

M E M O R A N D U M

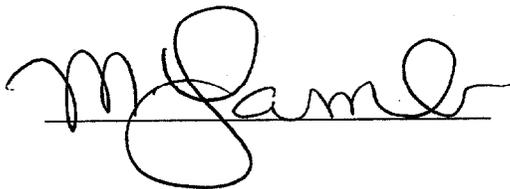
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH

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Date: February 8, 2000  
To: Dockets Management Branch (HFA-305)  
From: Melissa Lamb  
Office of Generic Drugs  
Subject: Supac Guidances Update

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: 180-Day Generic Drug Exclusivity for ANDAs  
Presented for: The Generic Pharmaceutical Industry 1999  
Fall Technical Workshop  
Date Presented: 10/18-19/99  
Presented by: Florence S. Fang  
Number of Pages: 7



Attachment

3864 '00 FEB 11 09:25

905-0308

M 656



**The Generic Pharmaceutical Industry  
1999 Fall Technical Workshop**

**Bethesda, MD  
October 18 - 19, 1999**

**SUPAC GUIDANCES UPDATE**

**Florence S. Fang  
Director, Division of Chemistry II  
Office of Generic Drugs  
Center for Drug Evaluation and Research**



**SUPAC Guidances**

***Regulatory Relief -- Continued Product Quality***

- **Science based**
- **Risk based**
- **Prescriptive**



## SUPAC Guidances

### *Development Strategy*

- **Dosage Specific**  
Commonly used dosage forms
- **Change Specific**  
Applicable to many dosage forms



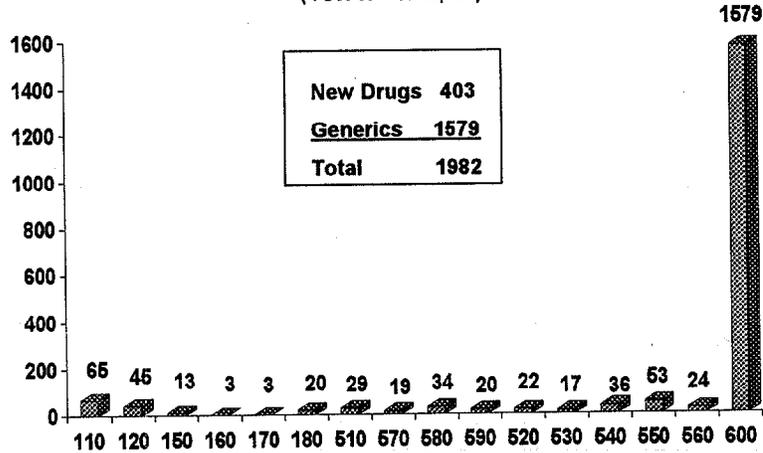
## SUPAC Guidances

<b>Immediate Release</b>	<b>IR</b>	<b>Nov 95</b>
<b>Semisolids</b>	<b>SS</b>	<b>May 97</b>
<b>Modified Release</b>	<b>MR</b>	<b>Sep 97</b>
<b>Analytical Testing Lab. Site</b>	<b>ATLS</b>	<b>Apr 98</b>



### SUPAC SUPPLEMENTS RECEIVED BY DIVISION

( 1 Dec 95 - 30 Sep 99 )

