

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

~~9842 '01 MAR -6 19:49~~

Date: March 2, 2001

To: Dockets Management Branch (HFA-305)

From: Melissa Lamb
Office of Generic Drugs

Subject: An Overview of the office of Generic Drugs

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: An Overview of the office of Generic Drugs

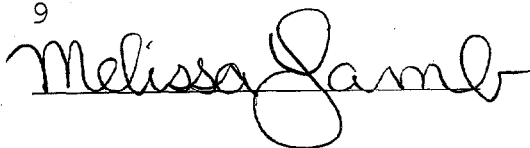
Presented for:

Date Presented: February 5, 2001

Presented by: Gary Buehler, Acting Director
Office of Generic Drugs

Number of Pages:

9

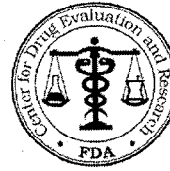


Attachment

90S-0308

M 696

An Overview of the Office of Generic Drugs



Gary J. Buehler
Acting Director
Office of Generic Drugs

February 5, 2001

Office of Generic Drugs' Mission Statement



To ensure through a scientific and
regulatory process, that generic drugs
are safe and effective for the
American public.

Did you know that Generic Drugs...

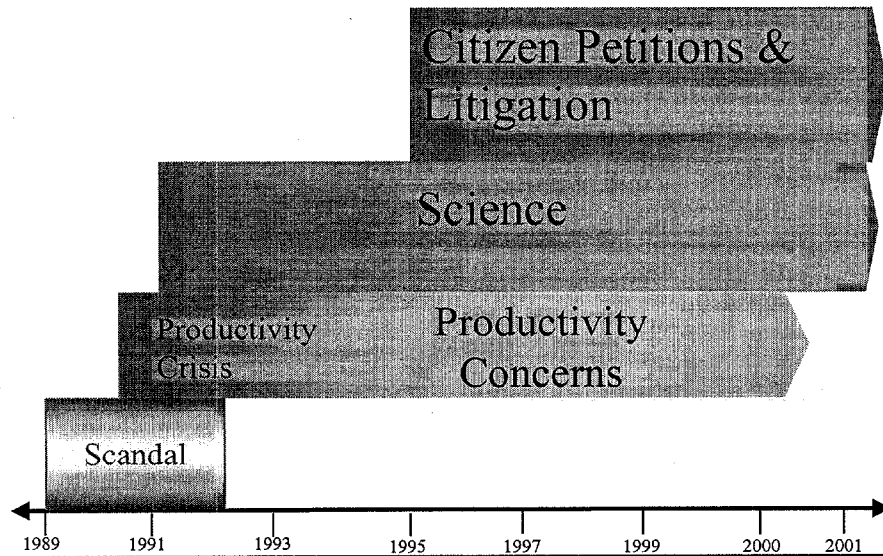
- Are safe and effective alternatives to brand name prescriptions
- Can help both consumers and the government reduce the cost of prescription drugs
- Are currently used in 43% of all prescriptions dispensed
- Save an average of \$45.50 for every prescription sold

And...

