GAO United States
General Accounting Office
Washington, D.C. 20548

Program Evaluation and
Methodology Division

B-271814

April 23, 1996

The Honorable Thomas J. Bliley
Chairman
Committee on Commerce
House of Representatives

Dear Mr. Chairman:

The Food and Drug Administration (FDA) is responsible for ensuring the safety of biologics, human drugs, medical devices, food additives, and animal drugs and the effectiveness of all but food additives. FDA's timeliness in clearing new products for marketing has become a topic of major concern. You asked for information on FDA resources, workload, and review time. In response, we presented your staff with data for fiscal years 1990-95 on the allocation of resources, the number of applications that were submitted to and reviewed by the agency for the five product types listed above, and the time FDA spent in reviewing these applications. The data appear in the enclosures.

It is important to note that we did not collect original data but relied on existing data (primarily information FDA provided to the Congress in the appropriations process and data contained in the agency's annual reports). For this reason, the measures of resources, workload, and review time that we present are not always the most appropriate. For example, appropriate indicators of FDA's performance with respect to product review are the number of decisions it has made and the median time it took to make them. What we discuss are the number of approvals FDA granted and the time it took to arrive at those approvals, because these are the measures that FDA reports consistently.

RESOURCES AND WORKLOAD

Workload is not easily quantified. The amount of resources required to review an application differs by product

type. For example, within medical devices, a premarket notification (510(k)) requires fewer resources for review than does an application for premarket approval (PMA). Therefore, to the extent that such data were available, we report the resources FDA used in terms of "full-time equivalents" (FTEs) by product type.

When we were not able to obtain data on resource use by product type, we used differences in review time as an indicator of relative demand for resources. For example, we relied on review time as an indicator for the Center for Drug Evaluation and Research, where the number of FTEs reported combined the activities devoted to the review of new drug applications (NDAs), NDA supplement applications, and investigational new drug (IND) applications. The adequacy of review time as an indicator of relative demand is supported by the fact that review times were considerably shorter for applications that demanded fewer resources (NDA manufacturing and NDA labeling supplements) than they were for applications that demanded more (full NDAs and NDA efficacy supplements).

FDA's overall resource demand depends also on the mix of product types at each of its product review centers.[1] Changing the mix at any one center would change the overall workload and, in turn, the review time for various products. For example, reviews for an equivalent number of PMAs and 510(k)s would require very different amounts of resources.

Resource demand within product type can also vary, and the variation is difficult to assess. The data we have do not provide any indication of whether the demand for resources for reviewing any particular product type remains constant. We have made no attempt to account for potential variation in resource demands within product type. Therefore, we did not determine, for example, whether the resources required to evaluate the safety of food additives have changed as the products have changed (that is, the new food macroadditives present different scientific questions from those posed by traditional types of food additives).

[1]The five centers are the Center for Biologics Evaluation and Research (CBER), Center for Drug Evaluation and Research (CDER), Center for Devices and Radiological Health (CDRH), Center for Food Safety and Applied Nutrition (CFSAN), and Center for Veterinary Medicine.

EFFICIENCY

The efficiency of the review process is important in that it defines the relationship between resources and workload, on the one hand, and review time, on the other. Unlike resources (which are determined by appropriations to FDA and the formula under user fees) and workload (which is determined by the volume and quality of applications submitted to FDA), efficiency is largely within the agency's control. FDA has instituted a number of changes in order to improve the efficiency of product review (the triage program for reviewing medical device applications at the Center for Devices and Radiological Health is one example). However, we have not evaluated the effectiveness of these changes and it is not possible for us to do so from the available data.

AN OVERVIEW OF OUR DATA

In the six pairs of enclosures, we detail in figures and tables and notes to them the information you requested. In enclosures I and II, we provide you with FTEs and salary outlays by activity for fiscal years 1990-95 (including estimates for 1996). These data are for the agency as a whole. In the remaining enclosures, we provide data on resources, workload, and review time for each center: biologics (enclosures III-IV), human drugs (enclosures V-VI), medical devices (enclosures VII-VIII), food additives (enclosures IX-X), and animal drugs (enclosures XI-XII).

In our figures and tables, we present review times for all applications according to the fiscal year in which the reviews for them were completed. We defined "workload" as the number of applications received each year plus applications from the previous year that had yet to be completed--that is, applications pending. However, the definition of "pending" differs somewhat for the individual centers. (Explanatory notes in the enclosures indicate the precise definition for each center.)

A ratio of the workload to the number of FTEs engaged in product review indicates the amount of work each reviewer is to accomplish. We constructed a second ratio to indicate the amount of work each reviewer actually accomplished--that is, the number of applications reviewed per center divided by the number of staff engaged in product review. When such data were available, we used "primary reviewer" and "direct FTE" to calculate the ratios. Otherwise, we used "program FTEs" that include management and support functions for product review.

As we noted above, review time can be used as an alternative indicator of resource demands by product type. For this purpose, FDA time (the amount of time an application was actually under FDA review) as distinguished from non-FDA time (the amount of time waiting for the applicant to respond) is a better indicator than one that combines FDA and non-FDA time.

Finally, throughout the data we present dollar amounts in constant dollars adjusted to the 1995 Consumer Price Index-Urban (CPI-U). I would be happy to answer any further questions you may have. Please call me at (202) 512-2900 or George Silberman at (202) 512-9226.

Sincerely yours,

Mary R. Hamilton

Mary R. Hamilton
Director for Program Evaluation
in Human Services Areas

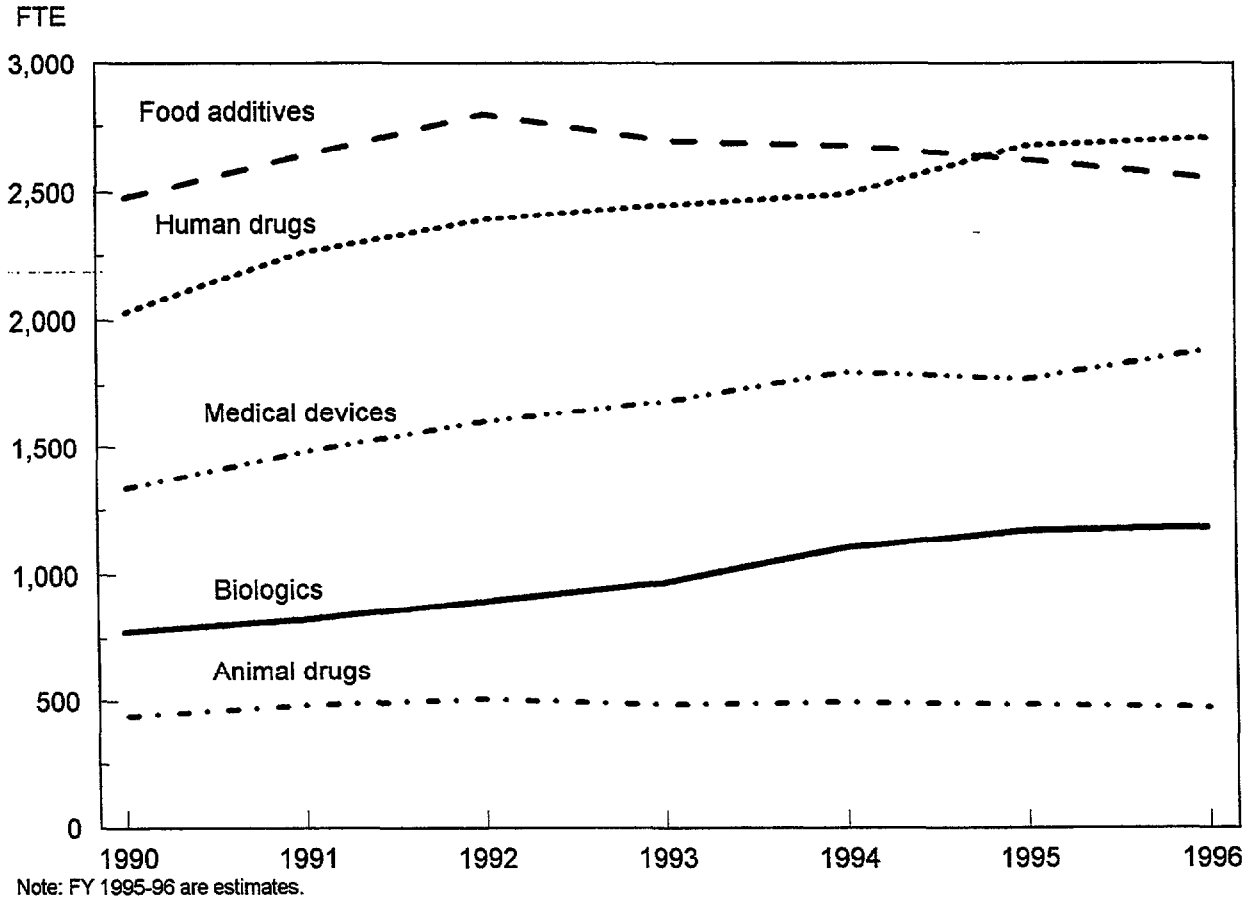
ENCLOSURES OF FIGURES AND TABLES

ABBREVIATIONS

510(k)	Premarket notification
AADA	Abbreviated antibiotic drug application
ANADA	Abbreviated new animal drug application
ANDA	Abbreviated new drug application
CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
CFSAN	Center for Food Safety and Applied Nutrition
CVM	Center for Veterinary Medicine
ELA	Establishment license application
FDA	Food and Drug Administration
FOIA	Freedom of Information Act
FTE	Full-time equivalent
GRAS	Generally recognized as safe
IDE	Investigational device exemption
INAD	Investigational new animal drug
IND	Investigational new drug
NADA	New animal drug application
NDA	New drug application
OTC	Over the counter
PLA	Product license application
PMA	Premarketing approval

