

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

Date: February 14, 2001
To: Dockets Management Branch (HFA-305)
From: Melissa Lamb
Office of Generic Drugs
Subject: Electronic Submissions

This memorandum forwards overheads of a presentation to the Dockets Management Branch for inclusion in Docket 90S-0308. The following is information on the presentation for the Docket records@.

Title of Presentation: Electronic Regulatory Submission and Review (ERSR) Project
Presented for: FDA OGD-UMBC Electronic Submission Training
Date Presented: January 19, 2001
Presented by: Richard Sponaugle, Computer Specialist
Number of Pages: 30

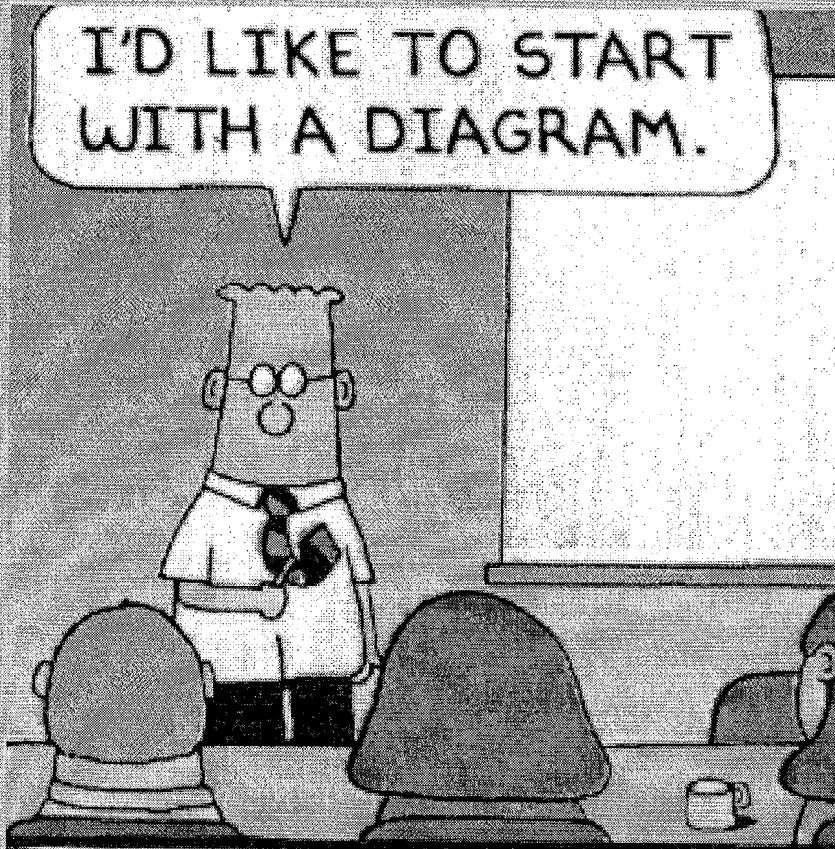
Melissa Lamb

Attachment

90S-0308

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Electronic Regulatory Submission and Review (ERSR) Project



