

M E M O R A N D U M

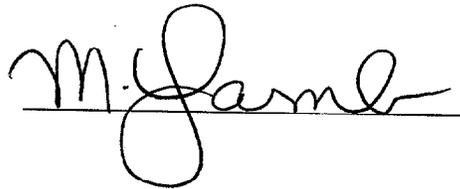
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH

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Date: February 8, 2000  
To: Dockets Management Branch (HFA-305)  
From: Melissa Lamb  
Office of Generic Drugs  
Subject: Electronic Abbreviated New Drug Applications

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: Panel Discussion  
Presented for: Panel Discussion  
Date Presented: 11/17/99  
Presented by: Ruth Warazala, Richard Sponaugle  
Barbara Davit, Susan Rosencrance  
Number of Pages: 16

  
M. Lamb

Attachment

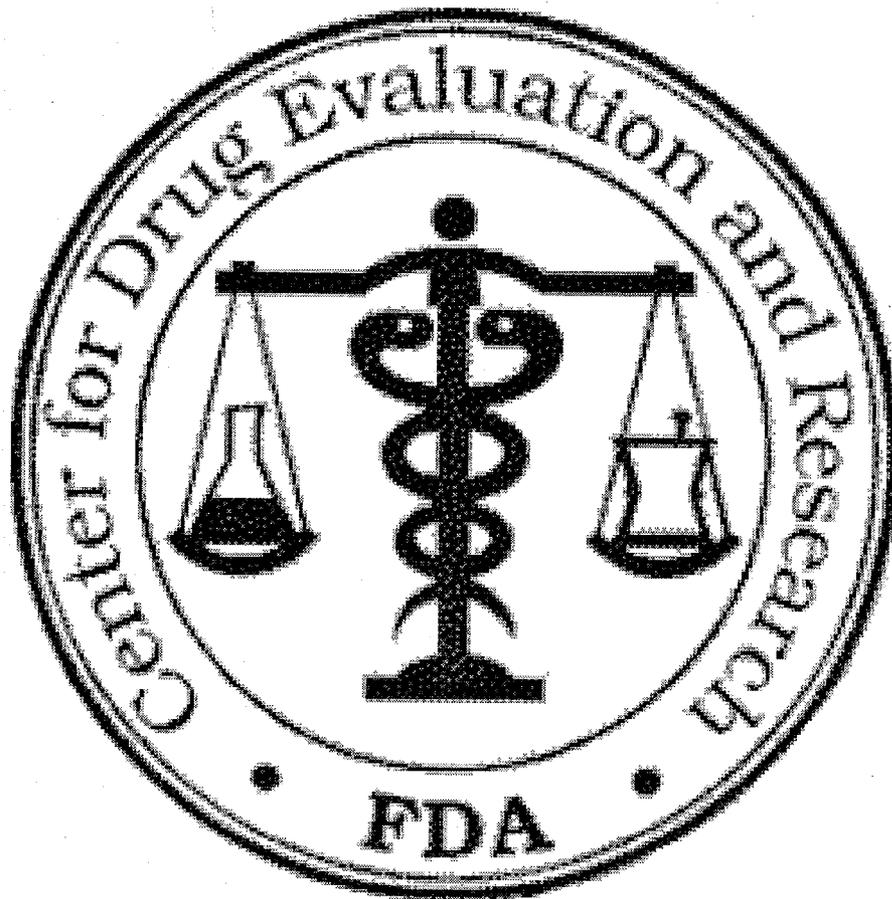
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905-0308

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• **Electronic Abbreviated New Drug Applications**

# **Panel Discussion**



Ruth Warzala

Richard Sponaugle

Barbara Davit, Ph.D.

Susan Rosencrance

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• **Electronic Abbreviated New Drug Applications**

