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

6618 '00 OCT 11 P1:44

Date: October 6, 2000

To: Dockets Management Branch (HFA-305)

From: Melissa Lamb
Office of Generic Drugs

Subject: Electronic Filing

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 Filing

Presented for: OGD Industry Meeting

Date Presented: September 20, 2000

Presented by: Richard Sponaugle

Number of Pages: 17

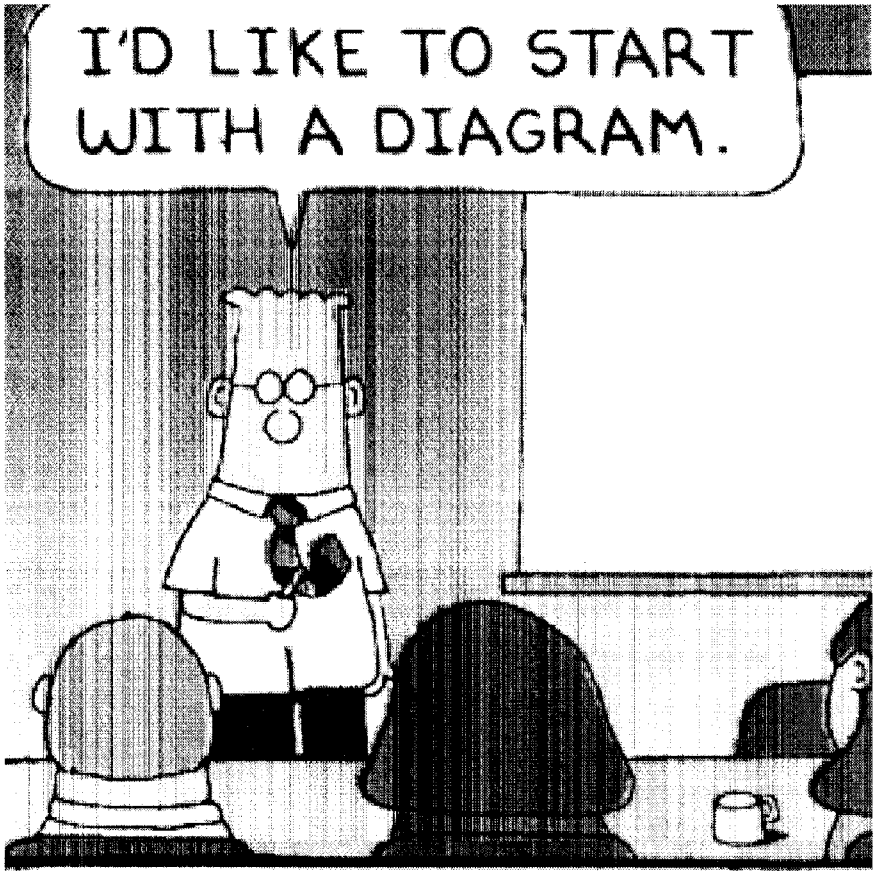
Melissa Lamb

Attachment

90S-0308

M687

ELECTRONIC FILING



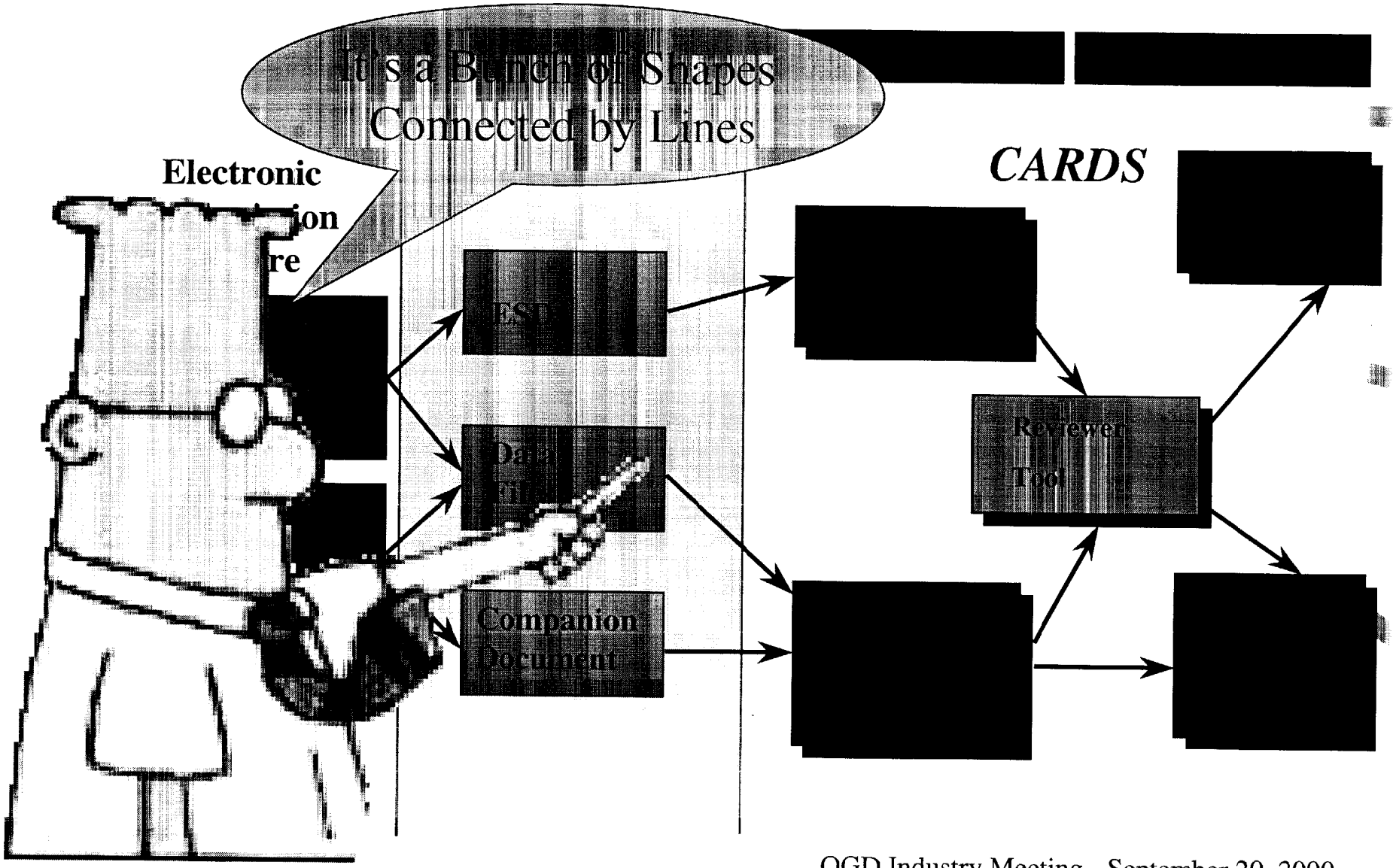
Richard Sponaugle

Computer Specialist,

Senior Systems Engineer -

OGD Electronic Submissions

ELECTRONIC FILING



ELECTRONIC FILING