RICHARD SPONAUGLE

Computer Specialist

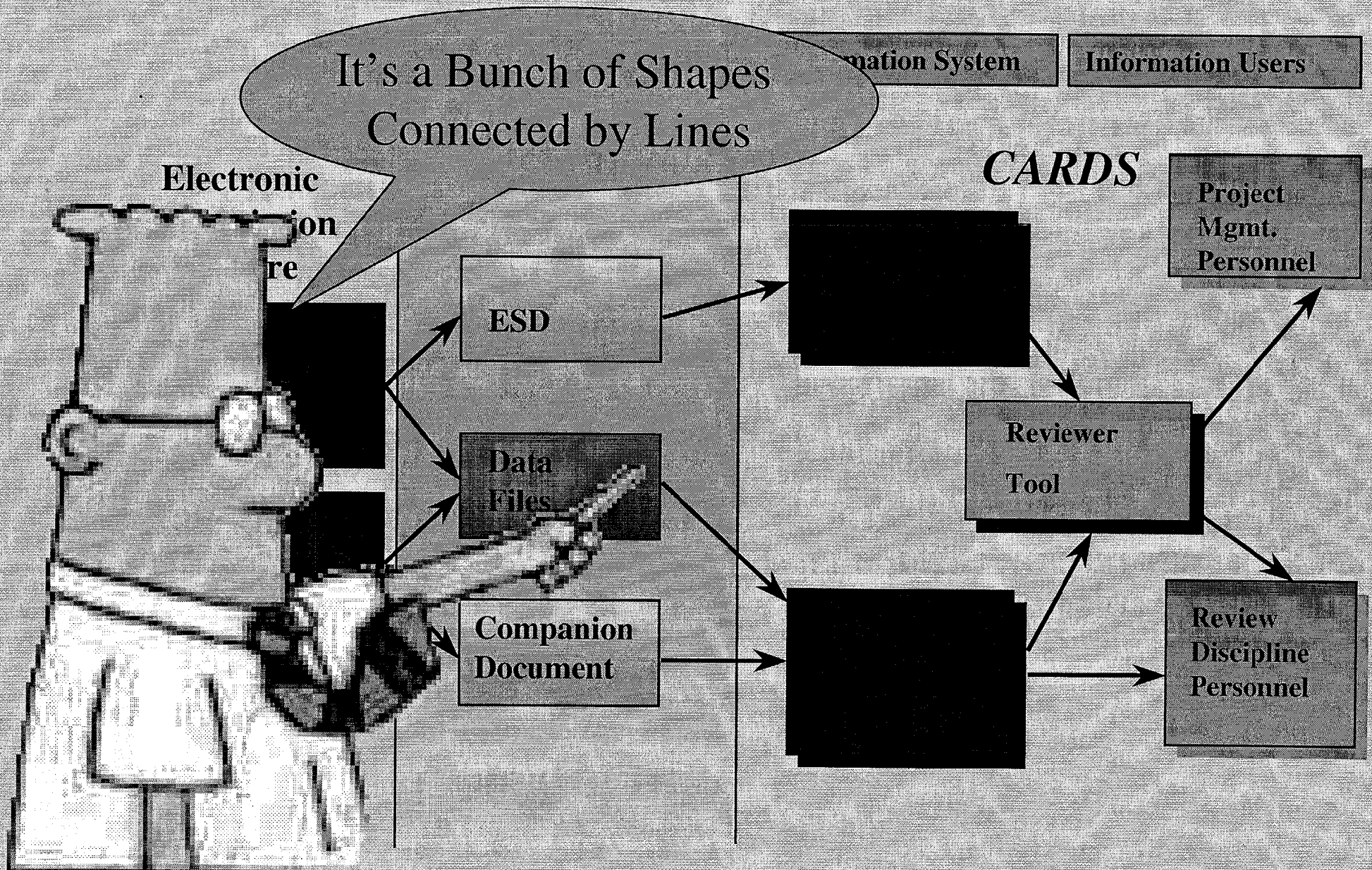
Senior Systems Engineer

Electronic Submissions

Office of Generic Drugs

CDER, FDA

ELECTRONIC FILING



ELECTRONIC FILING

- History
- Current Program
Overview
- Where We Are Going

ELECTRONIC FILING - History

- Program under development since 1992
- OGD database and reviewer tools
- Electronic submission formats
- Data entry tool
- Guidance

ELECTRONIC FILING - History

OGD Database

- Structure of the database was specified by FDA and based on application review requirements
- Oracle was chosen as the platform

ELECTRONIC FILING - History

Development of Reviewer Tools

- OGD and UMBC worked together to develop tools to assist with review
 - Support data exploration
 - Help reviewers to write final report
 - Minimize clerical tasks so that reviewers can concentrate on science

ELECTRONIC FILING - History

Development of Submission Formats

- The University of Maryland developed the ESD for data entry
 - Text file
 - Uses special mark-up notation
- Data File Formats were developed based on reviewer input

ELECTRONIC FILING - History

Industry Field Trials

- Started in 1994
- Discovered that
 - The ESD was very difficult to work with directly
 - Applicants wanted to provide more information in a less restricted format

ELECTRONIC FILING - History

Entry and Validation Application

- Developed in 1995 for BA/BE and in 1996 for CMC
- Extensively beta tested in Industry
- Provides data entry screens
- Prevents or checks for common formatting errors
- Produces the ESD automatically

ELECTRONIC FILING - History

Companion Document

- Less structured
- Provides a standard template for the sponsor to provide textual information and tabular data that does not easily fit into the other components of the Electronic Submission.

