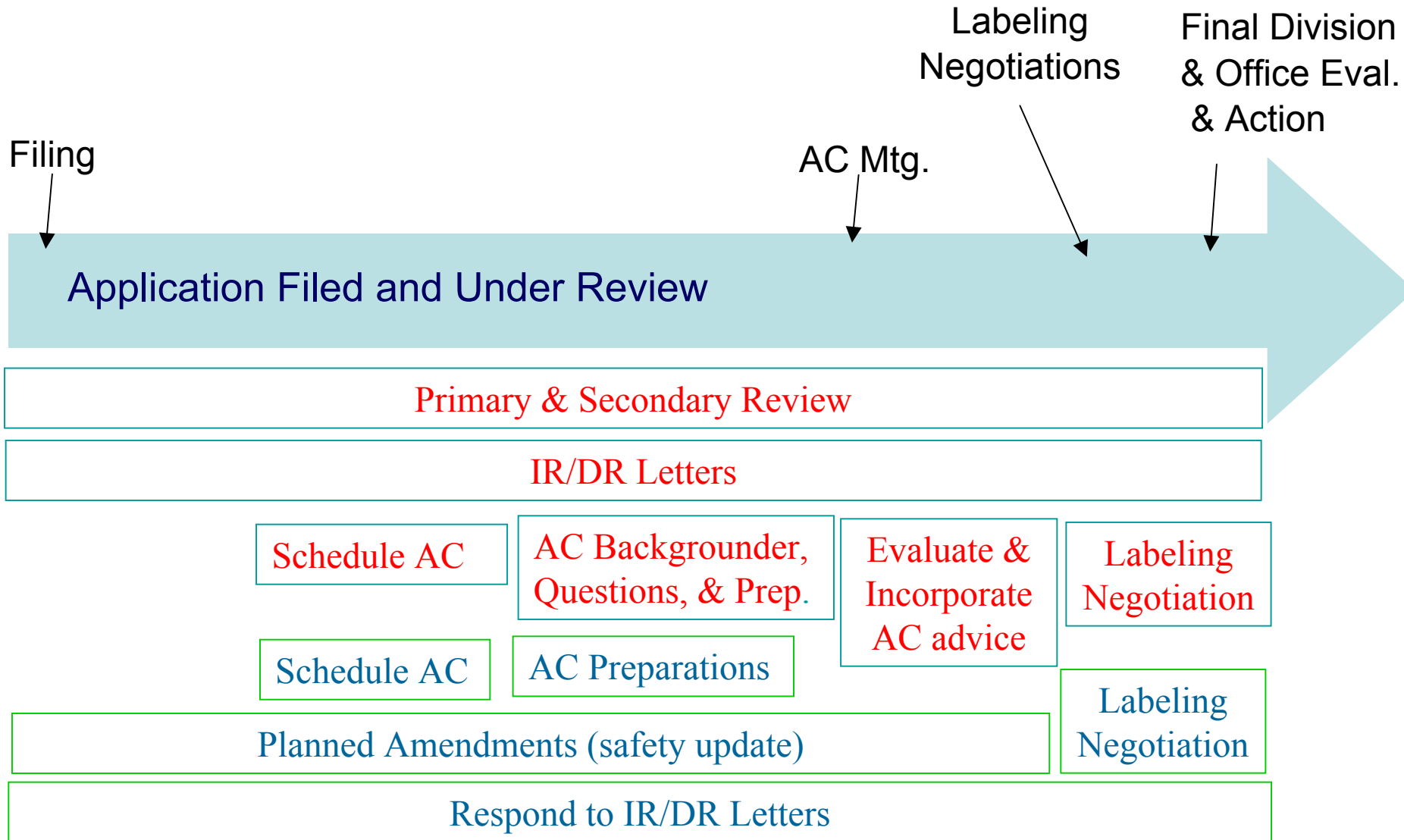
Inform of Filing Deficiencies

Background
Packages

Submit
App &
User
Fee

Respond to Filing Deficiencies

Guidance for Good Review Management Principles for PDUFA Products



Regulation



Guidance



Adapted from S. Woollen

The Shoe is on the Other Foot



Time for a Change?