# **Panel Discussion**

**Guidance for Industry:**

**Preparing Data for Electronic  
Submission in ANDAs**

**Participation Statistics**

**What Can You Expect Now?**

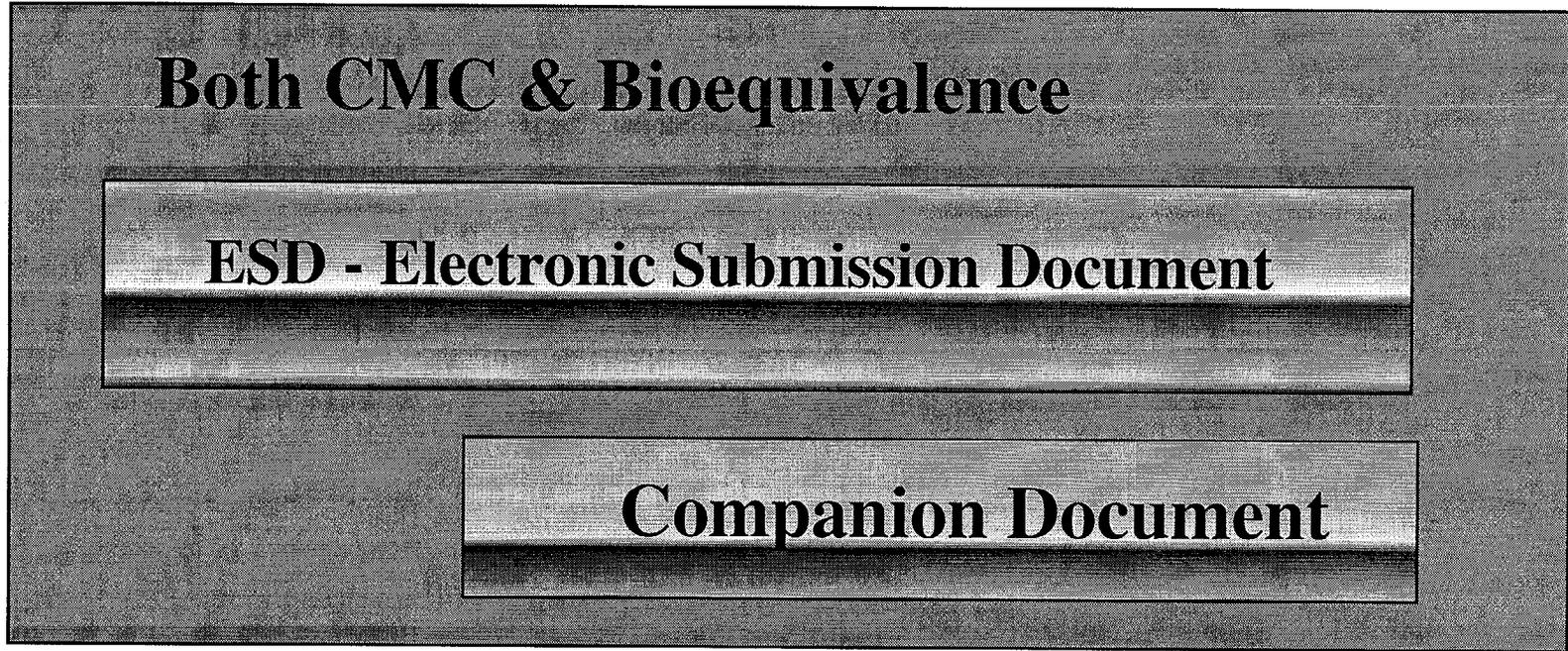
**What Can You Do to Help?**

**Reviewer Comments**

**Further Discussion**

- 
- **Electronic Abbreviated New Drug Applications**

# **Parts of an Electronic Submission**



**Bioequivalence Only**



# • •**Electronic