ELECTRONIC FILING - History

- Paper / Electronic Combination
 - Full Paper Submission Required with a Voluntary Structured Electronic Submission.
 - Bioequivalence since January 1997
 - CMC since March 1998

ELECTRONIC FILING - History

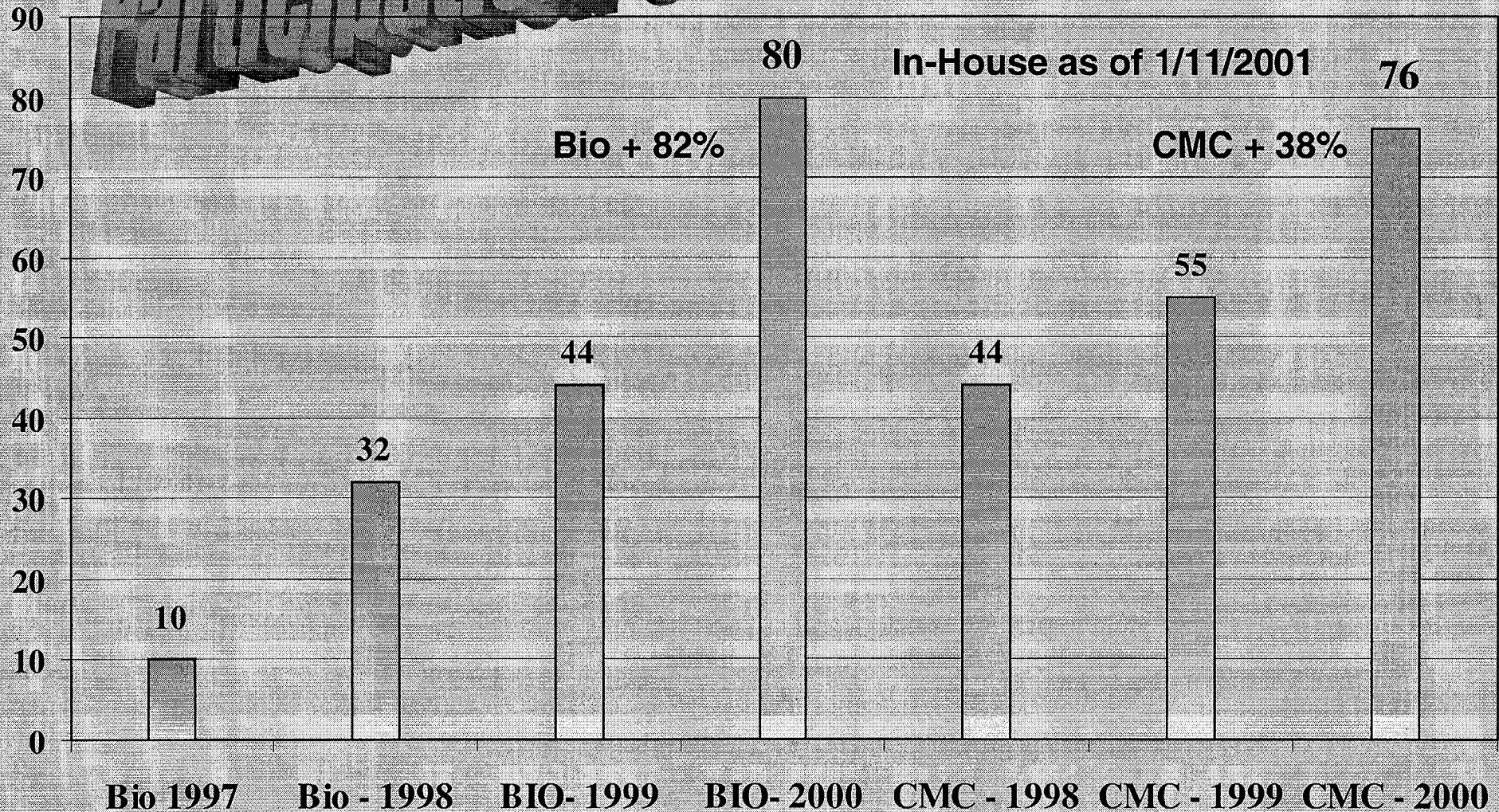
Guidance

- “Preparing Data for Electronic Submission in ANDAs”
- Released in September 1999
- Level Two Guidance
- Covers the program as it now exists
- Will be replaced when OGD is ready for paperless submissions