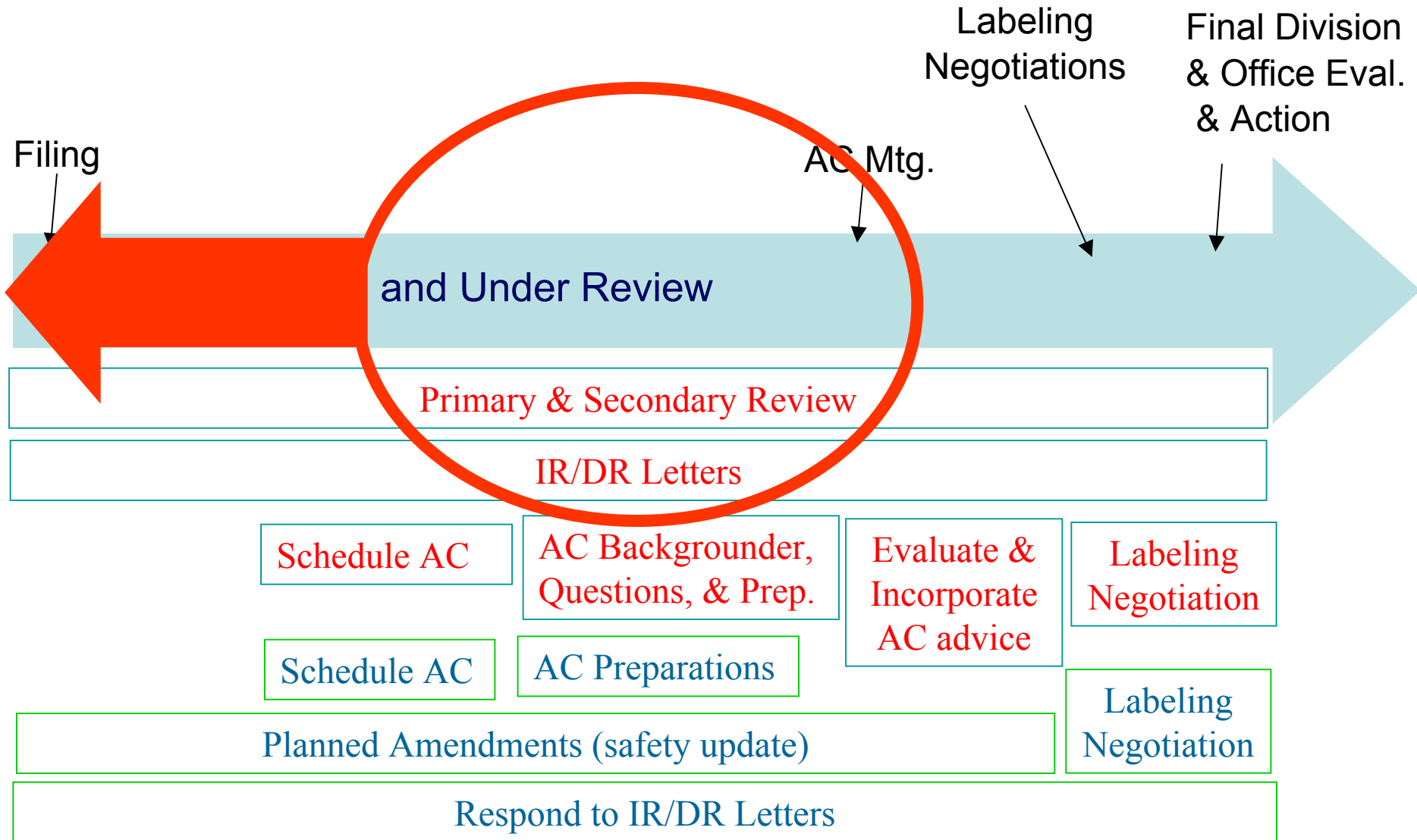
Is the GRMP another
annoying burden

or

“An OPPORTUNITY
disguised as a PROBLEM*”

?