FDA RESOURCE DISTRIBUTION FIGURES

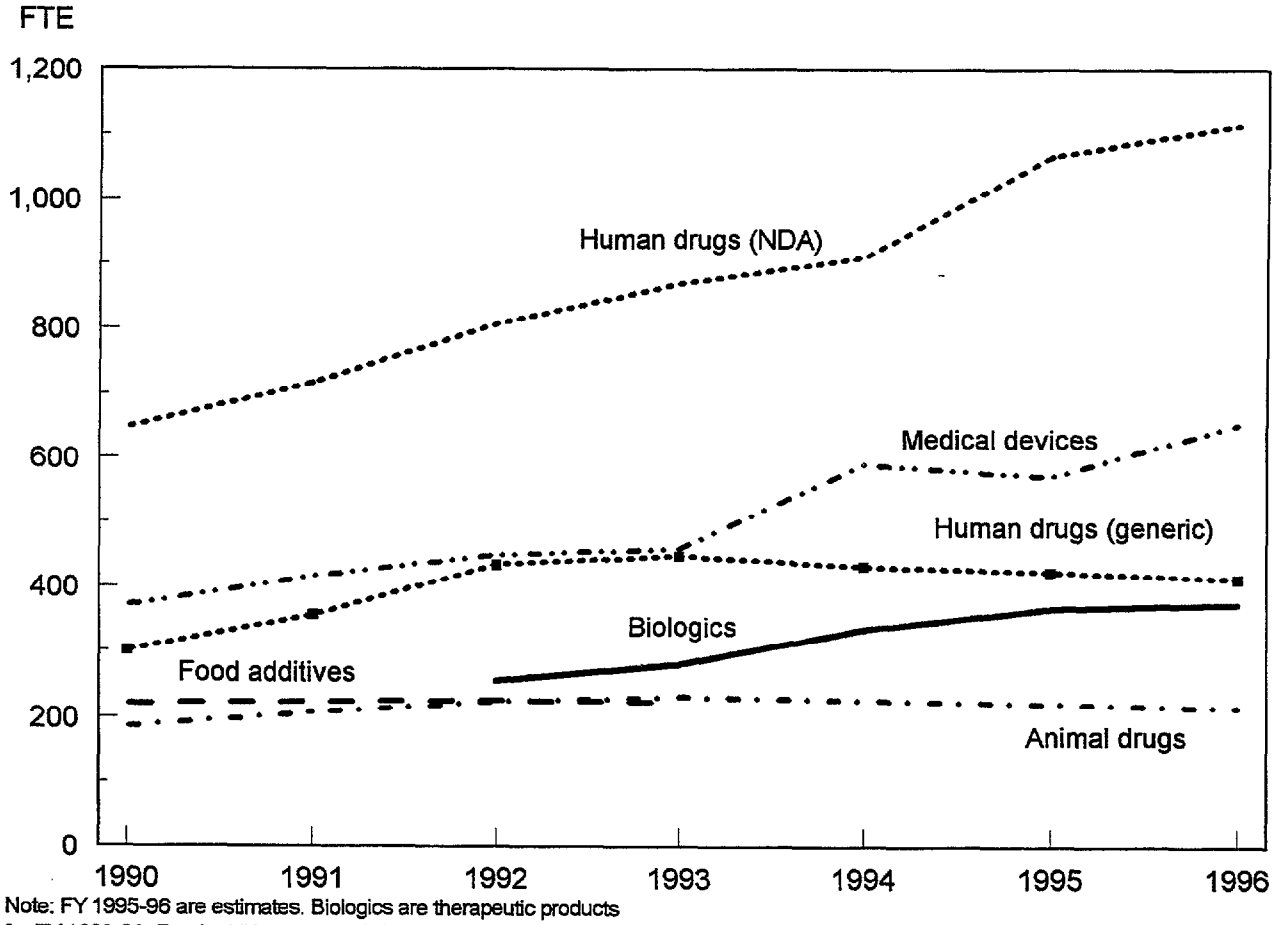
Figure I.1: FDA FTE Distribution by Activity, FY 1990-96



Note: FY 1995-96 are estimates.

ENCLOSURE I

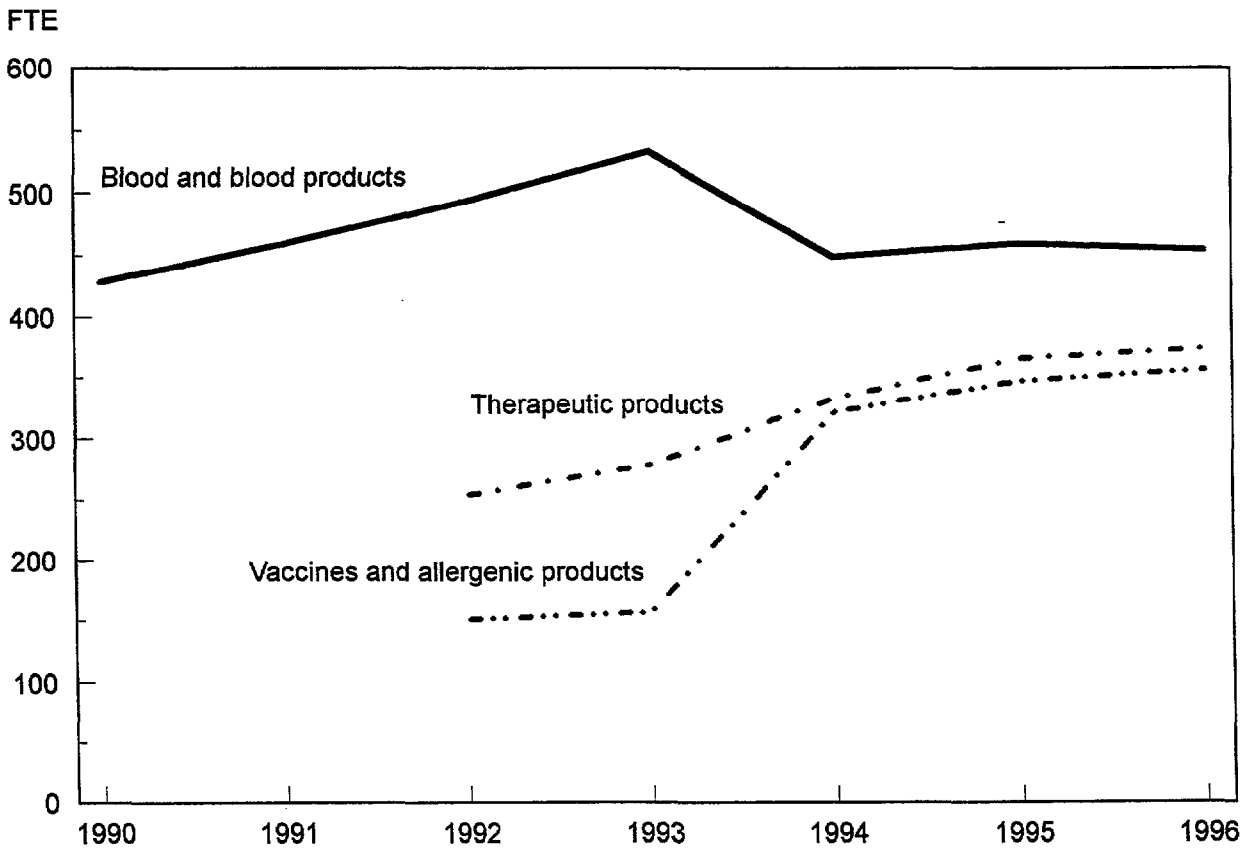
Figure I.2: FDA FTE Distribution for Product Review, FY 1990-96



Note: FY 1995-96 are estimates. Biologics are therapeutic products for FY 1993-96. Food additives not available after FY 1993.

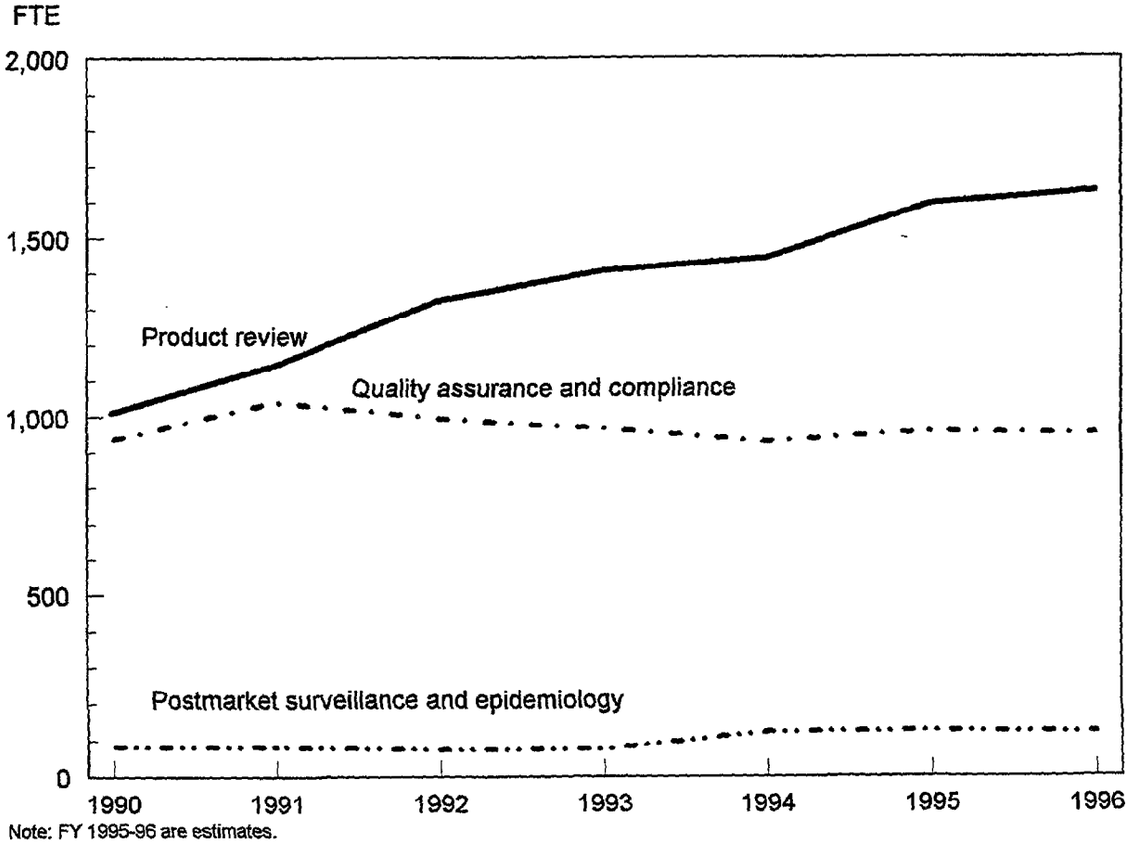
ENCLOSURE I

Figure I.3: Biologics FTE Distribution by Activity, FY 1990-96



Note: FY 1995-96 are estimates. FY 1990-92 not available for therapeutic products and vaccines and allergenic products.