Available at: <http://www.fda.gov/cder/guidance/index.htm>

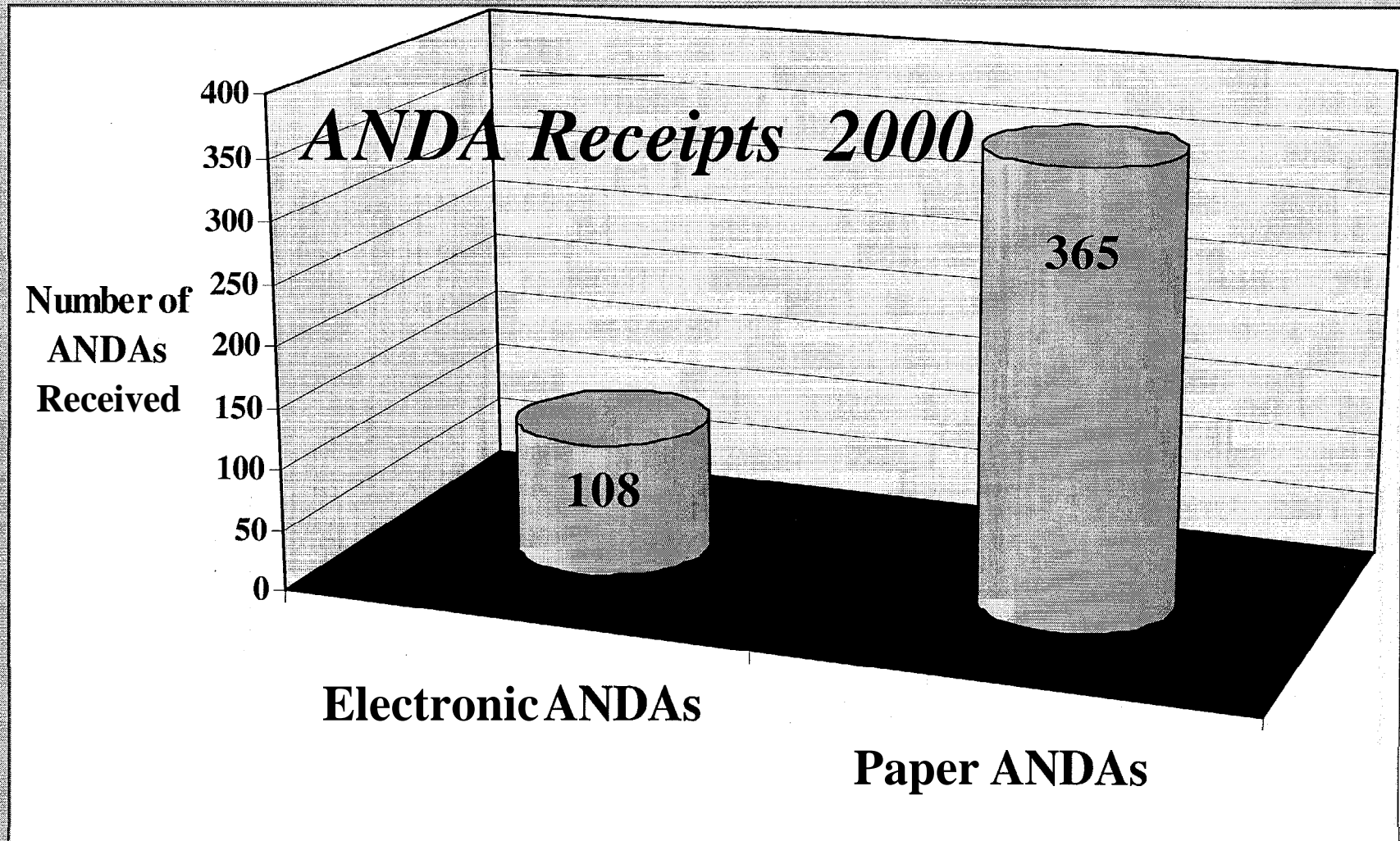
ELECTRONIC FILING - Participation

Participation Continues to Grow



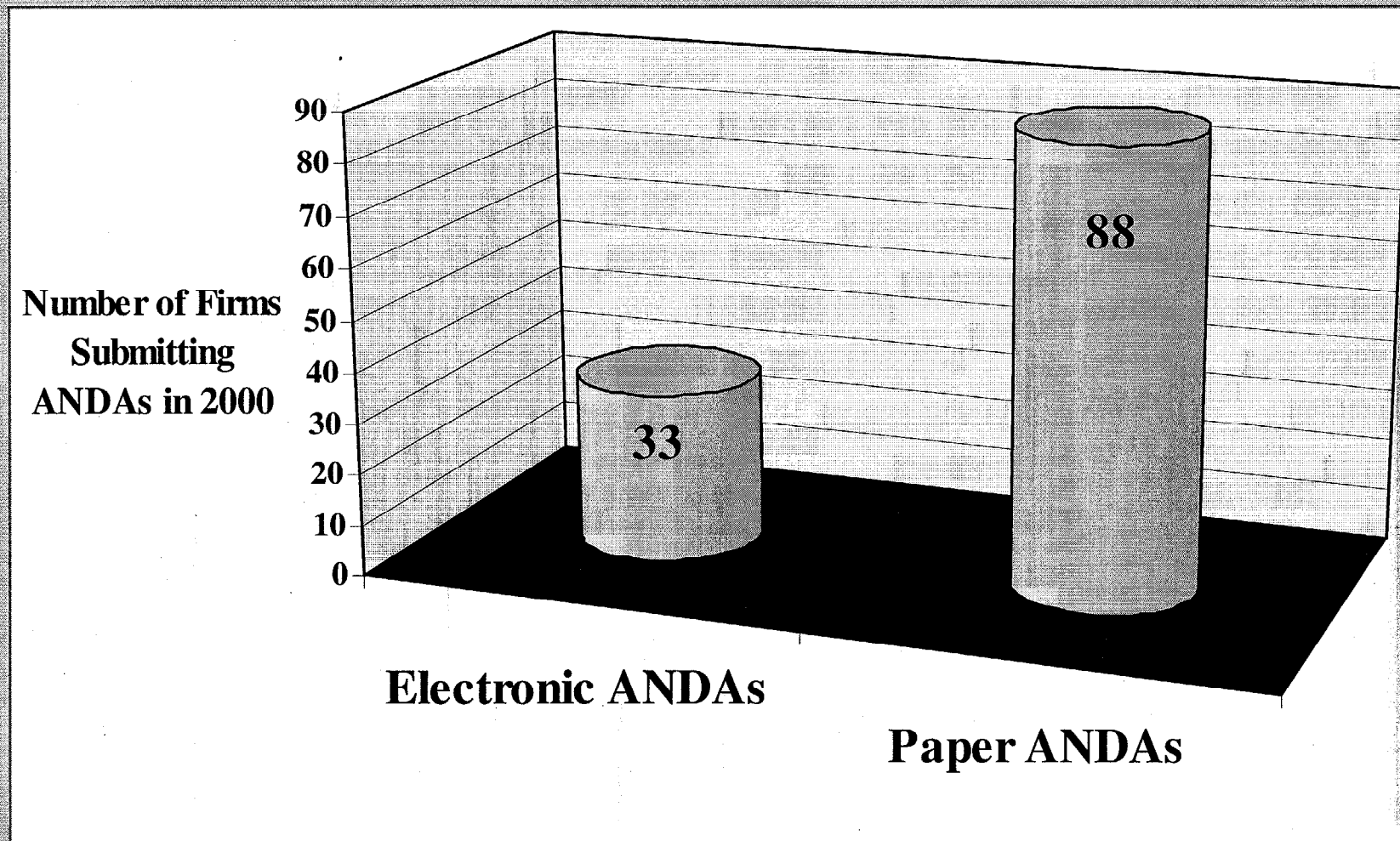
ELECTRONIC FILING - Participation

Twenty-Nine percent of all ANDAs received by OGD in 2000 included some portion in an electronic format.



ELECTRONIC FILING - Participation

Thirty-Seven and one-half percent of all active firms submitted in electronic format in 2000



ELECTRONIC FILING

Parts of an Electronic Submission

Both CMC & Bioequivalence

ESD - Electronic Submission Document

Companion Document

Bioequivalence Only



Data Files

Content of a BA/BE Electronic Submission

- ESD
 - Marked-up ASCII document that contains descriptive information about submission and provides context for data files