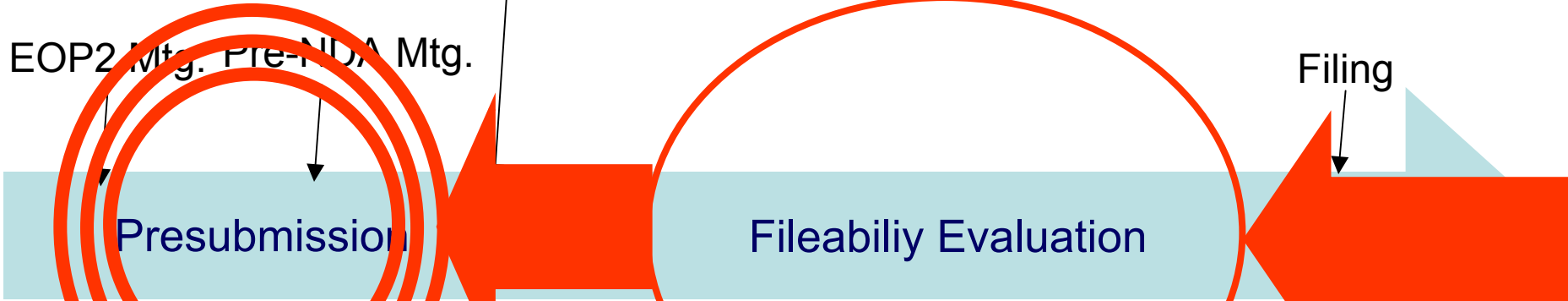
GRMP: Earlier/Better Communication



GRMP: A Pre-NDA eSub “Encounter”

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EOP2 Mtg. Pre-NDA Mtg.



Encourage Regular Mtgs.

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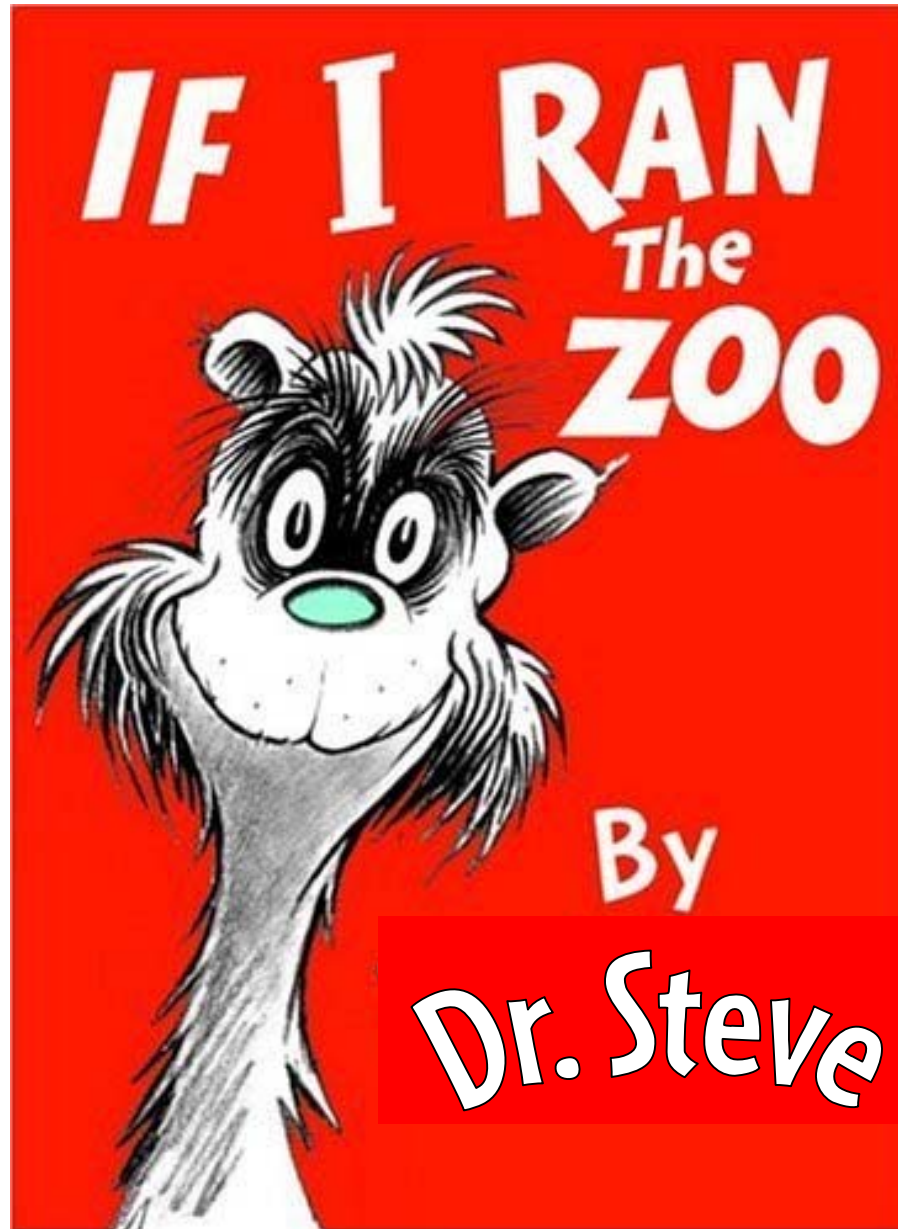
Inform of Filing Deficiencies