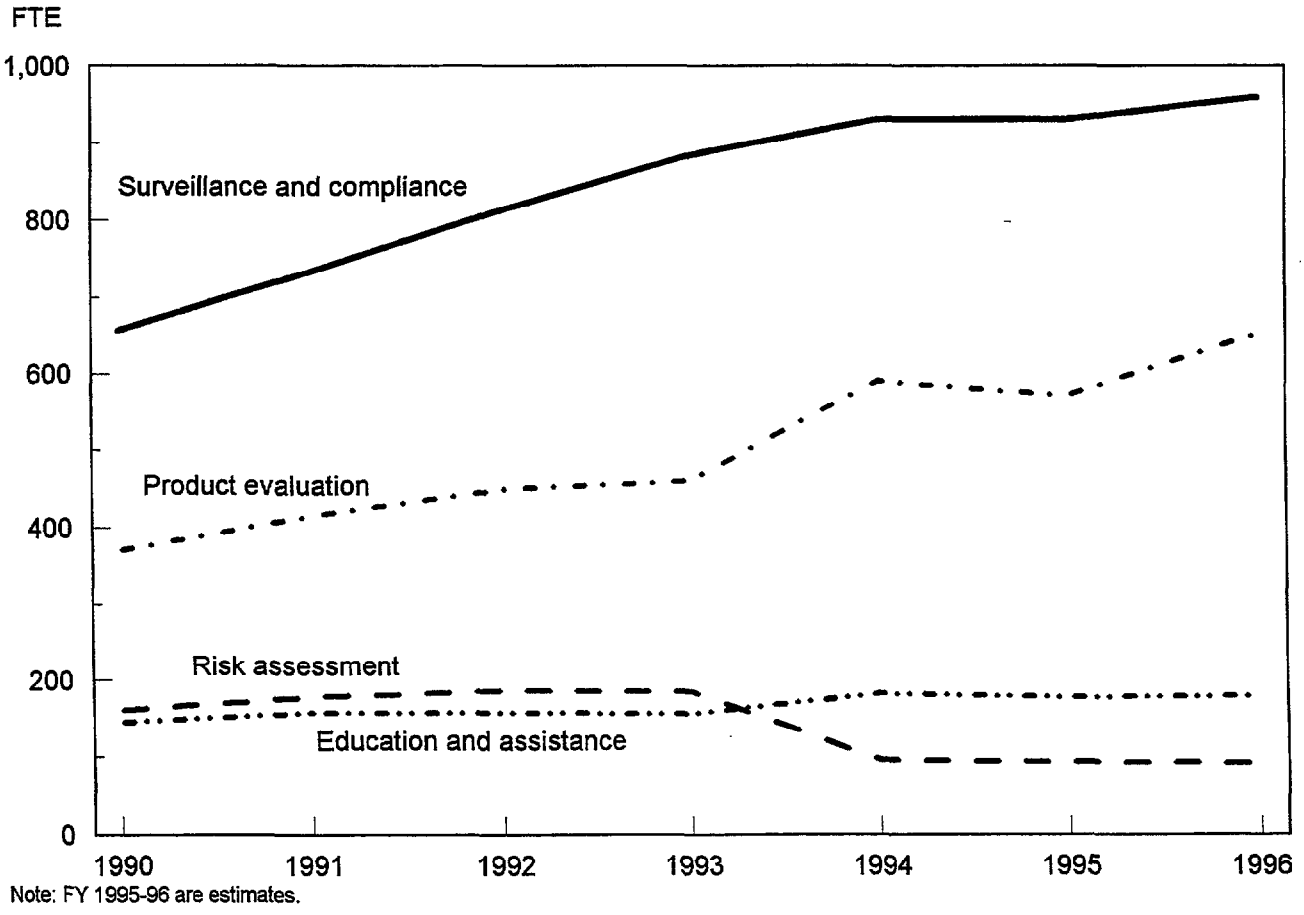
Figure I.4: Human Drugs FTE Distribution by Activity, FY 1990-96



Note: FY 1995-96 are estimates.

ENCLOSURE I

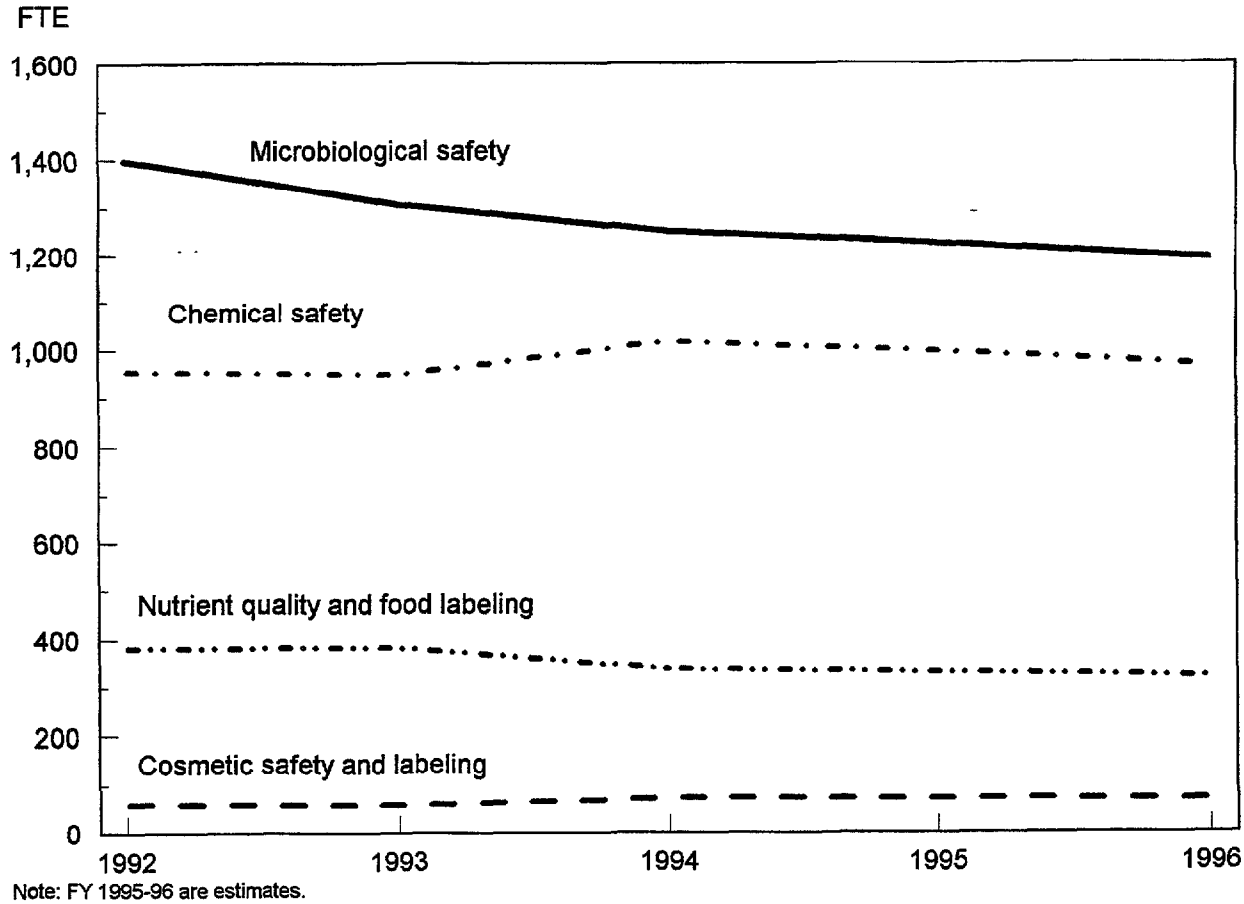
Figure I.5: Medical Devices FTE Distribution by Activity, FY 1990-96



Note: FY 1995-96 are estimates.