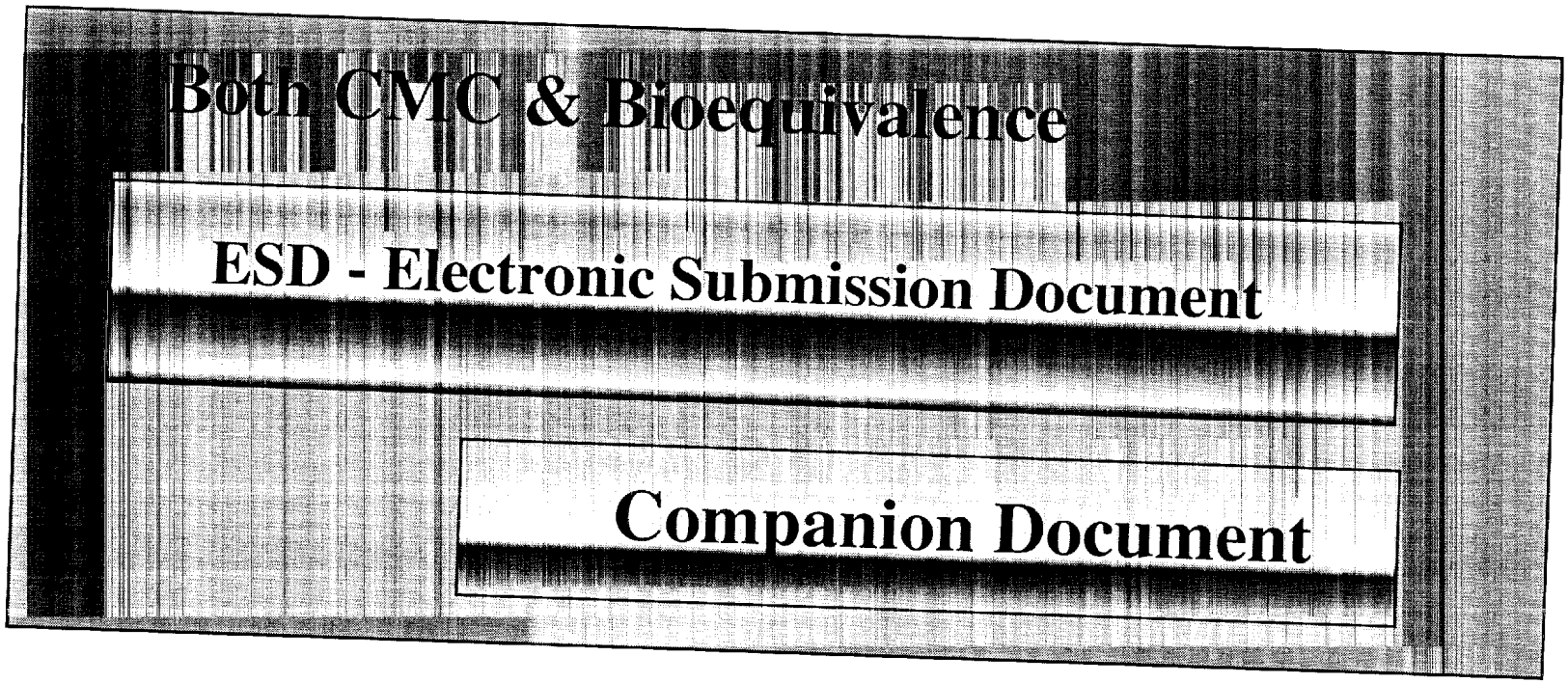
- Where We Are
- Current Participation
- Where We Are Going

ELECTRONIC FILING

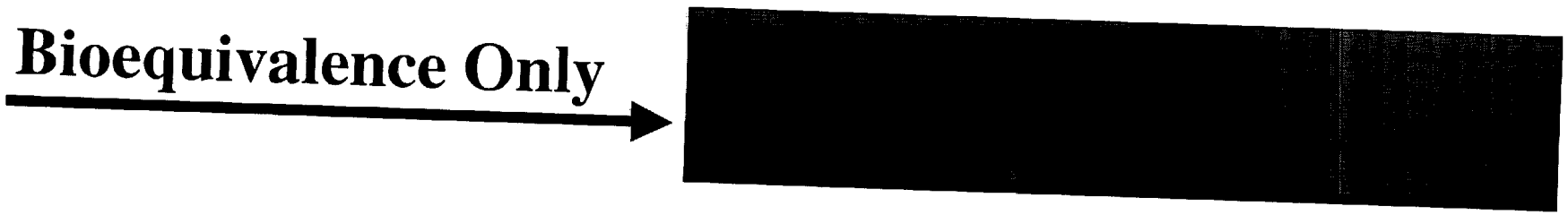
- Paper / Electronic Combination
  - Full Paper Submission Required along with a Voluntary Structured Electronic Submission.
    - Bioequivalence since January 1997
    - CMC since March 1998