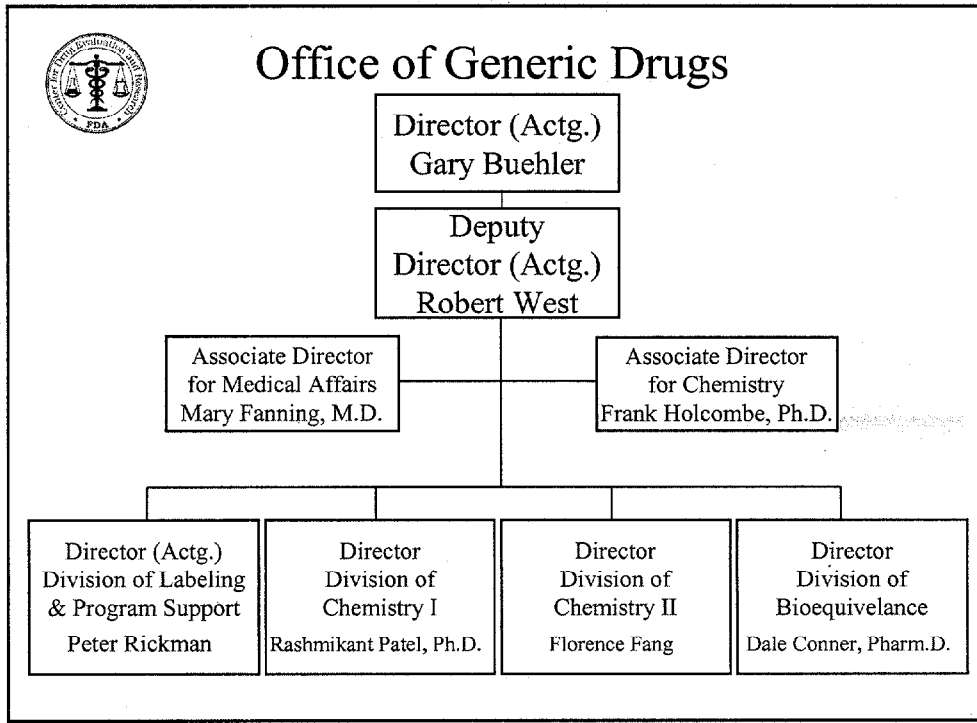
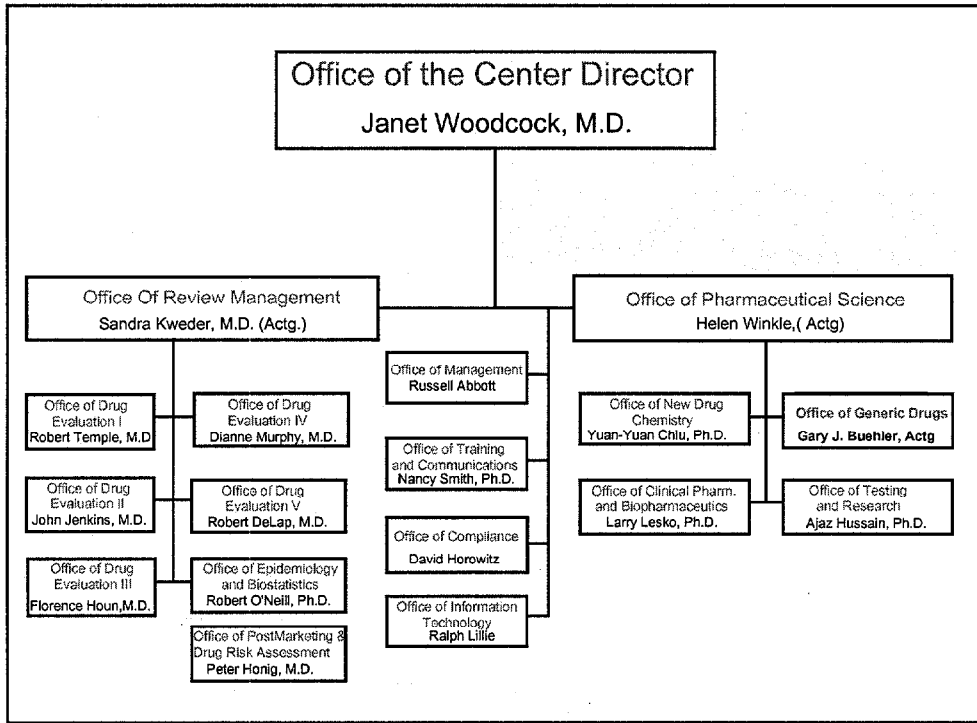
- Currently save consumers \$56.7 billion/year
- Can save consumers an additional \$1.32 billion/year for every 1% increase in the use of generic drugs
- Can save consumers an additional \$22 billion/year if generic drug alternatives were used in 60% of all the prescriptions sold.