ENCLOSURE I

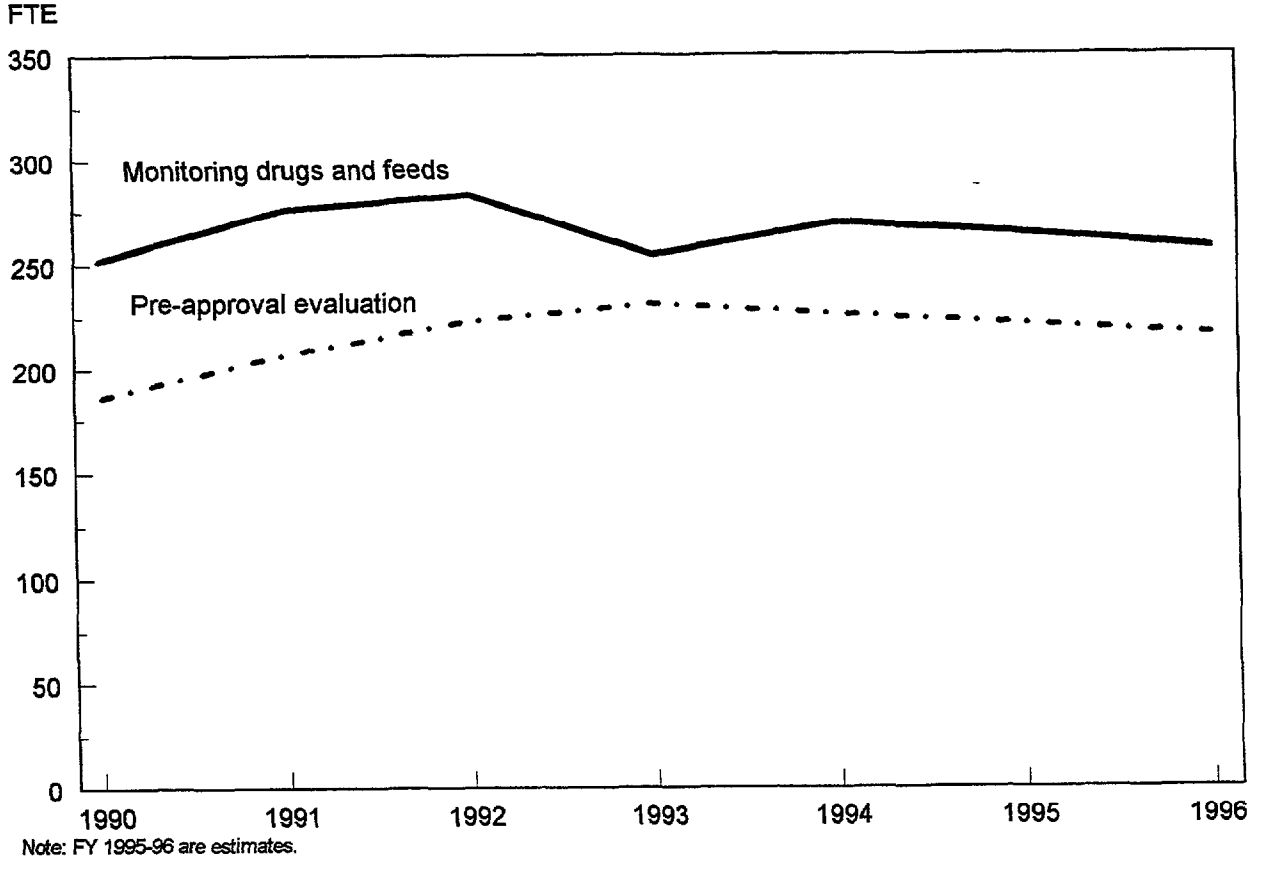
Figure I.6: Food Additives FTE Distribution by Activity, FY 1990-96



Note: FY 1995-96 are estimates.

ENCLOSURE I

Figure I.7: Animal Drugs FTE Distribution by Activity, FY 1990-96



Note: FY 1995-96 are estimates.

FDA RESOURCE DISTRIBUTION TABLES

In the tables in this enclosure, we present resource data for FDA as a whole. Resource distribution is based on what FDA calls "activities"--biologics, human drugs, medical devices, foods, animal drugs, toxicological research, and program management. For example, the 775 FTEs for fiscal year 1990 include resources at the Center for Biologics Evaluation and Research as well as any staff involved in the regulation and review of biologic products--inspectors of biologics manufacturing facilities at the Office of Regulatory Affairs, the general counsel at the Office of Policy, and others.

Tables II.1 and II.2 respectively provide the FDA resource distribution in terms of FTEs and salary outlays for fiscal years 1990 through 1996. Except for fiscal years 1995 and 1996, the data are actual amounts for the agency. Fiscal year 1995 and 1996 data are estimates. The relative distribution of resources among the seven activities is provided at the bottom of the tables. Since program management and toxicological research are not involved in product review, we do not discuss them.[1]

The budget categories are not consistent across the five activities that involve product review. In particular, biologics does not have a specific product review category. Moreover, organizational changes produced changes in the budget categories over the 7-year period. For example, since 1992, resources for biologics have been allocated according to three categories--blood and blood products, therapeutic products, and vaccines and allergenic products. Likewise, the ten categories under foods were reformulated into four, eliminating the food-and-color-petition review category. (In order to present information on resources devoted to product review for foods, we provide estimated fiscal year 1993 data for the ten categories as well as actual fiscal year 1993 data for the four categories.)

Dollars are constant dollars in thousands.

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[1]There is no organizational entity that corresponds to the program management category. The amount of resources listed here is the amount of resources required for various activities undertaken to manage the agency.

ENCLOSURE II

TABLE II.1: FDA FTE DISTRIBUTION BY ACTIVITY, FY 1990-96

	1990	1991	1992	1993	1994	1995	1996
Biologics							
Blood and blood products	428	459	493	533	448	459	454
Therapeutic products	na	na	254	279	333	365	373
Vaccines and allergenic products	na	na	151	157	322	347	356
Viral products	205	213	na	na	na	na	na
Bacterial and allergenic products	126	129	na	na	na	na	na
Bioresearch monitoring	16	23	na	na	na	na	na
Total	**775**	**824**	**898**	**969**	**1,103**	**1,171**	**1,183**
Human drugs							
New drug evaluation and orphan drugs	648	717	807	868	909	1,068	1,116
New drug evaluation	634	701	na	852	893	1,053	1,101
Orphan drug evaluation	14	16	na	16	16	15	15
Generic drug evaluation	300	355	434	448	432	424	413
OTC drug evaluation	61	69	81	90	99	101	99
Drug quality assurance	656	737	734	692	675	671	658
Bioresearch monitoring	142	141	151	170	158	191	198
Health fraud	37	46	64	61	52	51	50
Postmarketing surveillance and epidemiology	81	82	74	76	123	126	124
Prescription drug advertising and labeling	24	28	45	44	42	44	45
Biopharmaceuticals	77	88	na	na	na	na	na
Total	**2,026**	**2,263**	**2,390**	**2,449**	**2,490**	**2,676**	**2,703**
Medical devices							
Surveillance and enforcement	657	732	812	883	930	930	959
Product evaluation	370	415	449	459	590	571	652
Risk assessment	145	157	157	156	183	178	179
Education and assistance	160	178	186	185	96	93	92
Total	**1,332**	**1,482**	**1,604**	**1,683**	**1,799**	**1,772**	**1,882**
Foods							
Chemical safety	na	na	956	949	1,015	995	968
Microbiological safety	na	na	1,397	1,306	1,249	1,224	1,191
Nutrient quality and food labeling	na	na	380	381	338	331	322
Cosmetic safety and labeling	na	na	60	59	73	71	70
Total	na	na	**2,793**	**2,695**	**2,675**	**2,621**	**2,551**
Foods							
Foodborne biological hazards	918	1,023	1,042	1,089	na	na	na
Molecular biology and natural toxins: foods and cosmetics	177	170	214	172	na	na	na
Pesticides and chemical contaminants	498	516	525	533	na	na	na
Diet and toxicity interaction	68	94	68	94	na	na	na
Postmarket surveillance and epidemiology: foods and cosmetics	18	23	24	23	na	na	na
Technical assistance: foods and cosmetics	202	208	266	210	na	na	na
Food additives petition review and policy development	220	223	225	223	na	na	na
Risk assessment and policy development: foods and cosmetics	66	64	79	64	na	na	na
Food composition, standards, labeling, economics	244	248	288	259	na	na	na
Cosmetics and color technology	64	68	62	68	na	na	na
Total	**2,475**	**2,637**	**2,793**	**2,735**	na	na	na

ENCLOSURE II

Animal drugs							
Pre-approval evaluation	186	207	223	231	226	221	216
Monitoring of marketed drugs and feeds	252	276	283	254	269	264	257
Total	**438**	**483**	**506**	**485**	**495**	**485**	**473**
Total toxicological research	235	230	239	257	249	243	236
Program management	348	348	362	362	356	353	377
Total FTEs	**7,629**	**8,267**	**8,792**	**8,900**	**9,167**	**9,321**	**9,405**
Proportion of FTE allocation							
Biologics	10%	10%	10%	11%	12%	13%	13%
Human drugs	27	27	27	28	27	29	29
Medical devices	17	18	18	19	20	19	20
Foods	32	32	32	30	29	28	27
Animal drugs	6	6	6	5	5	5	5
Toxicological research	3	3	3	3	3	3	3
Program management	5	4	4	4	4	4	4

ENCLOSURE II

TABLE II.2: FDA SALARY DISTRIBUTION BY ACTIVITY, FY 1990-96 (in thousands)