- Data files
 - Data sets in specified SAS-readable formats
- Companion Document
 - Word processed report that presents textual information under standard headings

ELECTRONIC FILING

What Have We Learned? /

What are the Benefits?

- **Review Times Can be Shortened.**
- **Databases Can be Accurately and Quickly Populated From Electronic Submissions.**
- **Storage Space Can be Significantly Reduced.**

ELECTRONIC FILING

Where We Are Going?

Paperless Submissions

ELECTRONIC FILING

Where We Are Going - Paperless Submissions

GUIDANCE FOR INDUSTRY

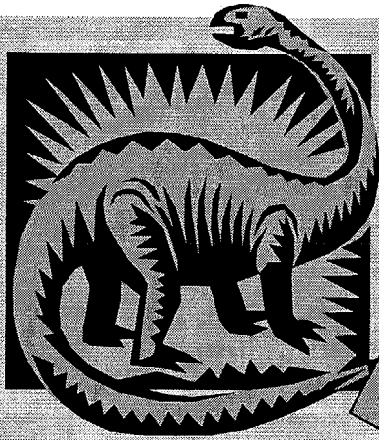
Providing Regulatory Submissions
in Electronic Format —
Abbreviated New Drug
Applications (ANDAs)

DRAFT

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

IT #
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We anticipate that we will release a draft guidance for comment within the next six to twelve months.



ELECTRONIC FILING

Evolution - from what we have to Paperless

- Apply Lessons Learned
- Harmonize with New Drug & ICH

Electronic Submission Efforts

- Make Use of New Technologies



ELECTRONIC FILING

Apply Lessons Learned

- Take Advantage of Positives
 - Eliminate Negatives
- Improve Reviewer Tools
 - Reduce Complexity of Preparation

ELECTRONIC FILING

Harmonize with New Drug & ICH

Electronic Submission Efforts

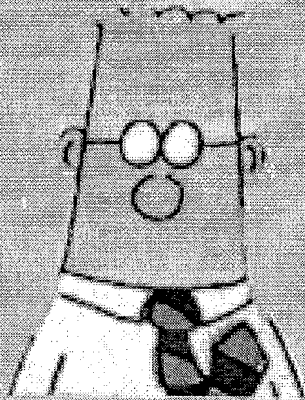


The Goal is to Reduce the Burden on Regulated Industry by Making All Submissions as Similar as Possible.

ELECTRONIC FILING

Probable Formats for Paperless Submissions

NOW I WILL
SAY SOME
IMPRESSIVE
WORDS.