Source: National Association of Pharmaceutical Manufacturers, December 15, 2000


OGD Eras



OGD Organizational Structure and Operations



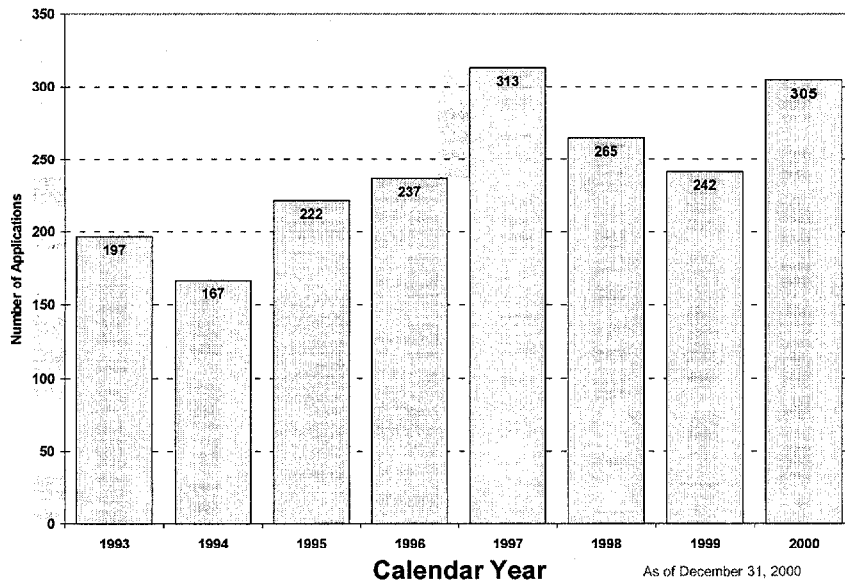
Breakdown of Onboard FTEs - OGD

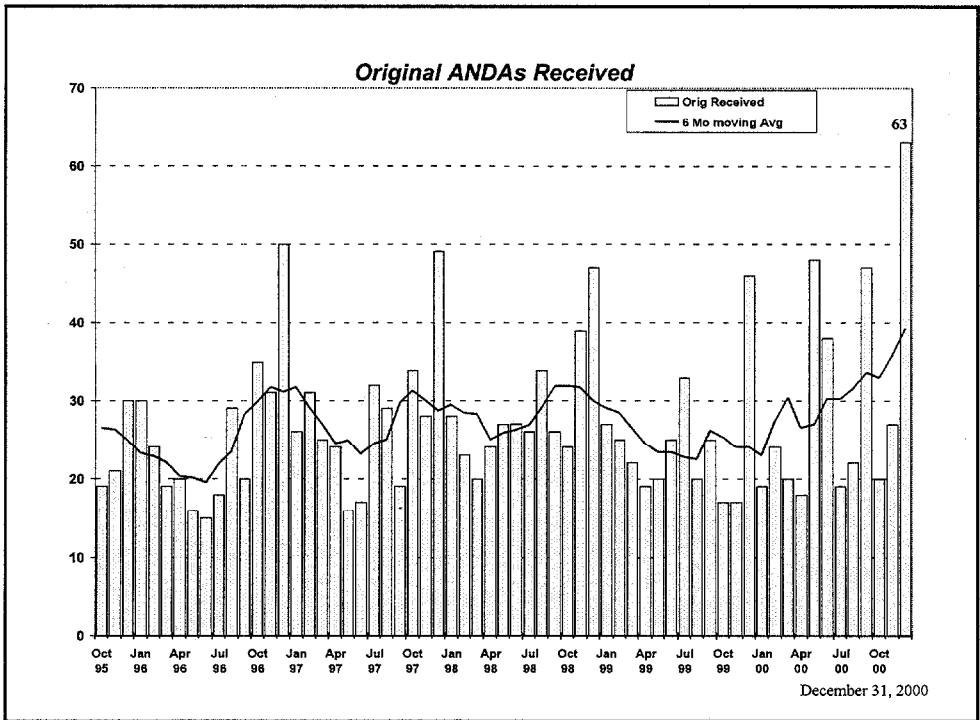