Abbreviated New Drug Applications**

## **Guidance for Industry**

### **Preparing Data for Electronic Submission in ANDAs**

U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)  
OGD  
July 1999

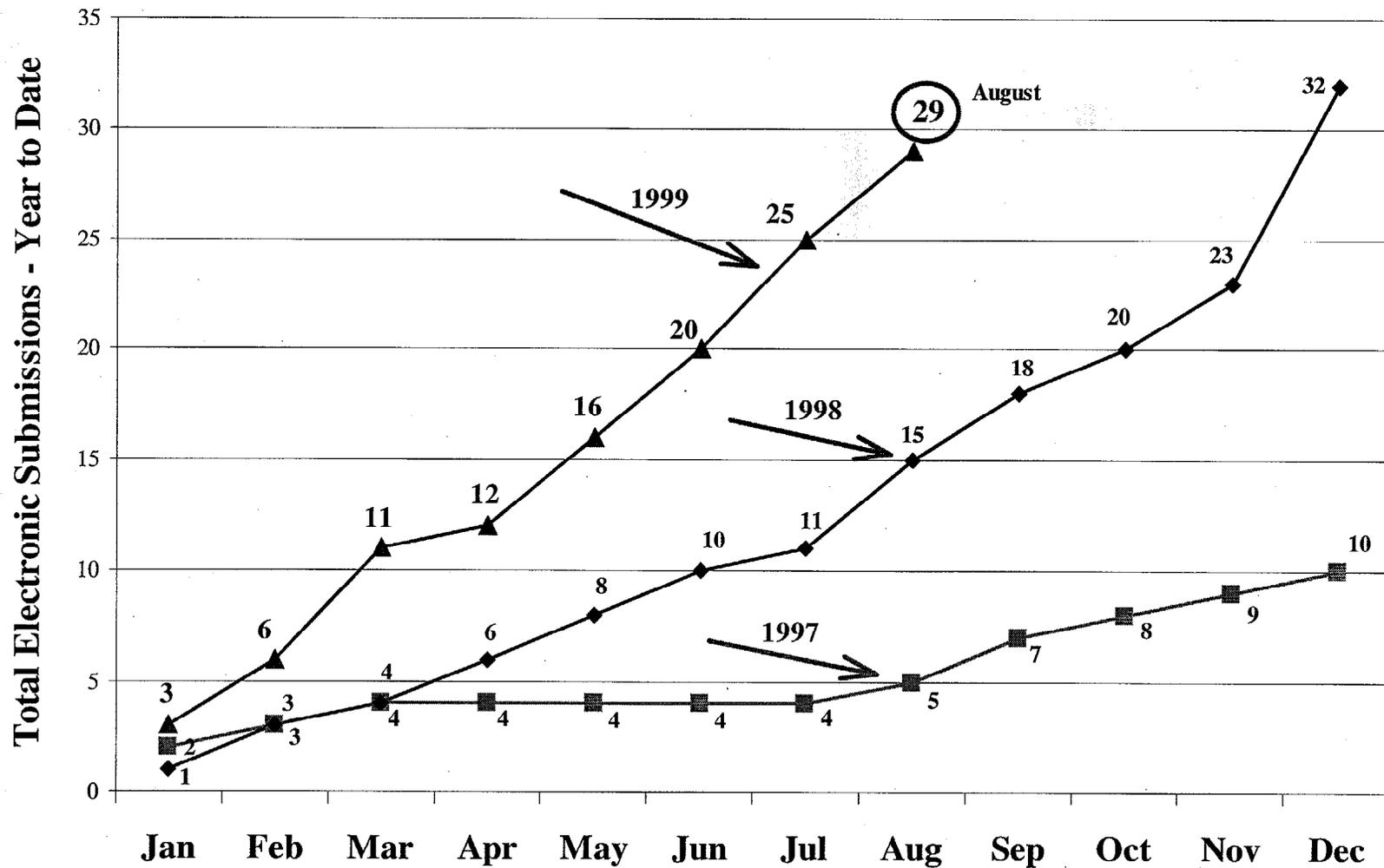
### **Level Two Guidance:**

- Addresses both  
CMC and  
bioequivalence**
- Covers the program  
as it now exists**
- Will be updated as we  
move to paperless  
submissions**