Extensible Markup
Language -XML

Portable Document
Format - PDF

SAS Transport

ELECTRONIC FILING

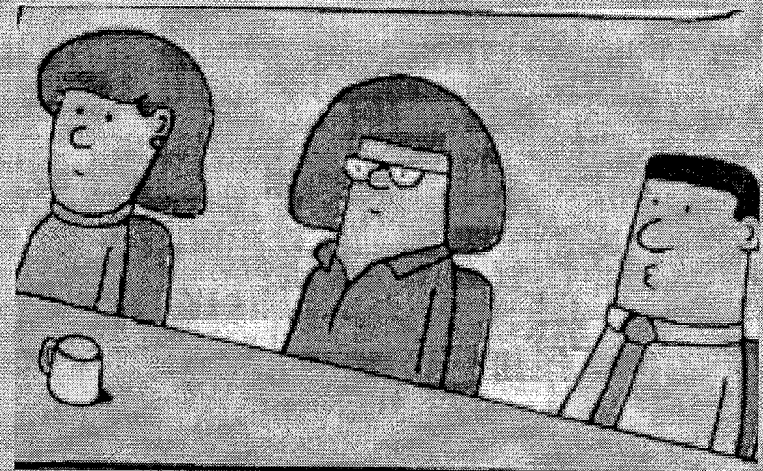
Extensible Markup Language - XML

A Tagging System Which Allows Pieces of Data (Information) in a Document to be Identified and Processed Electronically.

Advantages of XML:

Flexibility; The Tag Set is Not Fixed.

International Standard; There are many tools readily available.



ELECTRONIC FILING

Portable Document Format - PDF



What is PDF?

Portable Document Format, PDF is a file type created by Adobe Systems, Inc. that allows fully formatted, high-resolution, PostScript documents to be easily transmitted electronically and viewed on any computer that

has Adobe Acrobat Reader software (a proprietary viewer is available for free at the Adobe site).

ELECTRONIC FILING

SAS Transport

File Type Created by the SAS Institute for Transferring Electronic Data Sets

- Well Established and Widely Used System
- SAS is Commonly Used Analytical Tool (Agency & Industry)
- Easily Converted to Other Formats Using Off the Shelf Software
- Already Established as an Archival Standard by CDER OIT

ELECTRONIC FILING

Parts of an Electronic Submission

ESD - Electronic Submission Document
Proprietary ASCII Markup

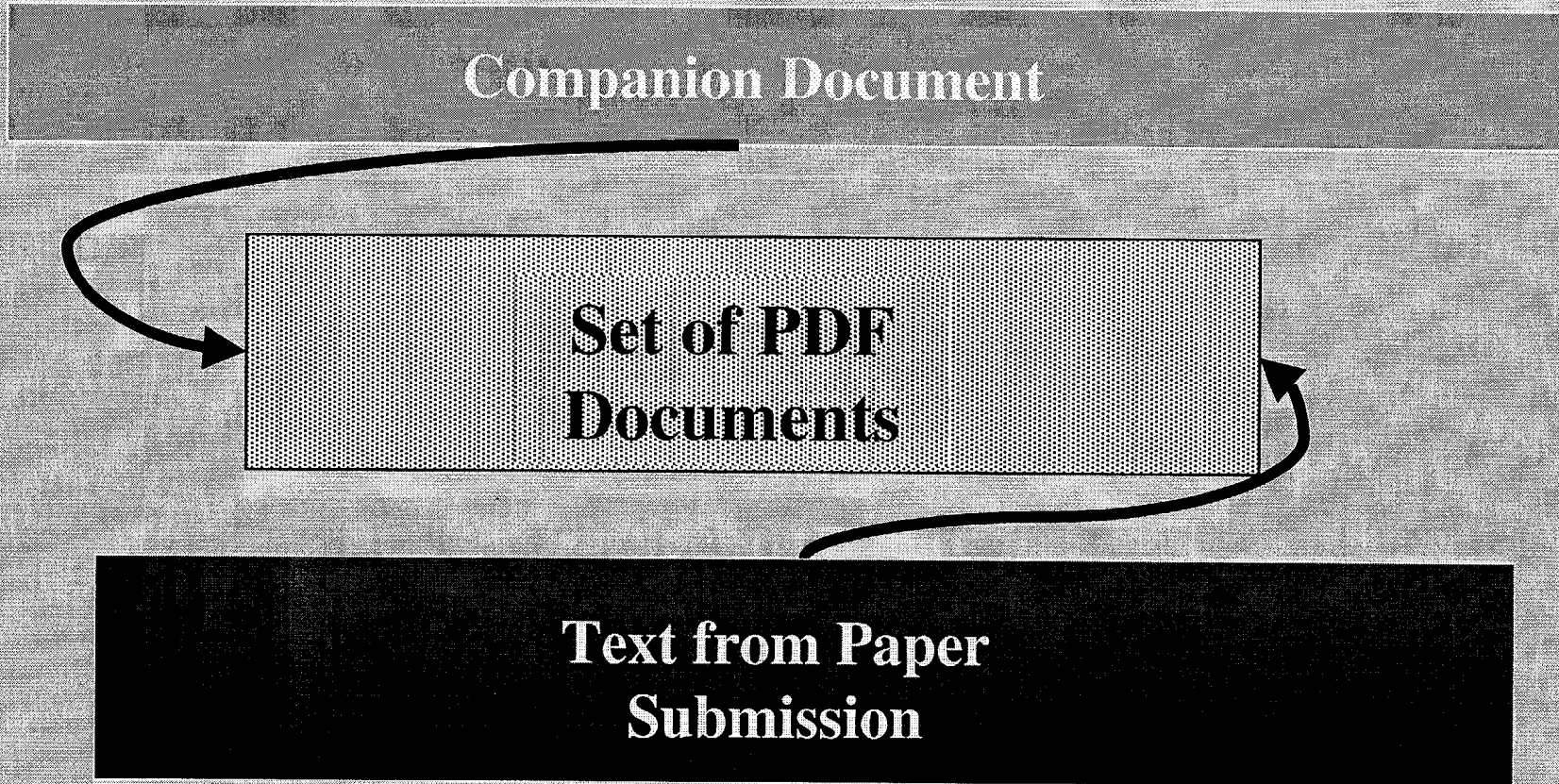
ESD - Electronic Submission Document
XML