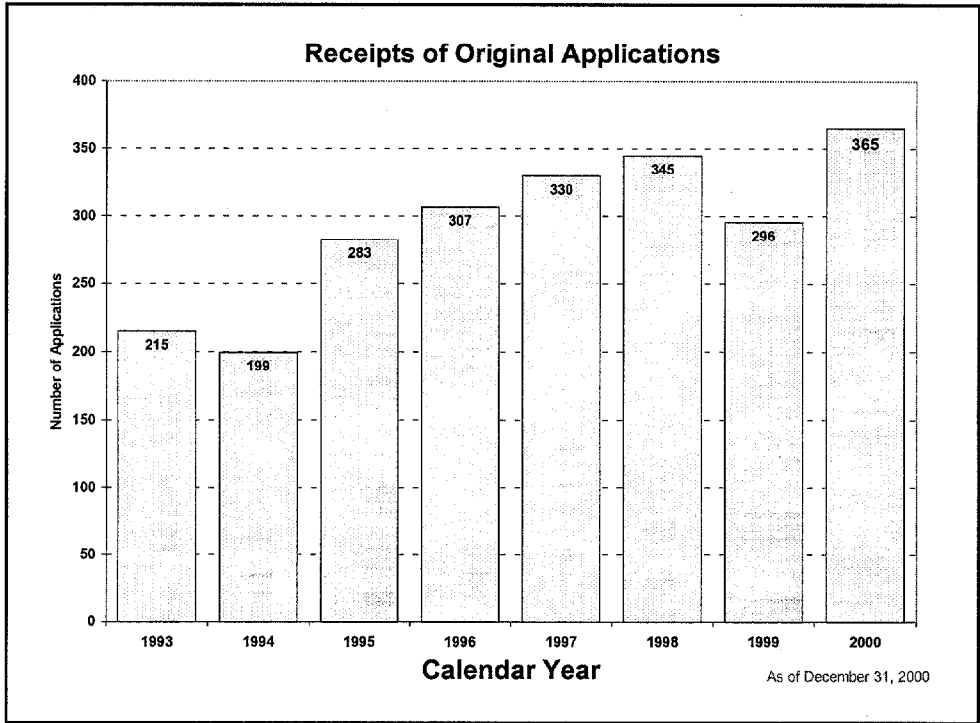
	Total	<u>141</u>
-	Chemists	65
-	Pharmacologists	15
-	Pharmacists	37
-	Medical Officer	1
-	Math Statistician	1
-	Microbiologists	4
-	Computer Specialist	2
-	Admin/Support Staff	16