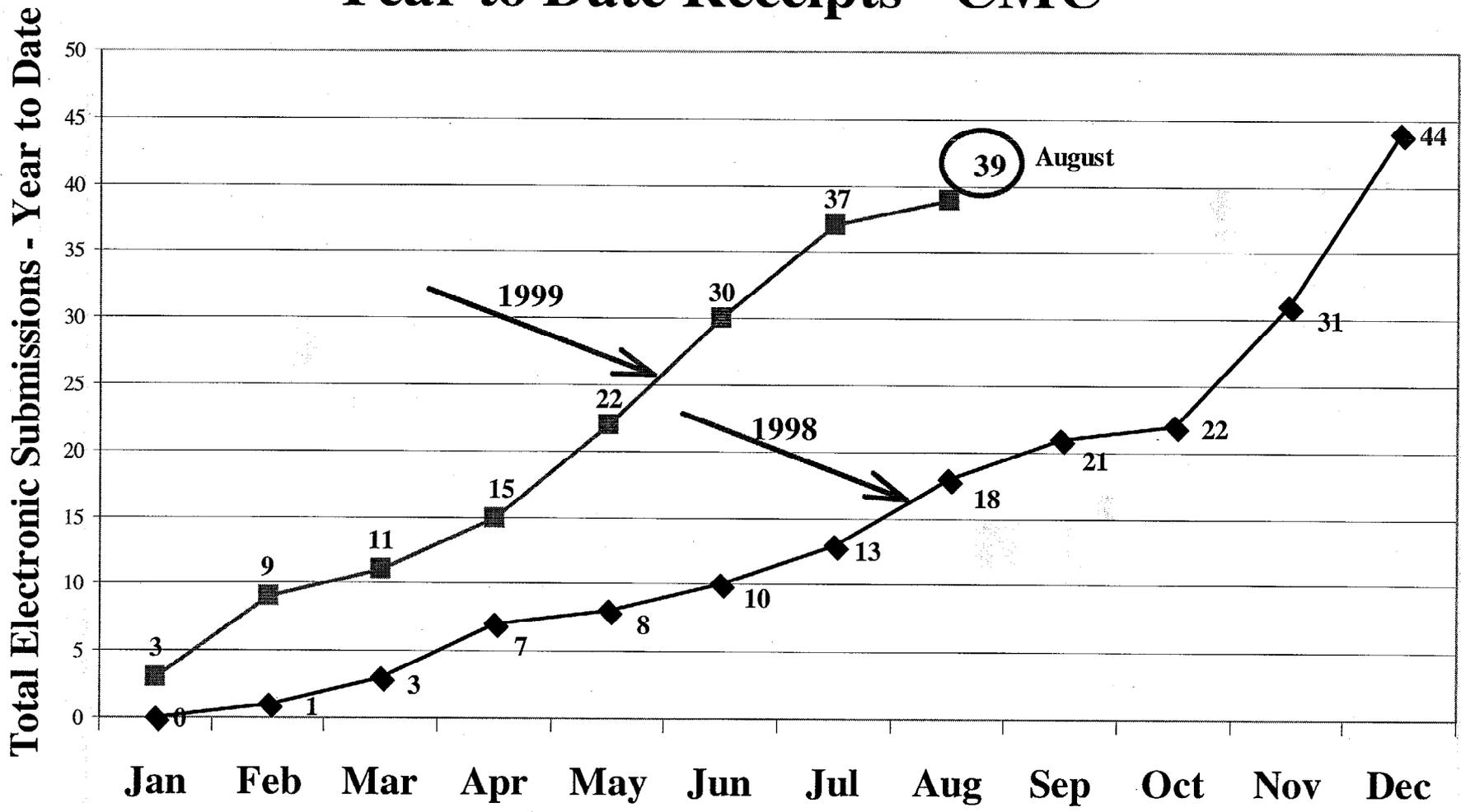
**Available at:**

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

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 • **Electronic Abbreviated New Drug Applications**  
**Electronic Submissions**  
**Year to Date Receipts - Bioequivalence**



# Electronic Abbreviated New Drug Applications Electronic Submissions Year to Date Receipts - CMC



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• **Electronic Abbreviated New Drug Applications**