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Remember the Disclaimer



If I Ran the Zoo:

Some of the Changes That I Would Like to See

- Earlier/Better Communication: A Pre-NDA e-Sub Discussion
- Metadata Standards for Data and Analysis
- Pre-NDA/CTD/eCTD “Encounter” re. Data Submission
- More Guidance re. e-Sub

An Improved Pre-NDA e-Sub Discussion

- Why not include in existing Pre-NDA meeting?
 - **Wrong audience** – (The bored and the lost)
 - **No time** – technical issues get moved to the end of the agenda
 - **Timing** - may be too early or too late
- Will it add value?
 - Yes – it is necessary
- How will it affect reviewers/ sponsors processes and procedures?

Pre-e-Submission Experience - A Data “Sampler” for the Statistician

- SDTM, ADaM analysis datasets, define.xml sampler submitted for pre-NDA meeting
- Provided valuable feedback to sponsor
- Allowed agency to test compatibility with standard tools and databases
- Tested content and structure of metadata, documentation and programs
- Identified technical problems early
- Highlighted possible areas of misunderstanding and differences in interpretation
- “Tuned-in” the reviewer

How to Provide “Clear Communication”

- Use the eCTD to provide a common organization and structure to the document.
 - Makes components easy to find
 - Allows standard tools to be used for navigation, browsing
- Use ADaM and SDTM dataset standards and metadata to describe the submitted data
 - Common look and feel for data, both within and across submissions
 - Allows standard tools to be used for navigation, browsing and analysis

Metadata Standards for Data and Analysis

- Enable reviewers to understand, replicate, explore, confirm, reuse, etc.
- Clear, unambiguous communication of decisions, analysis and results
- Underlying principles:
 - Can a reviewing statistician understand?
 - Can a reviewing statistician efficiently:
 - Quality Assure?
 - Validate?
 - Analyze?

OPBS: More Guidance on e-Sub



Can We (Industry/FDA) Change? An Old Married Couple?