	1990	1991	1992	1993	1994	1995	1996
Biologics							
Blood and blood products	$47,164	$51,728	$51,626	$54,003	$48,417	$50,673	$51,392
Therapeutic products	na	na	29,352	31,928	41,763	46,959	47,932
Vaccines and allergenic products	na	na	17,360	17,724	41,027	46,358	47,337
Viral products	22,589	24,117	na	na	na	na	na
Bacterial and allergenic products	13,885	14,642	na	na	na	na	na
Bioresearch monitoring	1,763	2,482	na	na	na	na	na
Total	**$85,401**	**$92,968**	**$98,339**	**$103,655**	**$131,207**	**$143,990**	**$146,661**
Human drugs							
New drug evaluation and orphan drugs	$60,651	$58,741	$82,272	$91,275	$110,235	$126,137	$129,621
New drug evaluation	50,699	47,426	na	79,194	98,455	110,987	114,471
Orphan drug evaluation	9,952	11,315	na	12,081	11,780	15,150	15,150
Generic drug evaluation	23,990	45,813	45,845	42,213	38,671	37,745	38,062
OTC drug evaluation	4,877	4,697	6,937	8,389	8,984	9,124	9,247
Drug quality assurance	52,458	51,695	53,278	51,248	52,724	53,120	53,783
Bioresearch monitoring	11,355	16,462	11,589	12,984	12,757	13,984	14,303
Health fraud	2,958	4,697	4,987	4,845	4,271	4,169	4,204
Postmarketing surveillance and epidemiology	6,477	7,047	6,458	7,790	12,703	13,308	13,538
Prescription drug advertising and labeling	1,919	1,184	4,295	4,474	4,363	4,614	4,699
Biopharmaceuticals	6,158	7,047	na	na	na	na	na
Total	**$170,844**	**$197,384**	**$215,661**	**$223,218**	**$244,707**	**$262,201**	**$267,457**
Medical devices							
Surveillance and enforcement	$51,396	$57,869	$62,437	$67,673	$90,063	$94,396	$104,893
Product evaluation	28,946	32,933	35,760	38,489	45,601	44,528	64,135
Risk assessment	11,344	12,345	13,794	13,850	17,419	17,060	18,658
Education and assistance	12,517	14,093	14,807	16,067	10,792	10,538	10,748
Total	**$104,202**	**$117,241**	**$126,798**	**$136,079**	**$163,875**	**$166,522**	**$198,434**
Foods							
Chemical safety	na	na	$77,611	$77,279	$86,332	$84,560	$90,041
Microbiological safety	na	na	106,387	99,450	96,427	94,447	105,504
Nutrient quality and food labeling	na	na	35,227	34,296	29,854	29,241	30,643
Cosmetic safety and labeling	na	na	4,872	4,855	6,437	6,305	6,718
Total	na	na	**$224,096**	**$215,880**	**$219,051**	**$214,553**	**$232,906**
Foods							
Foodborne biological hazards	$69,667	$80,066	$77,724	$76,452	na	na	na
Molecular biology and natural toxins: foods and cosmetics	13,433	13,210	18,413	18,112	na	na	na
Pesticides and chemical contaminants	37,793	40,208	38,513	37,883	na	na	na
Diet and toxicity interaction	5,161	7,346	6,133	6,033	na	na	na
Postmarket surveillance and epidemiology: foods and cosmetics	1,367	1,729	2,619	2,577	na	na	na
Technical assistance: foods and cosmetics	15,330	16,256	20,981	20,638	na	na	na
Food additives petition review and policy development	16,694	17,429	21,110	20,764	na	na	na
Risk assessment and policy development: foods and cosmetics	5,009	5,001	7,083	6,967	na	na	na
Food composition, standards, labeling, economics	18,517	19,302	26,475	26,042	na	na	na
Cosmetics and color technology	4,857	5,227	5,046	4,963	na	na	na
Total	**$187,826**	**$205,772**	**$224,096**	**$220,431**	na	na	na

ENCLOSURE II

Animal drugs							
Pre-approval evaluation	$15,186	$16,924	$18,941	$19,319	$19,360	$18,951	$19,241
Monitoring of marketed drugs and feeds	20,576	22,525	23,423	20,776	22,101	21,640	21,971
Total	**$35,762**	**$39,449**	**$42,364**	**$40,095**	**$41,461**	**$40,591**	**$41,212**
Toxicological research							
Integrated research	na	na	$18,797	$19,249	$20,704	$20,177	$20,356
Methods development	na	na	14,981	15,541	15,277	14,873	15,004
Total	**$31,828**	**$35,143**	**$33,779**	**$34,789**	**$35,981**	**$35,050**	**$35,360**
Program management	$42,989	$44,312	$47,465	$45,167	$44,002	$42,987	$43,432
Total salaries	**$658,853**	**$732,270**	**$788,501**	**$798,884**	**$880,283**	**$905,894**	**$965,462**
Percent salary allocation							
Biologics	13%	13%	12%	13%	15%	16%	15%
Human drugs	26	27	27	28	28	29	28
Medical devices	16	16	16	17	19	18	21
Foods	29	28	28	27	25	24	24
Animal drugs	5	5	5	5	5	4	4
Toxicological research	5	5	4	4	4	4	4
Program management	7	6	6	6	5	5	4
User fees							
Medical device user fees							($23,740)
Prescription drug user fees				($9,438)	($41,083)	($79,423)	(84,723)
Mammography quality standards						(6,500)	(13,000)
Import user fees							(15,000)
Certification funds and FOIA			(3,998)	(3,577)	(4,963)	(5,042)	(5,204)
Total			**($3,998)**	**($13,016)**	**($46,046)**	**($90,965)**	**($141,667)**

BIOLOGICS FIGURES

Figure III.1: CBER Applications Received by Product Type, FY 1990-95

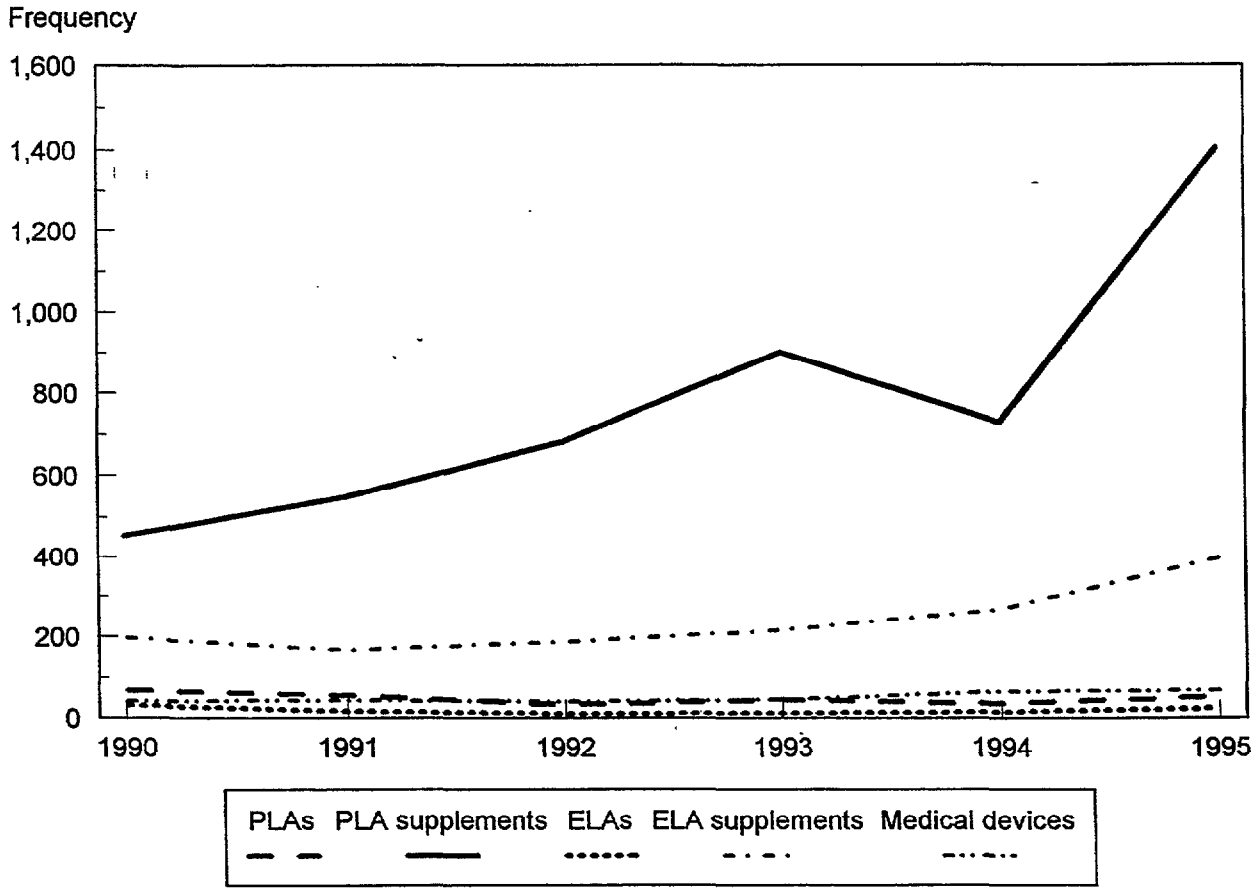
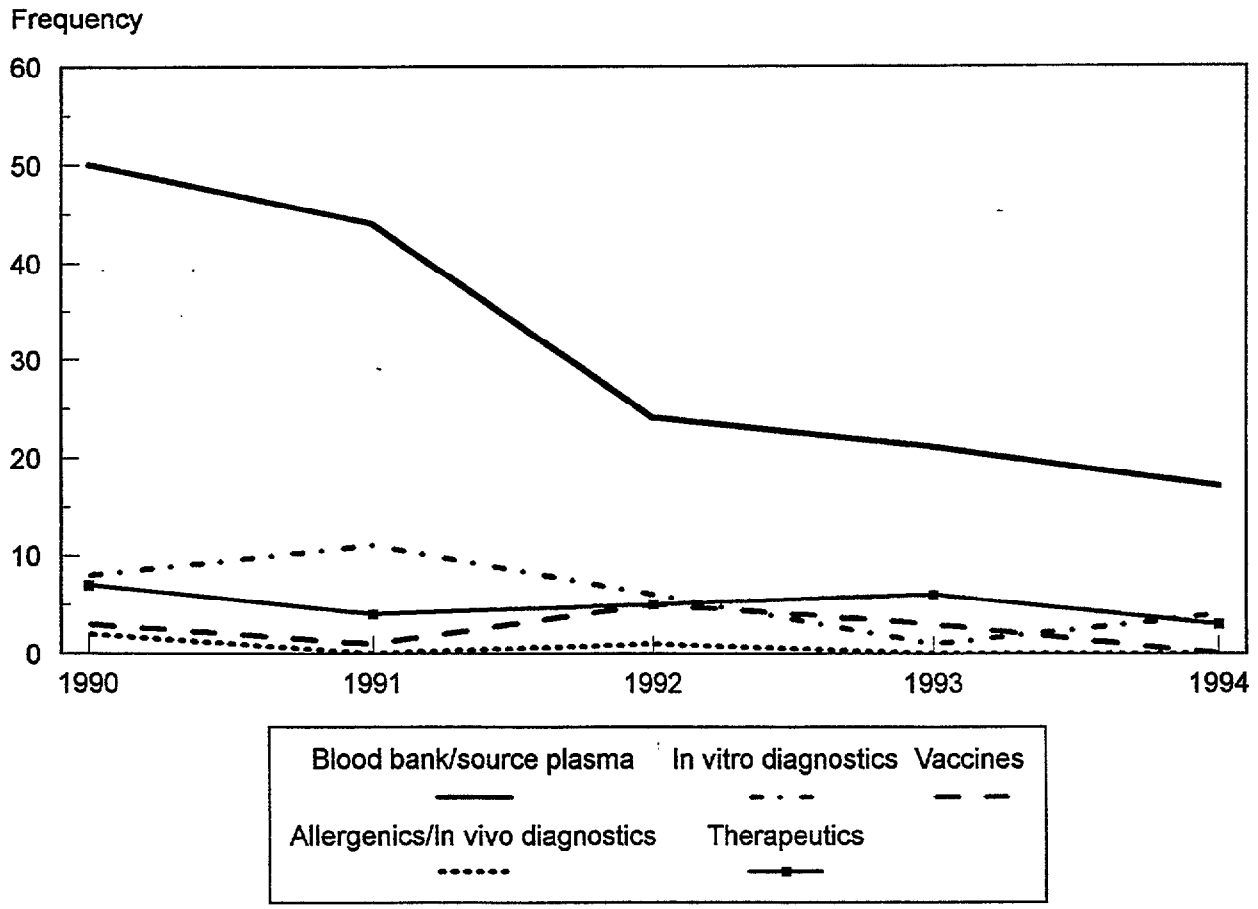