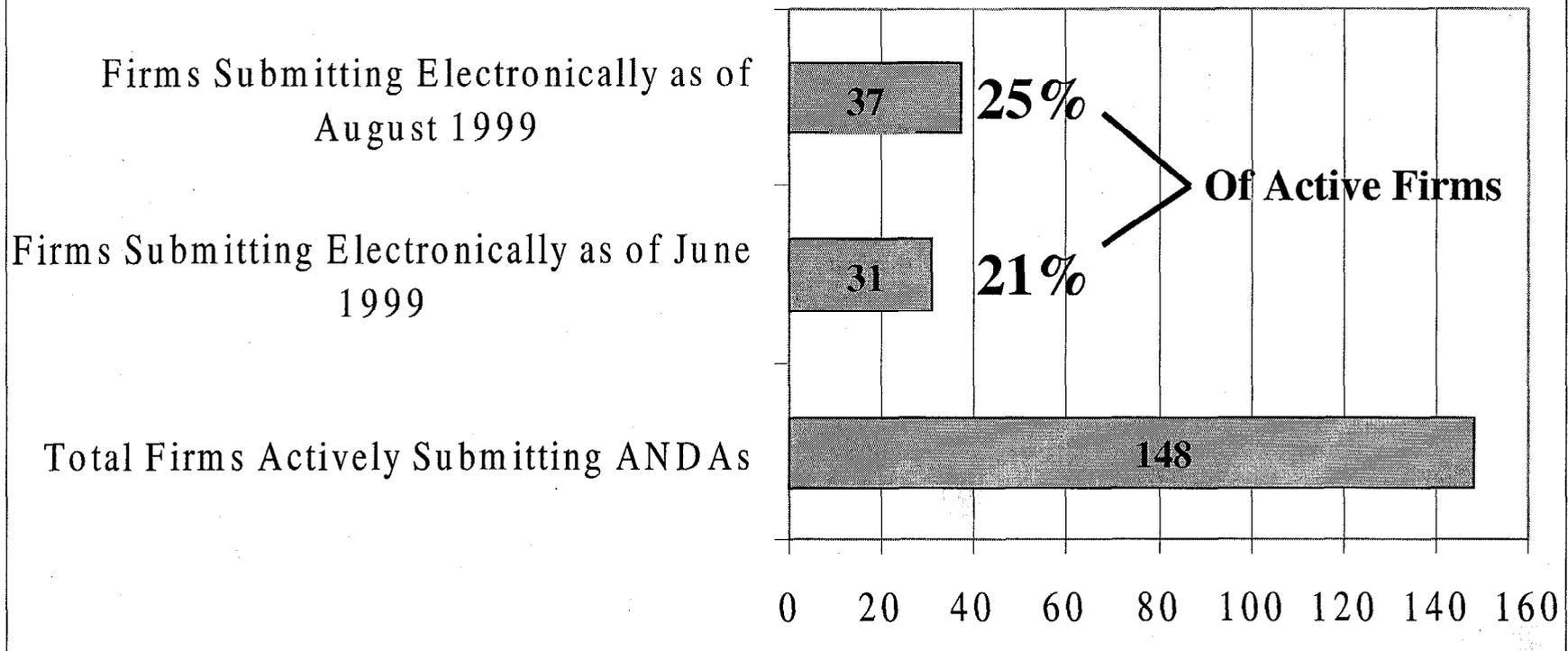
**Total Projected Receipts**

	Bioequivalence		
	1999	1998	1997
<b>Total Receipts for Year</b>	61 *	32	10
		CMC	
	1999	1998	1997
<b>Total Receipts for Year</b>	93 *	44	0
	* Projected		

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• **Electronic Abbreviated New Drug Applications**