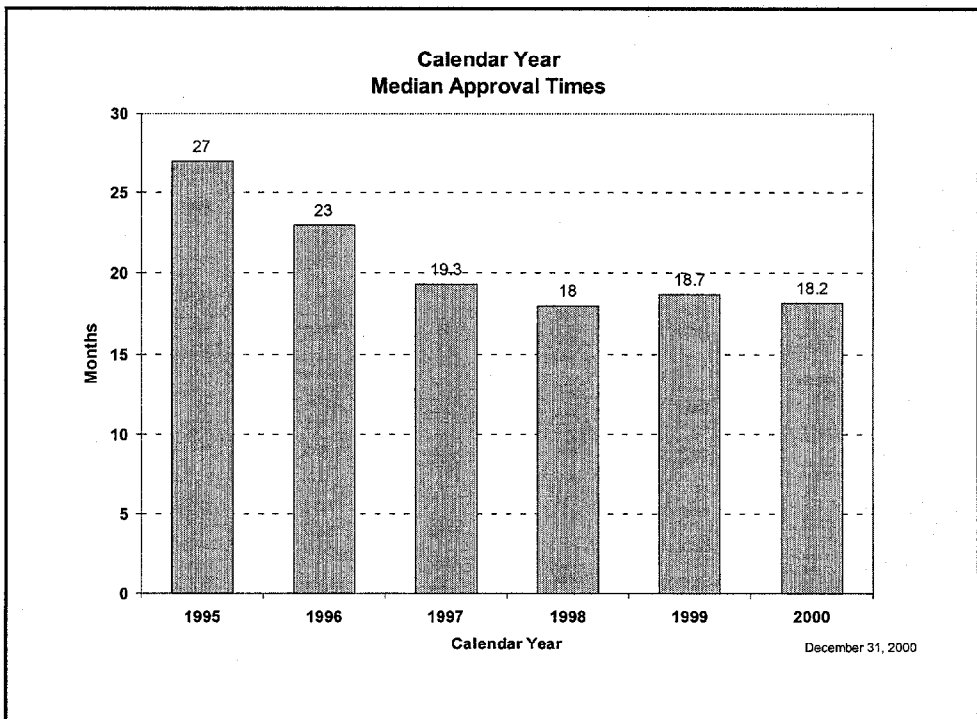
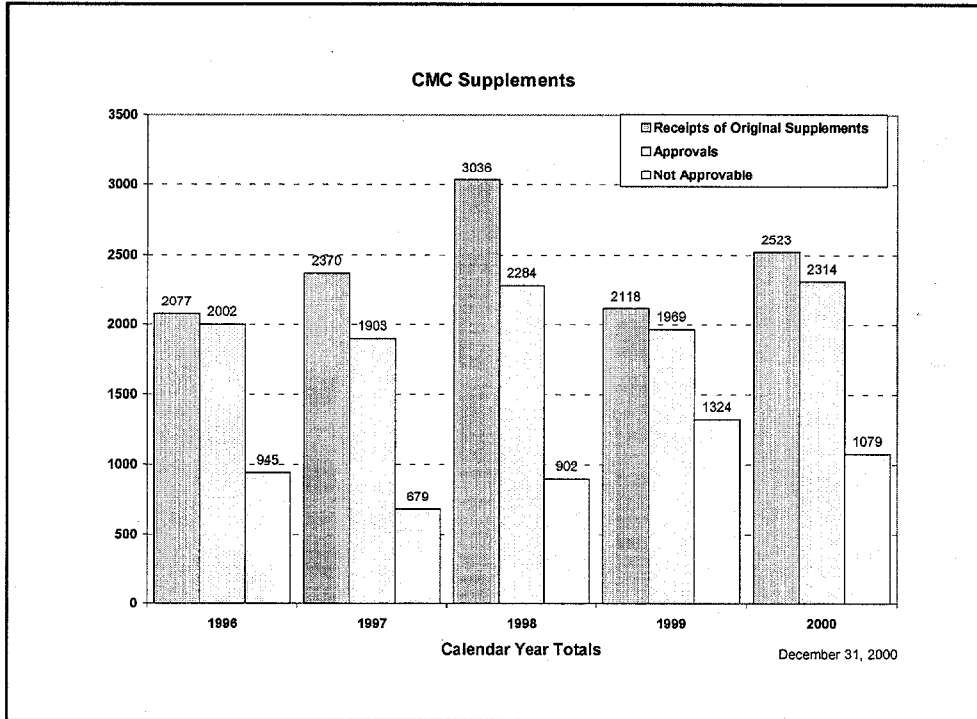
No positions are funded by User Fees

December 31, 2000

Approvals and Tentative Approvals







Public Perception of Generic Drug Products

“Generic Drugs are Safe, Effective Alternatives to Brand Names”

- Working with Trade Associations
- Internal Efforts
- Establishing Ties with Outside Organizations
 - Physicians
 - Pharmacists
 - Public

Into the Future

- Continue emphasis on communication with industry
 - Next OGD-Industry Meeting >Spring 2001
 - Controlled Correspondence
 - Web Initiatives
- Move forward with review refinements
- Emphasize quality of work life/training for OGD staff
- Focus on Science Base