Figure III.2: CBER PLAs Approved by Product Type, FY 1990-94



BIOLOGICS TABLE: APPLICATIONS SUMMARY, FTEs AND SALARIES, FY 1990-95

We do not have information on the number of biologics applications still to be completed at the end of the fiscal year --that is, applications pending. Without such information, we were not able to determine the workload for CBER.

Prior to 1993, CBER did not have the authority to issue "approvable" and "nonapprovable" letters. After it gained this authority, the time to approval did not seem to be affected, but there was a decrease in the percentage of applications approved. Whether the time to a decision was affected cannot be determined from the available data. Nonetheless, the change does not affect the use of review time as an indicator of the relative resource demands by product type within any given fiscal year.

The change does, however, have implications for determining the ratio of applications reviewed to number of reviewers. An approvable application that is later approved has gone through at least two decisions. This double-counting inflates the number of applications reviewed since 1993.

Resource information--program FTEs and salaries--is for original and supplement applications combined. The differences in their review times--original applications take longer to review than supplements--indicate that resource demands differ. This is true for both product license applications (PLAs) and establishment license applications (ELAs).

CBER also reviews NDAs. However, NDAs are tracked differently from other applications, and information is not readily available for them. Since fiscal year 1990, CBER has received approximately 7 NDAs and 350 NDA supplements.

Dollars are constant dollars in thousands.

BIOLOGICS TABLE: APPLICATIONS SUMMARY, FTEs AND SALARIES, FY 1990-95

	1990	1991	1992	1993	1994	1995
PLAs						
Applications received	67	53	30	42	33	52
Applications pending	na	na	na	na	na	na
Applications reviewed	90	78	51	61	96	92
Approved	70	60	41	32	24	42
% approved	78%	77%	80%	52%	25%	46%
Approvable	0	0	0	1	1	3
Mean months to approval	22.9	18.1	24.5	24.7	16.1	19.6
Median months to approval	18.8	15.7	20.7	23.3	13.7	12.2
Workload	na	na	na	na	na	na
PLA supplements						
Applications received	452	548	680	899	726	1,403
Applications pending	na	na	na	na	na	na
Applications reviewed	364	409	635	650	939	1,963
Approved	314	363	570	501	536	895
% approved	86%	89%	90%	77%	57%	46%
Approvable	0	0	0	0	5	19
Mean months to approval	8.5	9.9	9.2	9.8	14.5	12.3
Median months to approval	6.4	6.6	6.2	6.3	10.0	8.3
Workload	na	na	na	na	na	na
PLA and PLA supplements						
Applications received	519	601	710	941	759	1,455
% originals	13%	9%	4%	4%	4%	4%
% supplements	87%	91%	96%	96%	96%	96%
Program FTEs	na	na	na	124	151	133
Ratio (workload/program FTE)	na	na	na	na	na	na
Ratio (decisions/program FTE)	na	na	na	5.7	6.9	15.5
Salary outlays for product review	na	na	na	$7,722	$9,666	$8,666

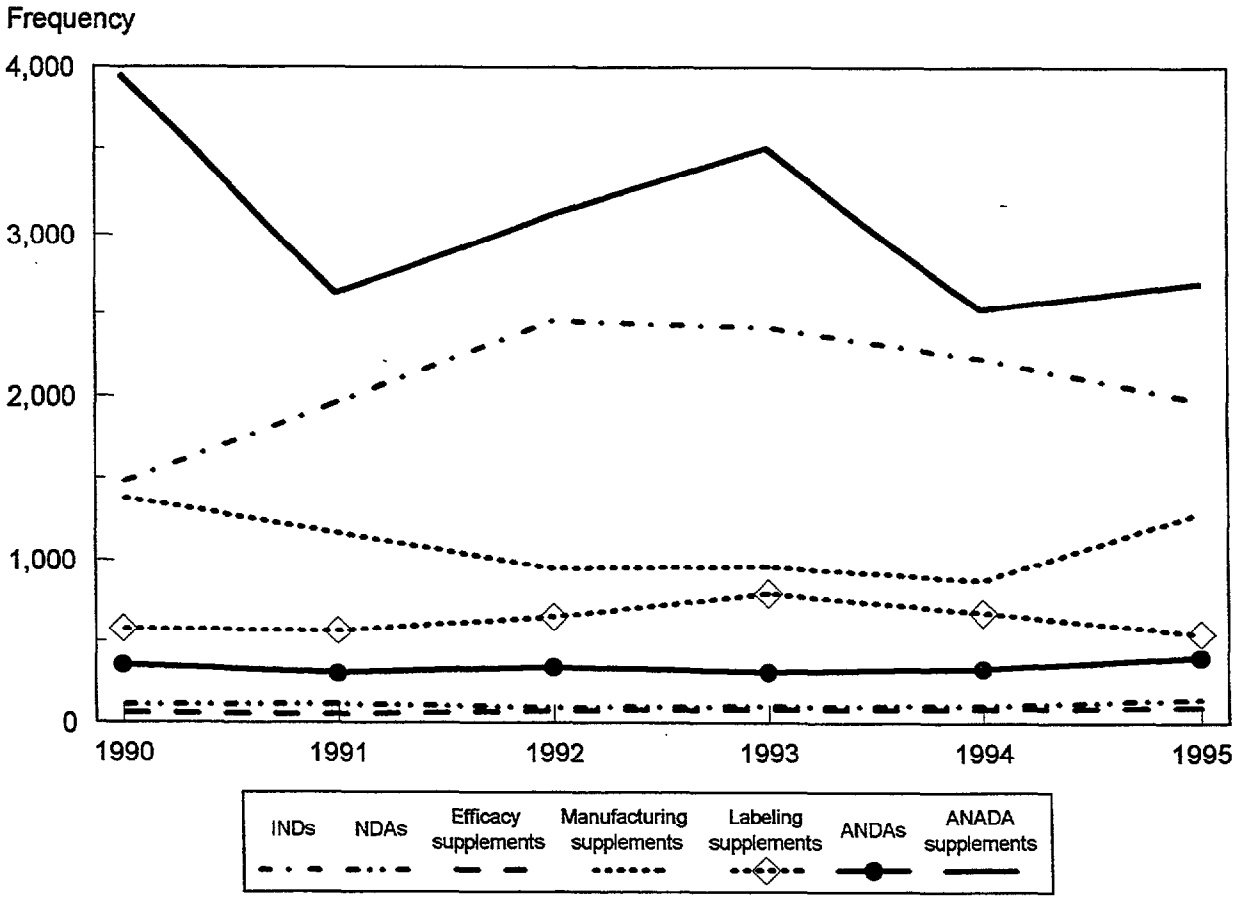
ELAs						
Applications received	30	16	9	11	14	22
Applications pending	na	na	na	na	na	na
Applications reviewed	35	25	14	17	36	38
Approved	29	19	13	9	10	18
% approved	83%	76%	93%	53%	28%	47%
Approvable	0	0	0	0	1	2
Mean months to approval	18.9	19.1	25.3	25.1	14.6	18.8
Median months to approval	13.1	17.6	23.9	28.7	11.0	11.2
Workload	na	na	na	na	na	na
ELA supplements						
Applications received	197	167	186	215	267	397
Applications pending	na	na	na	na	na	na
Applications reviewed	176	150	150	268	394	521
Approved	156	139	136	197	251	423
% approved	89%	93%	91%	74%	64%	81%
Approvable	0	0	0	0	2	10
Mean months to approval	10.7	9.7	13.9	14.1	11.2	6.9
Median months to approval	7.7	8.4	9.8	8.2	5.8	2.8
Workload	na	na	na	na	na	na
ELA and ELA supplements						
Applications received	227	183	195	226	281	419
% originals	13%	9%	5%	5%	5%	5%
% supplements	87%	91%	95%	95%	95%	95%
Program FTEs	na	na	na	37	37	35
Ratio (workload/program FTE)	na	na	na	na	na	na
Ratio (decisions/program FTE)	na	na	na	7.7	11.6	16.0
Salary outlays for product review	na	na	na	$2,304	$2,368	$2,280

Other products: medical devices						
Applications received						
PMAs and PMA supplements	5	3	3	3	2	9
510(k)s	35	38	35	39	62	57
Applications reviewed						
PMAs and PMA supplements	6	5	1	4	6	6
510(k)s	34	22	28	39	48	95
Applications approved or found substantially equivalent						
PMAs and PMA supplements	4	4	1	3	4	3
510(k)s	32	18	25	36	37	48
% approved or substantially equivalent						
% PMAs and PMA supplements	67%	80%	100%	75%	67%	50%
% 510(k)s	94%	82%	89%	92%	77%	51%
Percent applications received						
PLAs	9%	6%	3%	3%	3%	3%
PLA supplements	58%	66%	72%	74%	66%	72%
ELAs	4%	2%	1%	1%	1%	1%
ELA supplements	25%	20%	20%	18%	24%	20%
Medical devices	5%	5%	4%	3%	6%	3%
Number of applications	786	825	943	1,209	1,104	1,940
Percent program FTEs						
PLAs and PLA supplements	na	na	na	77%	80%	79%
ELAs and ELA supplements	na	na	na	23%	20%	21%
Number of FTEs	na	na	na	161	188	168

ENCLOSURE V

HUMAN DRUGS FIGURE

Figure V.1: CDER Applications Received by Product Type, FY 1990-95



HUMAN DRUGS TABLE: APPLICATIONS SUMMARY, FTEs AND SALARIES, FY 1990-95

As of fiscal year 1994, "type 6" NDAs--applications for a new indication for a drug that was already approved for marketing--were considered NDA efficacy supplements rather than original NDAs. (In fiscal year 1994, this change involved 7 applications.)