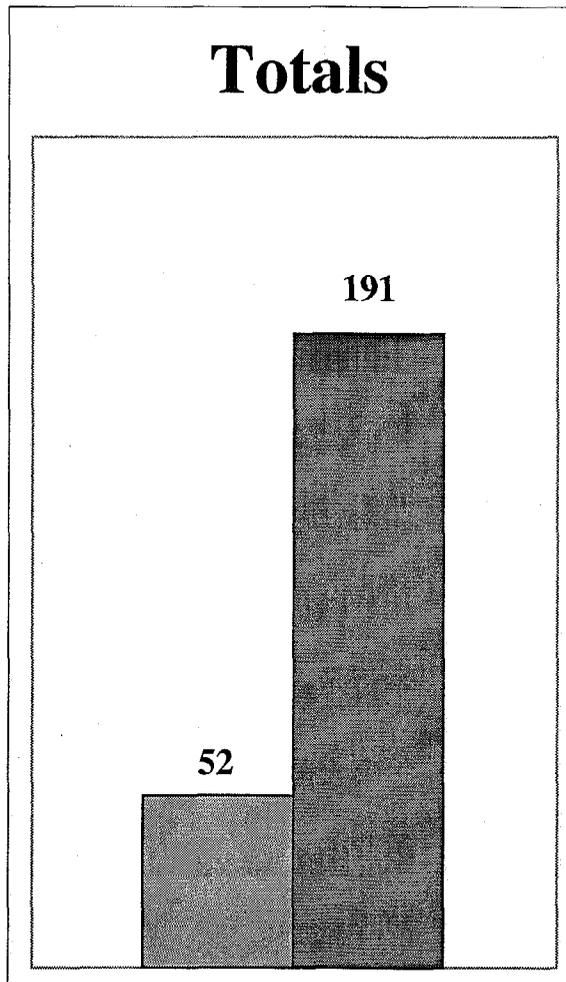
**Firms Participating**

**Number of Firms Participating in the OGD Electronic Submission Program**

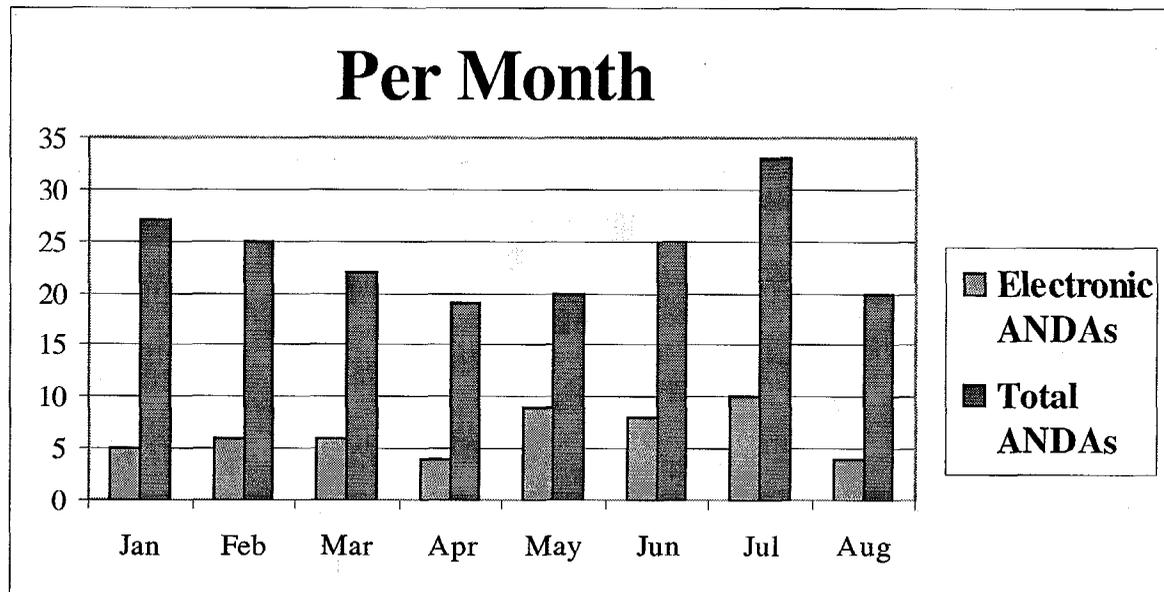


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- **Electronic Abbreviated New Drug Applications**

## ANDA Receipts January to August 1999



Twenty-seven percent of all ANDAs received by OGD in 1999 included some portion in an electronic format



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• **Electronic Abbreviated New Drug Applications**

**What can you expect now?**

- Continued refinement of the structured data elements.
- The addition of a PDF component
- Paperless Archive
- Web site will be migrated to CDER
- Training will continue to be available from the University of Maryland

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• **Electronic Abbreviated New Drug Applications**  
**What can you do to help?**

• **Participate!!!!**

• Improve Quality Control

• Ask Questions

Call Technical Support

New Phone Number: 301-827-5845

Get Documentation from the Web Site

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## Advantages for DBE, Industry

- A well-organized submission reduces time spent reviewing BA/BE portion of ANDA
  - Reduces clerical tasks
  - Presents data in concise, well-organized format
  - Data files readily accessible for statistical analyses
- Regulatory decisions made faster

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## Recurring Problems for DBE

- Discrepancies between data in ESD, data files, archival copy
- Failure to meet 30-day grace period
- Biopharmaceutics data often not included in ESD, data files
  - Dissolution, potency, formulation, waiver info
- Companion document difficult to use
  - Poorly-organized or incomplete

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## Overall Impact in DBE

- Good electronic submissions save time, improve reviewer efficiency
  - Has contributed to reduction in backlog, queue time in DBE
- Poor electronic submissions result in time wastage
  - Time spent in troubleshooting, looking for information, awaiting receipt of new data sets

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- **Electronic Abbreviated New Drug Applications**

## CMC Perspective

- Still in the learning phase
- Goal: Have all experienced chemists review an electronic submission by the end of the calendar year
- Companion Document:
  - Helps review time if well prepared (e.g., cutting & pasting information)
  - Hinders review time if poorly organized/incomplete (e.g., too many references to the hard copy)
- Data discrepancies between the ESD, the companion document, and the hard copy
  - Need good quality control with respect to the data

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- **Electronic Abbreviated New Drug Applications**

**Thank you for your support!!!**

**Continued support and feedback from  
industry is critical to the success of  
electronic submissions!**

**Discussion**