ASCII
Data Files

SAS Transport
Data Files

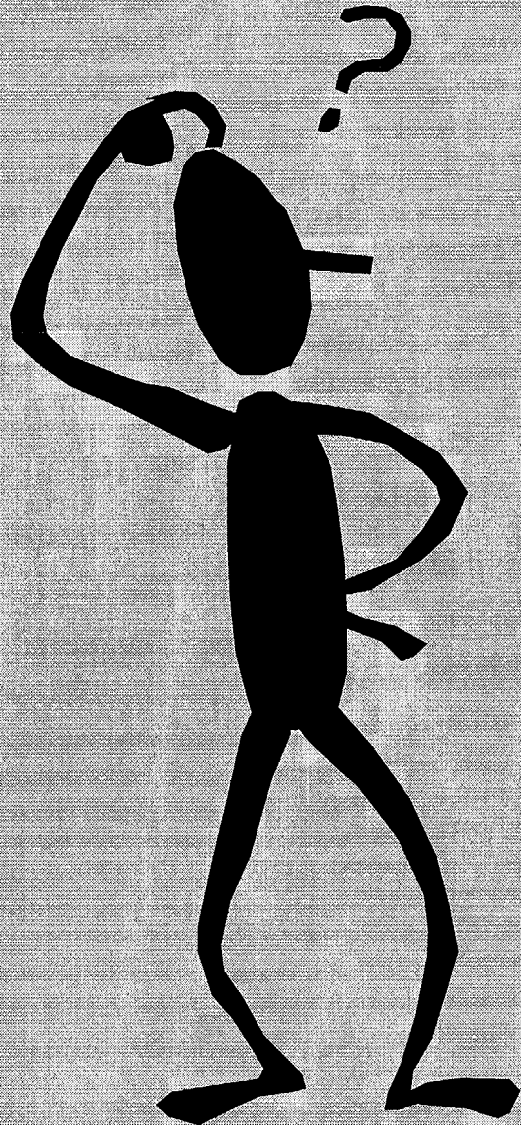
ELECTRONIC FILING

Parts of an Electronic Submission



The information in the companion document will be available in the new PDF documents

ELECTRONIC FILING



Questions?