

M E M O R A N D U M

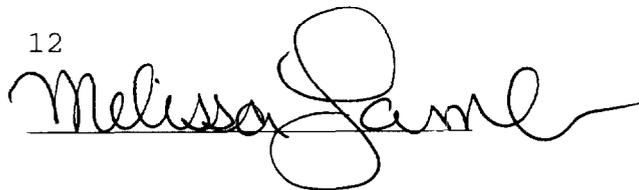
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH

5504 '00 MAR 22 10:16

Date: March 10, 2000  
To: Dockets Management Branch (HFA-305)  
From: Melissa Lamb  
Office of Generic Drugs  
Subject: ESD/EVA Advanced Training Introduction

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:

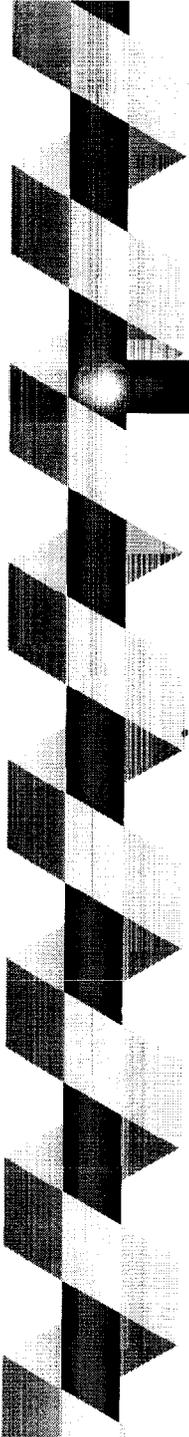
Title of Presentation: ESD/EVA Advanced Training Introduction  
Presented for: ESD/EVA Advanced Training at UMBC  
Date Presented: 3/10/200  
Presented by: Richard Sponaugle  
Number of Pages: 12



Attachment

90S-0308

M681



# **ESD / EVA Advanced Training Introduction**

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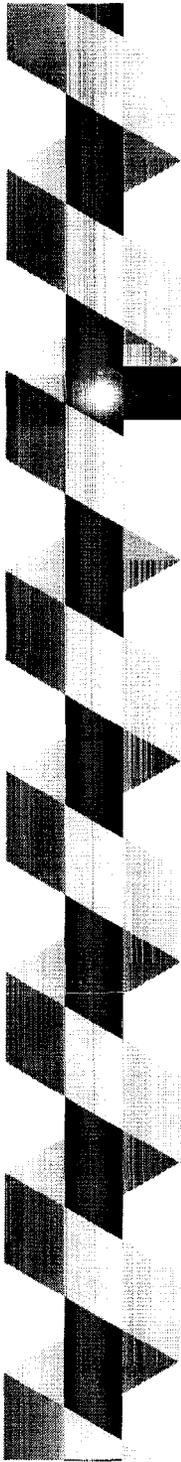
Richard Sponaugle