CDER defines "pending" as an application that is either under active FDA review or in the agency's review queue. Applications that are waiting for additional information from the sponsor are considered active but not pending.

In this table, all decisions, not just the final decision, are counted for each application. Since each application can have more than one decision, the "total decision" variable is not a good indicator of the number of applications reviewed. Accordingly, we did not calculate the second ratio--the number of applications reviewed per reviewer.

We do not have data on resources for each product type. Specifically, resource information is available for INDs, NDAs, and NDA supplements combined. Resource information is also available for ANDA and ANDA supplements combined.[1] The differences in review time for the different products indicate differences in resource demands. Program FTEs include overall FDA overhead as well as FTEs for primary or nonsupervisory reviewers.

Dollars are constant dollars in thousands.

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[1]For NDAs and NDA supplements, "primary reviewer" includes chemists, dental officers, mathematical statisticians, medical officers, microbiologists, pharmacists, pharmacologists, physiologists, psychologists, and toxicologists. For ANDAs and ANDA supplements, "primary reviewer" consists of the chemistry and bioequivalence reviewers. Labeling reviewers and other supervisory staff are not included.

HUMAN DRUGS TABLE: APPLICATIONS SUMMARY, FTEs AND SALARIES, FY 1990-95

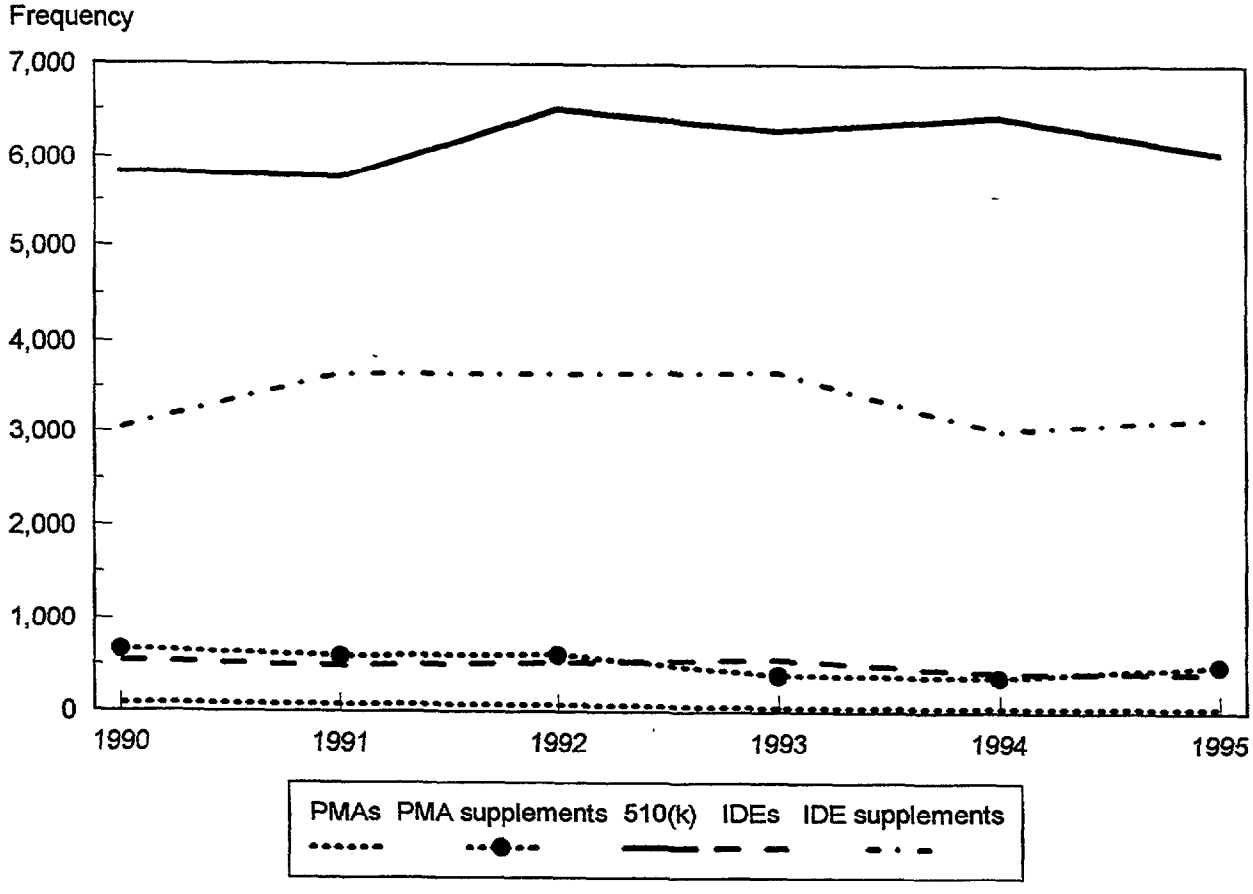
	1990	1991	1992	1993	1994	1995
INDs						
Applications received	1,473	1,963	2,452	2,413	2,223	1,972
Actions	2,378	3,609	3,707	4,015	4,266	4,404
Applications active at end of FY	9,506	9,958	10,261	10,682	11,171	11,678
NDAs						
Applications received	106	108	89	97	102	140
Applications filed	98	88	73	86	96	111
Applications pending	240	203	156	174	182	165
Total decisions	241	275	279	241	191	201
Workload	na	348	292	253	276	322
Applications approved	69	62	86	83	62	71
% decisions that were approvals	29%	23%	31%	34%	32%	35%
Mean months to approval	31.7	29.2	30.0	34.3	27.3	25.7
Median months to approval	23.8	24.2	24.2	26.8	20.8	18.7
NDA efficacy supplements						
Applications received						
Originals	55	50	69	77	81	93
(Amendments)	183	160	241	276	369	399
Applications filed	51	52	56	89	82	76
Applications pending	116	120	103	102	134	97
Total decisions	97	87	112	152	119	169
Workload	na	166	189	180	183	227
Applications approved	35	19	52	54	50	61
% decisions that were approvals	36%	22%	46%	36%	42%	36%
Mean months to approval	31.9	25.8	40.2	28.1	16.5	21.4
Median months to approval	24.3	21.3	23.1	17.7	13.2	18.1
NDA manufacturing supplements						
Applications received						
Originals	1,379	1,166	949	964	879	1,288
(Amendments)	1,014	707	705	717	843	794
Applications filed	1,378	1,162	947	1,046	868	1,248
Applications pending	1,102	1,263	966	1,094	599	578
Total decisions	1,515	1,314	1,476	1,151	1,582	1,674
Workload	na	2,268	2,212	1,930	1,973	1,887
Applications approved	949	817	926	848	1,065	1,024
% decisions that were approvals	63%	62%	63%	74%	67%	61%
Mean months to approval	7.8	10.7	14.4	14.0	11.9	9.9
Median months to approval	6.2	9.1	10.5	8.2	7.7	5.9
NDA labeling supplements						
Applications received						
Originals	580	569	656	802	685	556
(Amendments)	414	378	334	441	485	417
Applications filed	579	569	654	797	685	556
Applications pending	1,258	1,333	1,558	1,402	1,440	1,255
Total decisions	473	820	703	854	764	857
Workload	na	1,827	1,989	2,360	2,087	1,996
Applications approved	295	398	437	406	504	505
% decisions that were approvals	62%	49%	62%	48%	66%	59%
Mean months to approval	11.7	13.9	12.4	12.4	13.4	14.4
Median months to approval	5.7	7.1	7.9	5.1	7.4	8.3