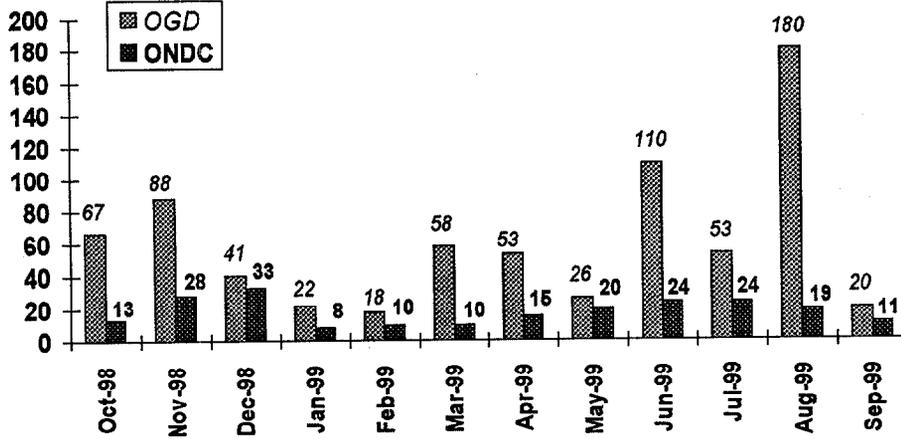


### Division Number / Corresponding Therapeutic Area

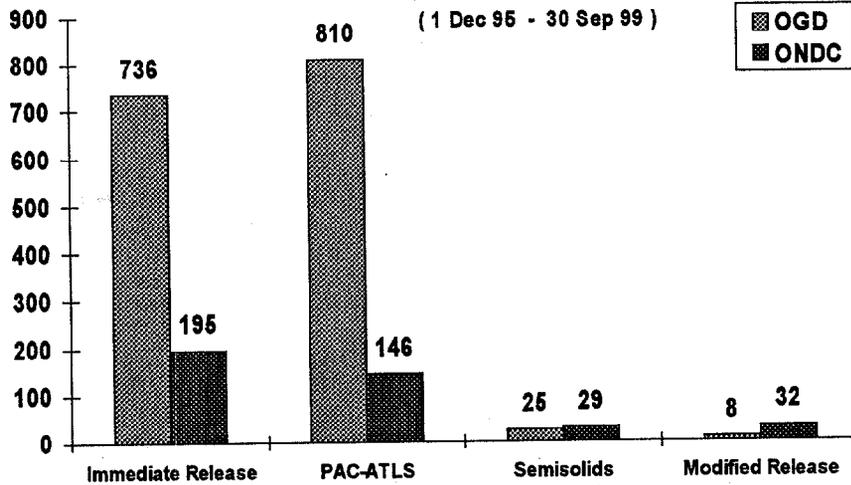
- 110 - Cardio-Renal
- 120 - Neuropharmacological
- 150 - Oncologic
- 160 - Radiopharmaceutic, Medical Imaging
- 170 - Anesthetic, Critical Care, Addiction
- 180 - GI and Coagulation
- 510 - Metabolic and Endocrine
- 520 - Anti-Infective
- 530 - Anti-Viral
- 540 - Dermatologic and Dental
- 550 - Anti-Inflammatory, Analgesic, Ophthalmologic
- 560 - Over-The-Counter
- 570 - Pulmonary
- 580 - Reproductive and Urologic
- 590 - Special Pathogen and Immunologic
- 600 - Generics



### SUPAC SUPPLEMENTS RECEIVED LAST 12 MONTHS

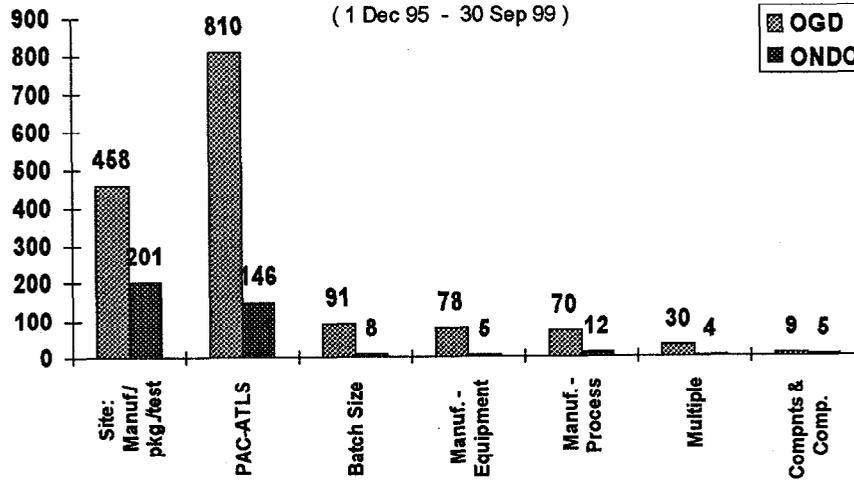


### SUPAC SUPPLEMENTS BY GUIDANCE





### TYPE of CHANGES SUBMITTED as SUPAC SUPPLEMENTS



### SUPAC - Work in Progress

#### *SUPAC IR Revision      Draft*

- Consolidation into one document
- Further application of research data
- Reevaluation of Case C dissolution
- Coverage of multiple changes



## SUPAC - Work in Progress

### BACPAC I            Draft with Public Comments

- All changes up to the final intermediate
- Equivalence of analytical profiles of
  - isolated intermediate    *or*
  - drug substance

### BACPAC II            Draft

- Changes from final intermediate to drug substance



## SUPAC - Work in Progress

SUPAC - TDS	Draft
PAC - SAS	Draft
AMPAC	Planning
PACPAC	Planning



## **SUPAC Guidances**

### ***Making a Difference***

- **Regulatory Relief  
Planning, Control, Cost**
- **Review Consistency  
Standards for Review for OPS**



## **SUPAC Guidances**

### ***After FDAMA***

- **Reporting categories, if different,  
superseded by final 314.70 guidance**
- **Data requirements remain applicable**
- **Revision planned**