Computer Specialist

Senior Systems Engineer -

Electronic Submissions

Office of Generic Drugs

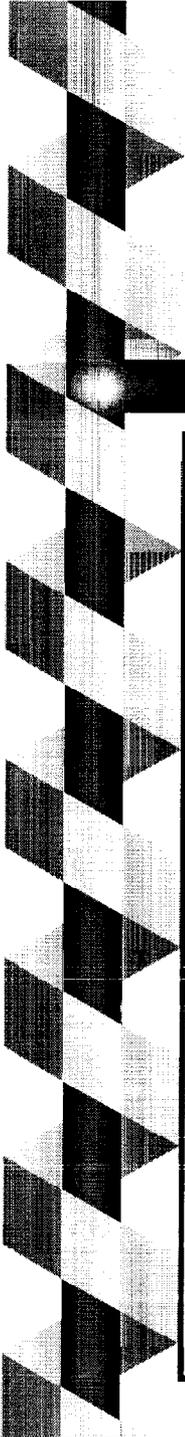


# **ESD / EVA Advanced Training Introduction**

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Participation Statistics

Introduction to Amendments



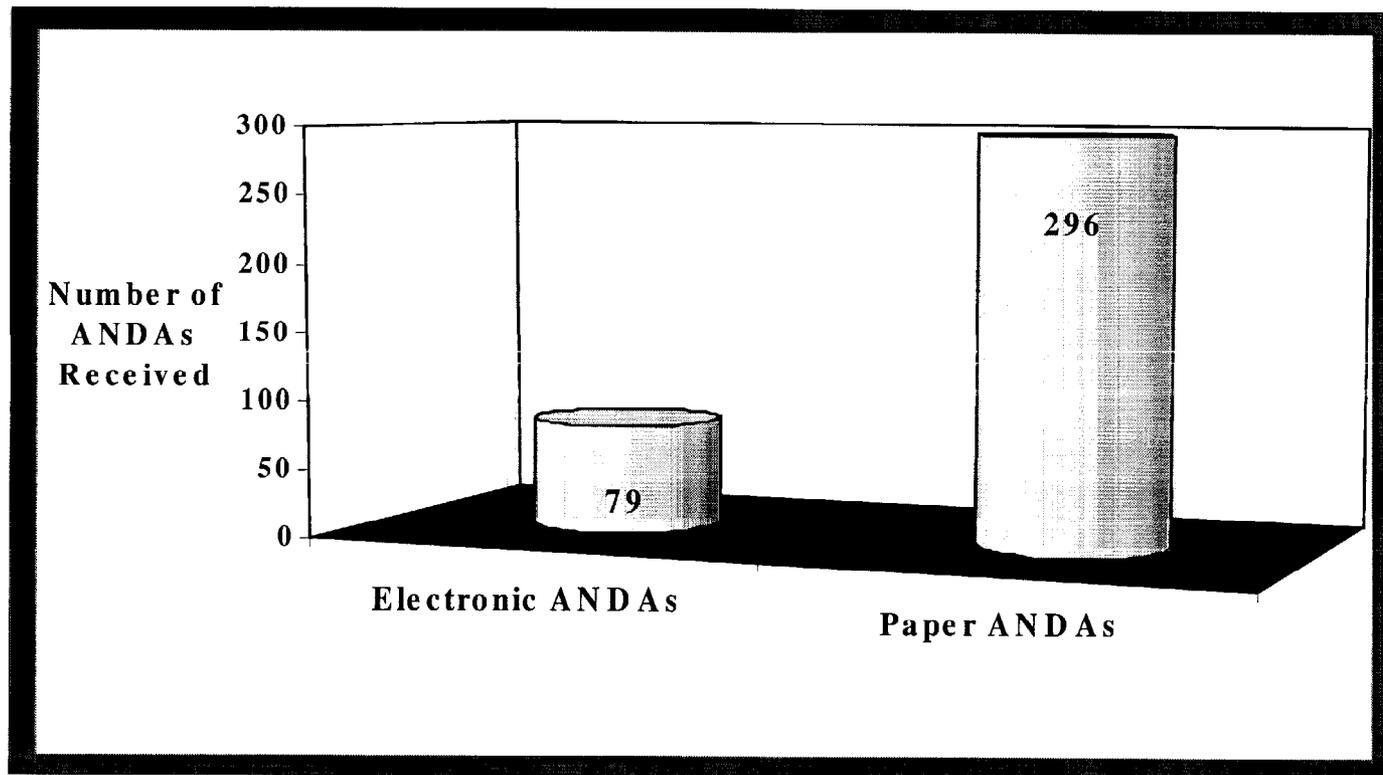
## *Electronic Submission -Participation Statistics*

	<u>1999</u>	<b>CMC</b> <u>1998</u>	<u>1997</u>
<b>Total Receipts For Year</b>	<b>55</b>	<b>44</b>	<b>0</b>
		<b>Bioequivalence</b> <u>1998</u>	<u>1997</u>
<b>Total Receipts For Year</b>	<b>44</b>	<b>32</b>	<b>10</b>