ELECTRONIC FILING

Parts of an Electronic Submission



Bioequivalence Only



ELECTRONIC FILING

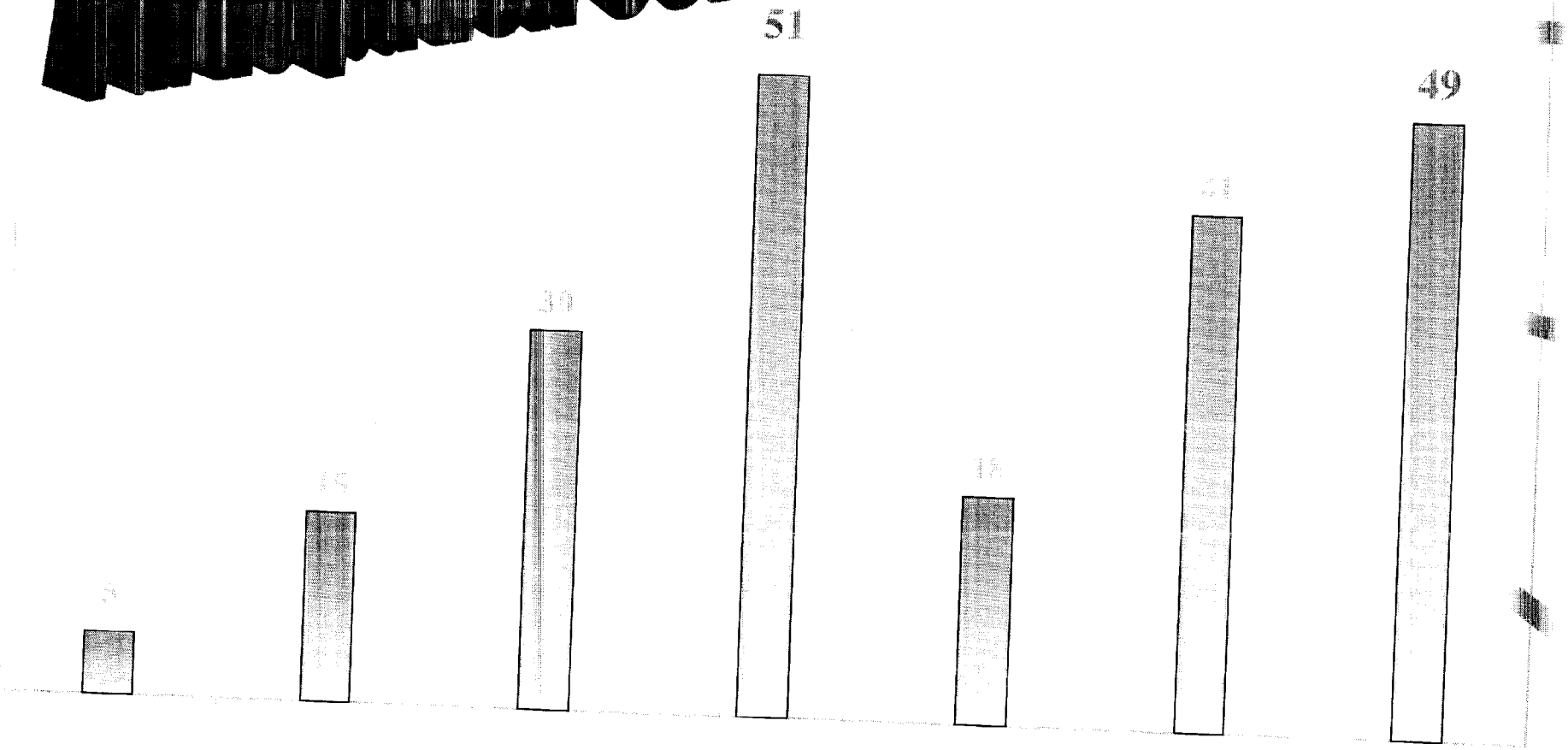
What Have We Learned? /

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

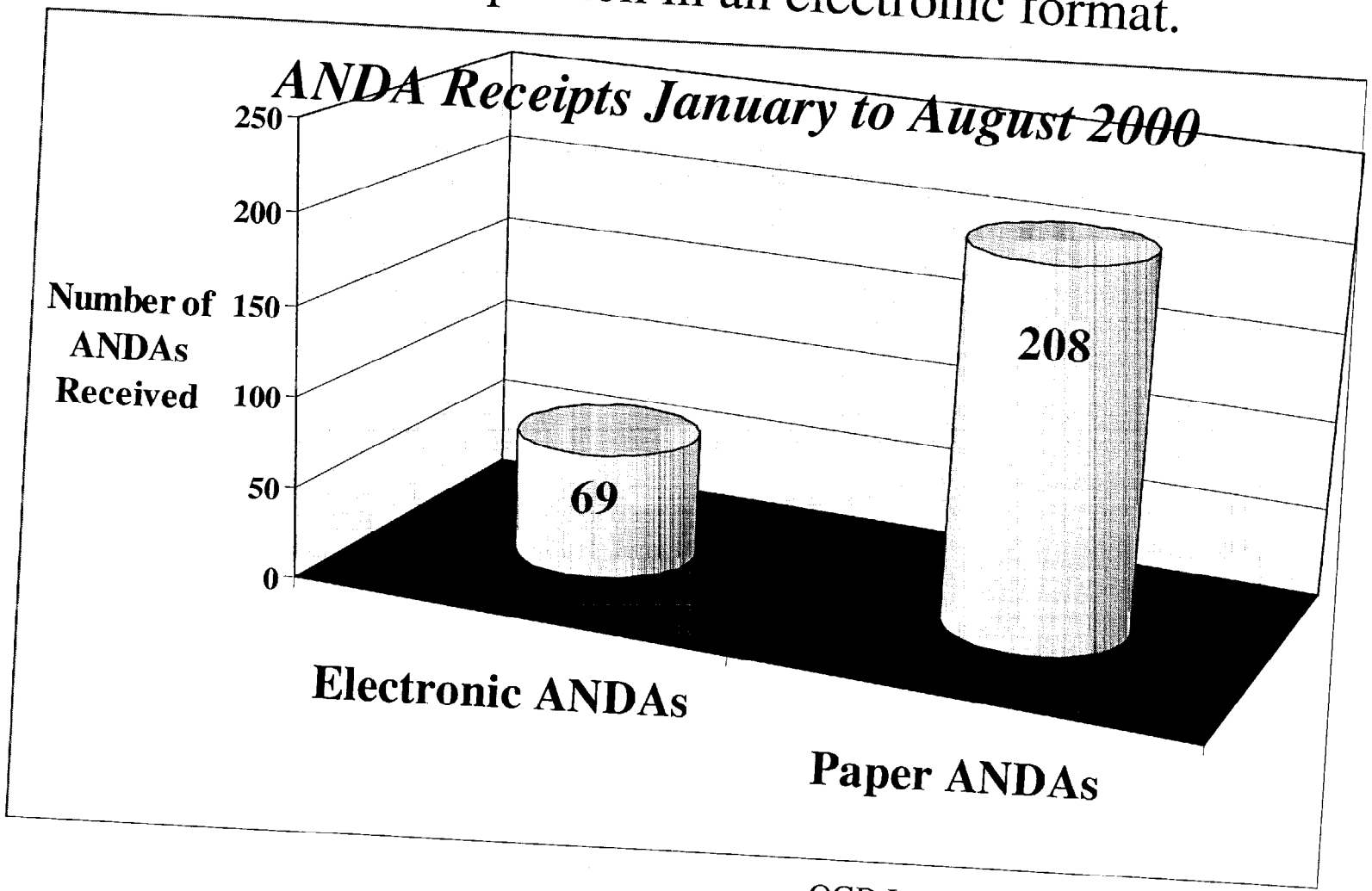
Participation Continues to Grow



Electronic Submissions January to August

ELECTRONIC FILING

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