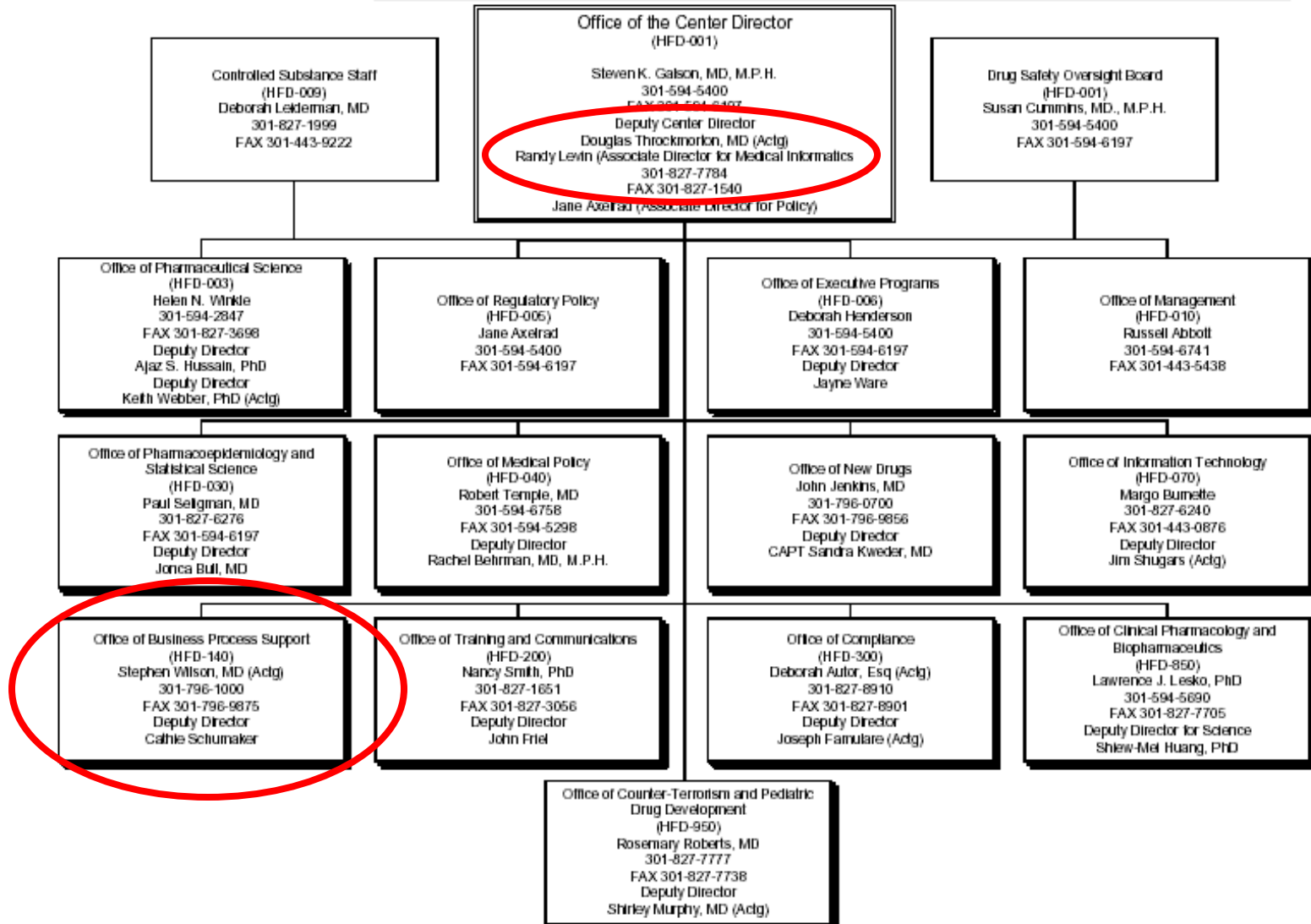
Yes: By Helping Each Other



CDER: OBPS

CENTER FOR DRUG EVALUATION AND RESEARCH

Tuesday, September 06, 2005



THANK YOU

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