# *Electronic Submission -Participation Statistics*

## **Total ANDA Receipts CY 1999**

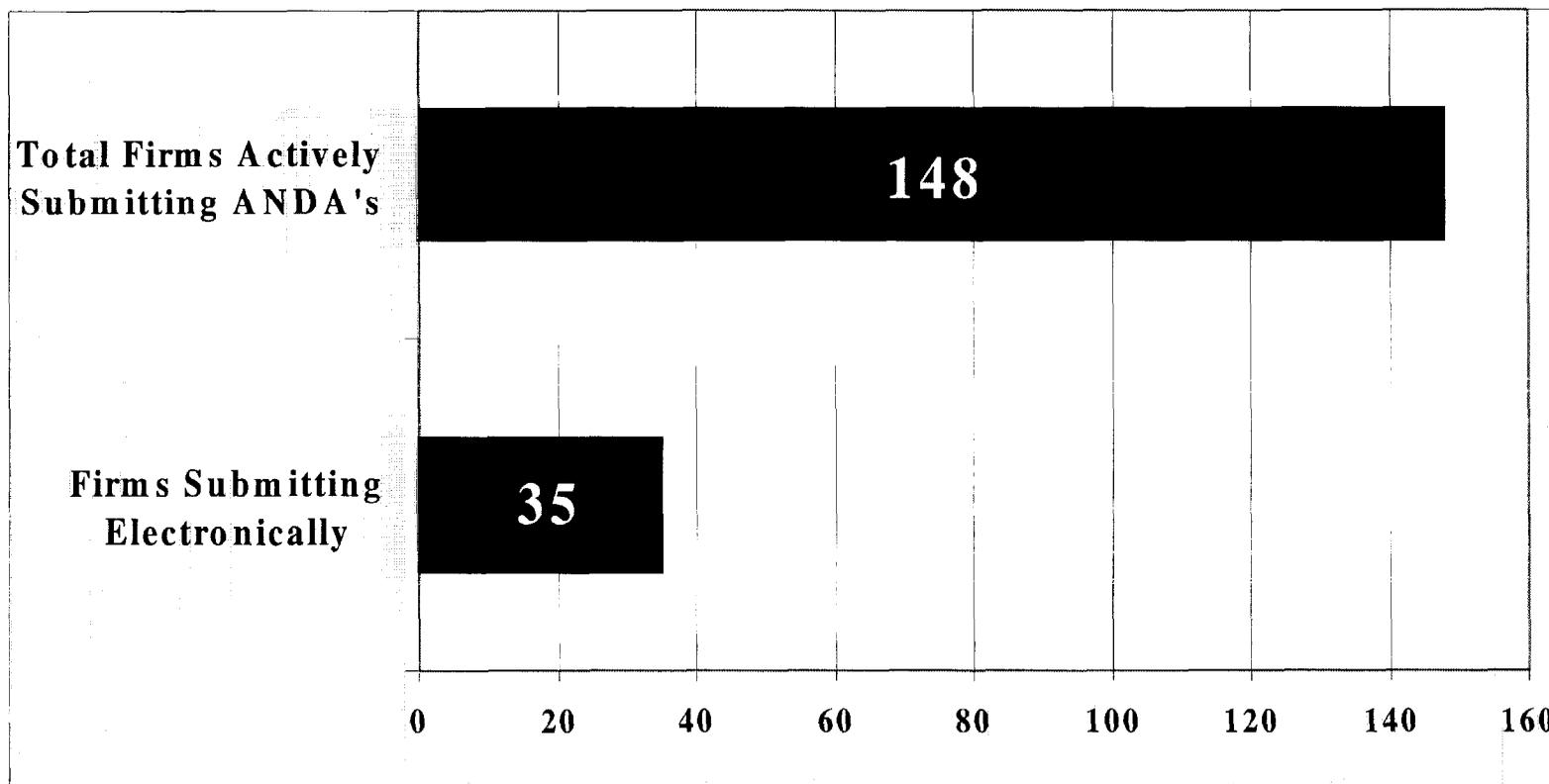
Twenty-seven percent of all ANDAs received by OGD in 1999 included some portion in an electronic format