ELECTRONIC FILING

Where We Are Going - Paperless Submissions

GUIDANCE FOR INDUSTRY

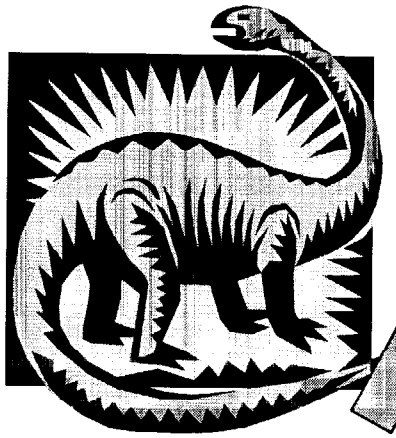
Providing Regulatory Submissions
in Electronic Format —
Abbreviated New Drug
Applications (ANDAs)

DRAFT

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

IT #
MMM YYYY

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

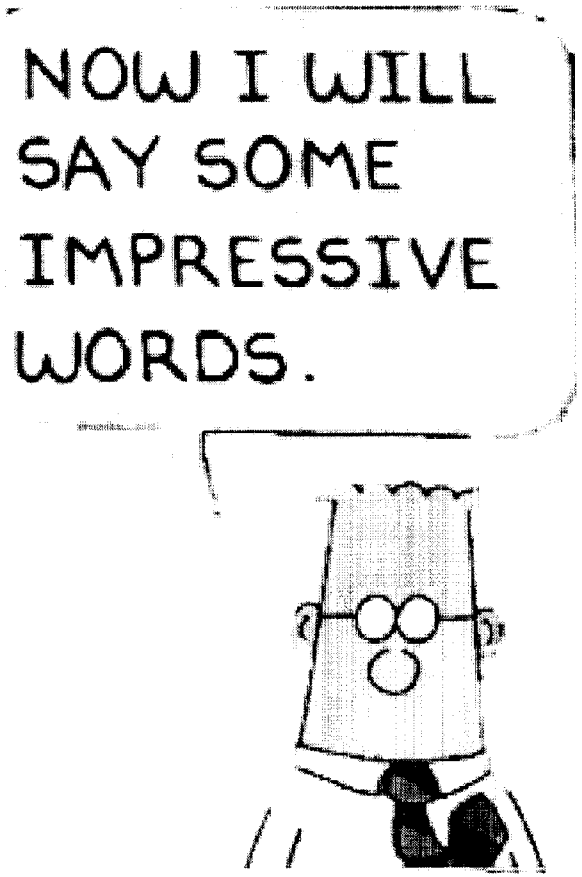