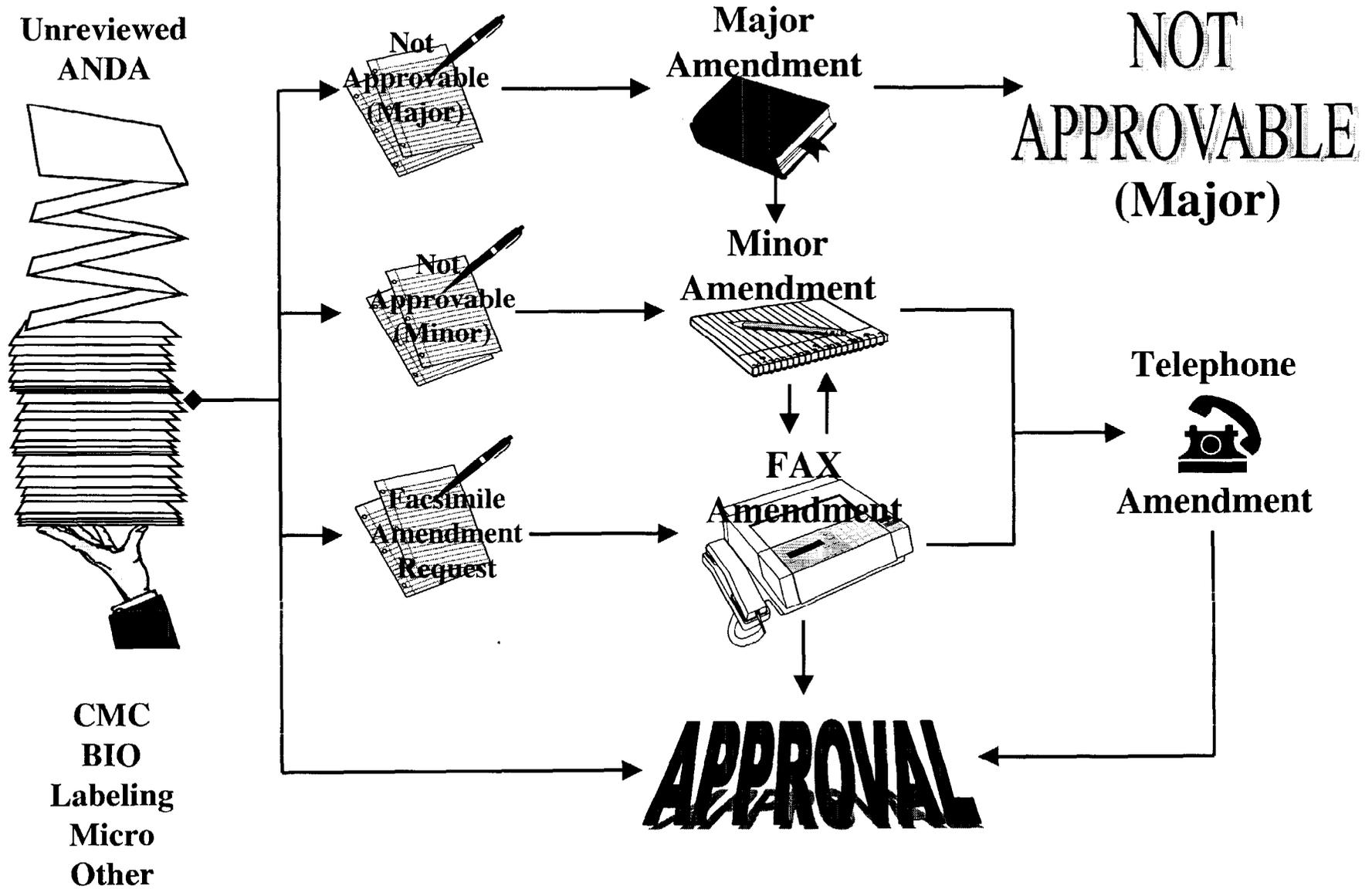
# *Electronic Submission -Participation Statistics*

## Number of Firms Participating

Twenty-Four percent of active firms are submitting electronically.



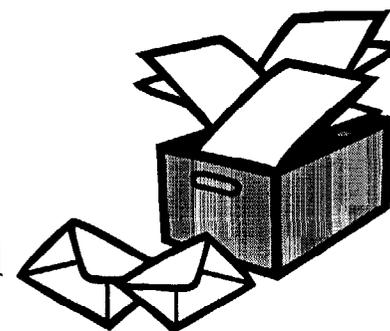
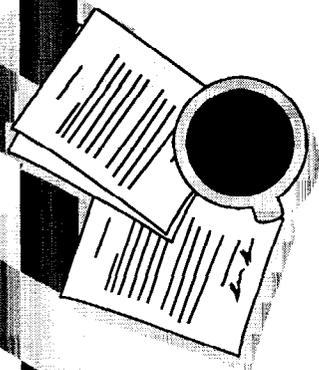
# Classification of Amendments in OGD