Harmonize with New Drug & ICH Electronic Submission Efforts

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

OGD Industry Meeting - September 20, 2000

ELECTRONIC FILING

Probable Formats for Paperless Submissions



Extensible Markup Language -XML

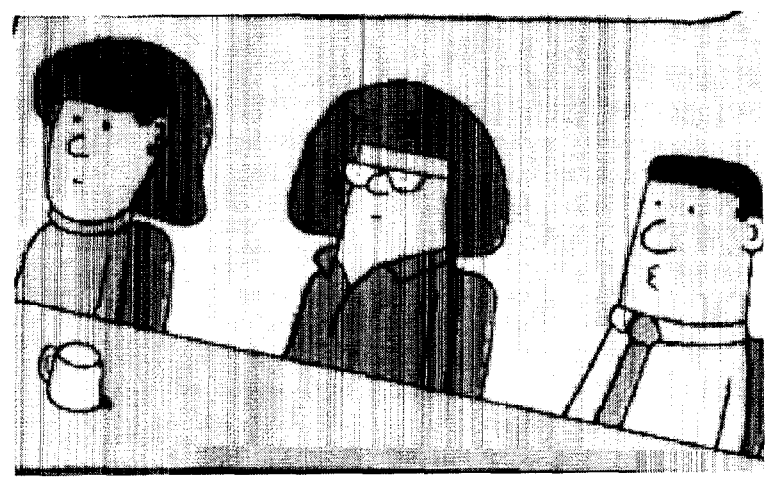
Portable Document Format - PDF

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).

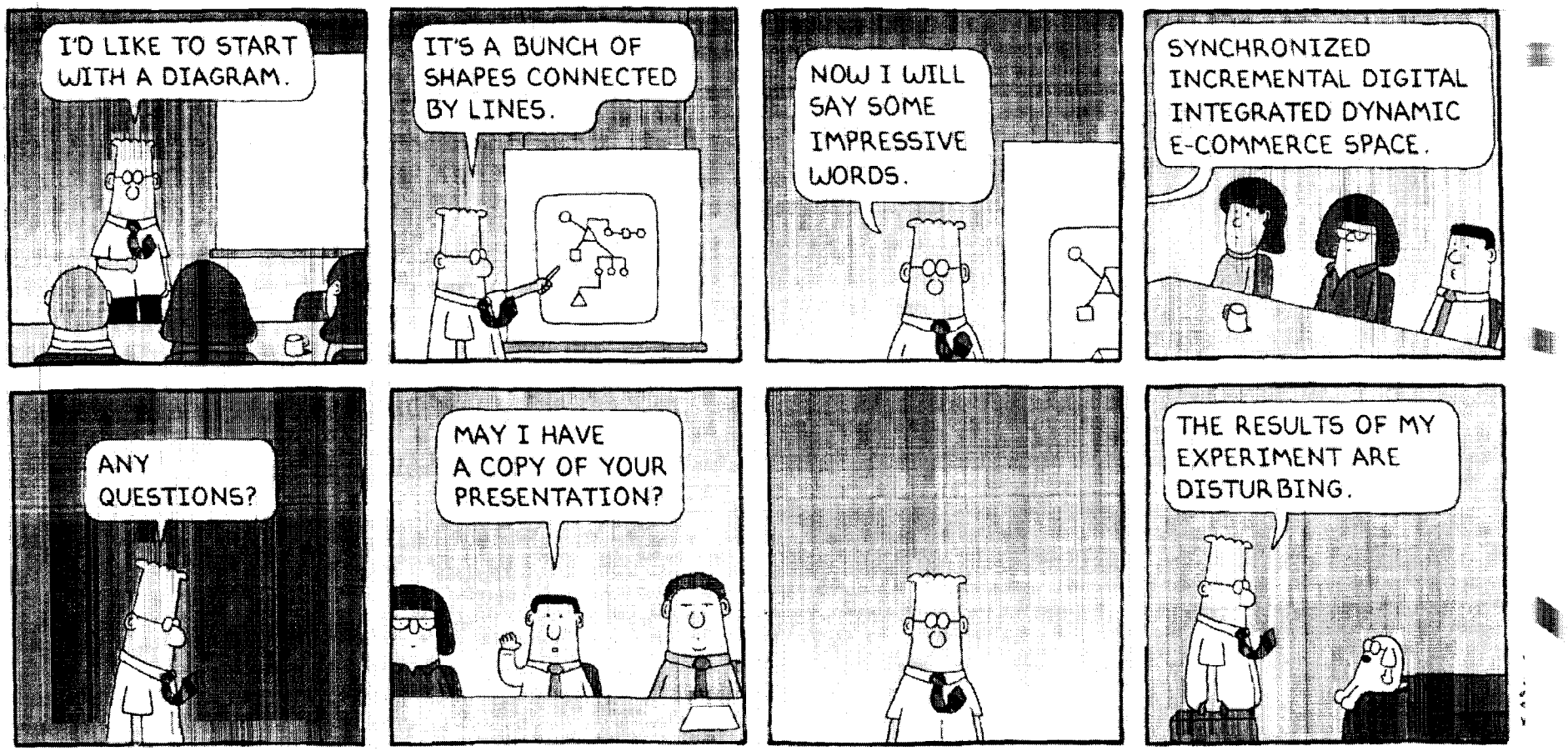
ELECTRONIC FILING

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



THANK YOU