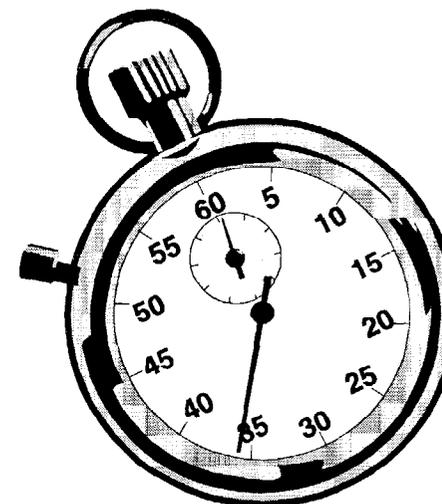
Also: Gratuitous Amendment

# Why Different Types of Amendments?

- Facilitate approval of applications with few deficiencies over those with multiple deficiencies.



- Increased control over OGD review clock



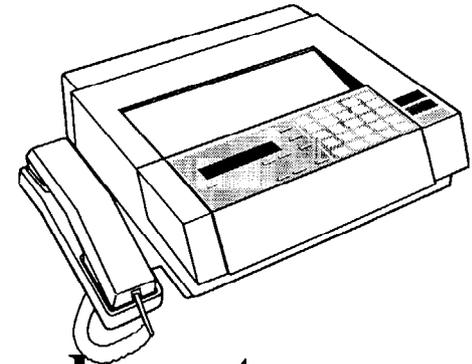
# MAJOR AMENDMENT

- **> One Hour CMC Review Time**
- **> One Day Microbiology Review Time**
- **Bioequivalence Study Needed**
- **Poor Overall Submission Quality**
  - **Absence of LOA to DMF**
  - **Absence of Stability Data**
  - **Need to Repeat Stability Studies**

# MINOR AMENDMENT

- **< One Hour CMC Review Time**
- **< One Day Microbiology Review Time**
- **No Significant Bioequivalence Deficiencies**
- **Deficiencies Outside the Control of the Applicant (DMF, CGMP)**

# **FAX AMENDMENT**



**Same Criteria as for Minor Amendment  
EXCEPT**

**All Deficiencies Within Immediate Control of Applicant  
(No DMF or CGMP Deficiencies)  
AND**

**Applicant Able to Respond to All Issues Within 30 Days**

## **Other Points**

- **Limited to One Per Review Cycle**
- **Does Not Stop Review Clock**
- **Converted to Minor If Not Received Within 30 Days**
- **Labeling Deficiencies**

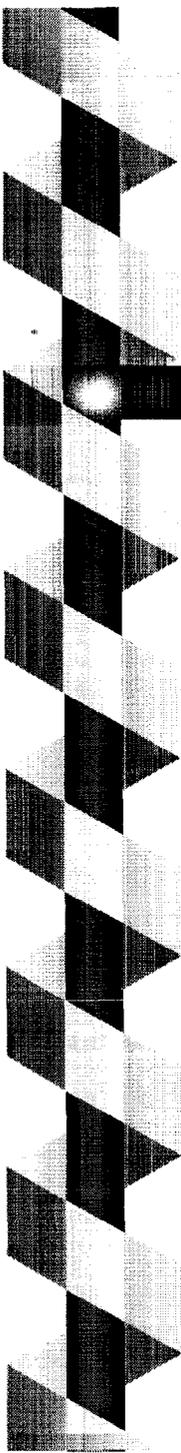
# TELEPHONE AMENDMENT

**Same Criteria as for FAX Amendment  
EXCEPT  
Applicant Able to Respond to All Issues  
Within 10 Days**

## **Other Points**

- **Frequently Used By Division of Bioequivalence**
- **Must Follow a Minor or FAX Action**
- **Does Not Stop Review Clock**
- **Converted to Minor If Not Received Within 10 Days**





# ***Should The Electronic Submission Also Be Amended?***

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**YES**

**IF -**

**What has been Amended changes anything  
that is in the electronic submission**

**Is there a grace period for electronic amendments?**

**Only for Major Chemistry Amendments**