Percent INDs, NDAs, and NDA supplements received						
INDs	41%	51%	58%	55%	56%	49%
NDAs	3	3	2	2	3	3
NDA supplements	56	46	40	42	41	48
Efficacy supplements	2	1	2	2	2	2
Manufacturing supplements	38	30	23	22	22	32
Labeling supplements	16	15	16	18	17	14
Number of applications	3,593	3,856	4,215	4,353	3,970	4,049
Resources for INDs, NDAs, and NDA supplements combined						
Program FTEs	588	630	650	769	824	923
Primary reviewer	286	310	313	312	411	497
Workload	na	6,572	7,134	7,136	6,742	6,404
Ratio (workload/primary reviewer)	na	21.2	22.8	22.9	16.4	12.9
Salary outlays for program FTEs	$37,891	$39,309	$41,005	$47,186	$51,789	$56,705
Primary reviewer	$21,629	$23,454	$23,791	$22,264	$29,588	$35,205
Program outlays	$60,647	$68,564	$74,024	$87,963	$101,526	$109,236
ANDAs (including AADAs)						
Applications received	352	300	339	308	332	404
Applications pending	1,159	803	421	485	460	591
Total decisions	1,625	1,101	1,499	1,177	1,216	1,215
Workload	na	1,459	1,142	729	817	864
Applications approved	73	145	239	215	255	288
% decisons that were approved	4%	13%	16%	18%	21%	24%
ANDAs tentatively approved	0	4	18	41	20	42
Mean months to approval	na	37.8	35.1	37.5	30.3	34.2
Median months to approval	23.0	33.0	34.5	38.0	24.0	27.0
ANDA supplements						
Applications received	3,946	2,632	3,117	3,506	2,528	2,694
Applications pending	3,217	1,550	793	1,334	1,390	1,129
Total decisions	5,311	5,551	5,153	3,969	3,879	3,663
Workload	na	5,849	4,667	4,299	3,862	4,084
Applications approved	2,489	3,413	3,470	2,635	2,486	2,468
% decisions that were approved	47%	61%	67%	66%	64%	67%
Mean months to approval	na	na	na	na	na	na
Median months to approval	na	na	na	na	na	na
Percent ANDAs and ANDA supplements received						
ANDAs and AADAs	1%	2%	2%	2%	2%	2%
ANDA supplements	92%	90%	90%	92%	88%	87%
Number of applications	4,298	2,932	3,456	3,814	2,860	3,098
Resources for ANDAs and ANDA supplements combined						
Program FTEs	139	271	328	331	303	300
Primary reviewer	54	58	74	68	65	58
Workload	na	7,308	5,809	5,028	4,679	4,948
Ratio (workload/primary reviewer)	na	126.0	78.5	73.9	72.0	85.3
Salary outlays for program FTEs	$7,682	$14,844	$18,753	$19,693	$18,604	$18,431
Primary reviewer	$2,984	$3,712	$5,089	$4,673	$4,609	$4,108
Program outlays	$11,914	$26,406	$37,286	$33,206	$28,820	$28,095

ENCLOSURE VII

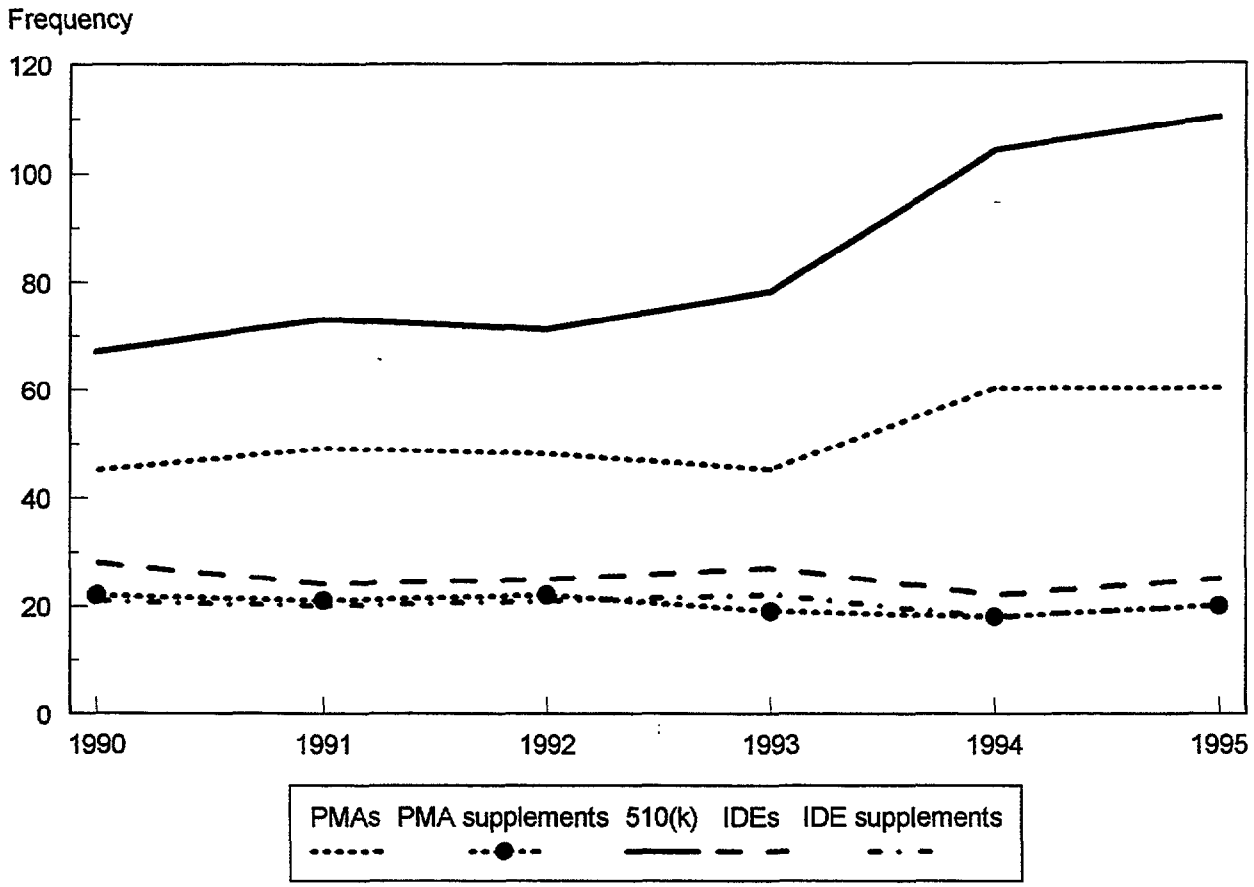
MEDICAL DEVICES FIGURES

Figure VII.1: CDRH Applications Received by Product Type, FY 1990-95



ENCLOSURE VII

Figure VII.2: CDRH Primary Reviewer FTEs by Product Type, FY 1990-95



ENCLOSURE VIII

MEDICAL DEVICES TABLE: APPLICATIONS SUMMARY, FTEs AND SALARIES, FY 1990-95

The number of medical devices applications pending includes applications under active FDA review as well as those on hold. Given the shorter time periods for reviewing device applications, especially 510(k) devices, holds may not necessarily be for extended periods.

For IDEs, IDE supplements, and 510(k)s, we have data on the number of applications reviewed. For PMAs and PMA supplements, however, the total number of decisions are provided. For example, an application that is found approvable and then subsequently approved has gone through at least two decisions. Therefore, for PMAs and PMA supplements, we do not provide the second ratio--applications reviewed per reviewer.

The salary outlays for program FTEs include salaries for primary reviewers--that is, nonsupervisory staff. Program outlays is the sum of CDRH's operating costs and salary outlays. The salary amounts for fiscal year 1995 are estimates but FTEs are actual.

Dollars are constant dollars in thousands.

ENCLOSURE VIII

MEDICAL DEVICES TABLE: APPLICATIONS SUMMARY, FTEs AND SALARIES, FY 1990-95

	1990	1991	1992	1993	1994	1995
IDEs and IDE amendments						
Applications received	540	496	526	561	424	424
Originals	252	213	229	241	171	214
Amendments	288	283	297	320	253	210
Applications pending	49	37	42	30	22	23
Originals	20	12	21	14	11	15
Amendments	29	25	21	16	11	8
Applications reviewed	518	507	512	572	430	423
Applications approved	218	205	195	153	156	215
% approved	42%	40%	38%	27%	36%	51%
Mean days to approval (IDE and amendments)	187	189	188	212	242	232
FDA time	73	71	79	83	83	70
Non-FDA time	114	118	109	129	159	162
Program FTEs	50	42	45	48	39	54
Primary reviewer	28	24	25	27	22	25
Workload	567	545	563	603	454	446
Ratio (workload/primary reviewer)	11.3	13.0	12.5	12.6	11.6	8.3
Ratio (decisions/primary reviewer)	10.4	12.1	11.4	11.9	11.0	7.8
Program outlays	$3,551	$2,986	$3,237	$3,419	$3,025	$3,384
Salary outlays for program FTEs	$3,323	$2,773	$3,031	$3,189	$2,647	$3,060
Primary reviewer	$1,861	$1,584	$1,684	$1,794	$1,493	$1,700
Operating expenses	$227	$214	$206	$230	$378	$324
IDE supplements						
Applications received	3,043	3,647	3,644	3,668	3,020	3,171
Applications pending	245	189	359	213	160	149
Applications reviewed	2,968	3,705	3,469	3,814	3,070	3,181
Program FTEs	38	36	37	39	33	37
Primary reviewer	21	20	21	22	18	20
Workload	3,213	3,892	3,833	4,027	3,233	3,331
Ratio (workload/primary reviewer)	84.6	108.1	103.6	103.3	98.0	90.0
Ratio (decisions/primary reviewer)	78.1	102.9	93.8	97.8	93.0	86.0
Program outlays	$2,722	$2,559	$2,669	$2,789	$2,564	$2,726
Salary outlays for program FTEs	$2,526	$2,377	$2,492	$2,591	$2,240	$2,448
Primary reviewer	$1,396	$1,320	$1,414	$1,462	$1,222	$1,360
Operating expenses	$196	$182	$177	$197	$324	$278

ENCLOSURE VIII

PMAs						
Applications received	79	75	65	40	43	39
Applications filed	53	52	46	33	38	33
% filed	52%	50%	54%	62%	60%	60%
Applications pending	116	135	164	150	139	125
Active	44	49	87	94	67	69
On hold	72	86	77	56	72	56
Total decisions	111	100	49	68	66	47
Applications approved	47	27	12	24	26	27
% decisions that were approved	42%	27%	24%	35%	39%	57%
Approvable decisions	45	46	18	23	22	16
Mean days to approval	415	633	310	799	823	773
FDA time	302	335	236	547	649	606
Non-FDA time	113	298	74	252	174	167
Program FTEs	81	88	86	80	107	81
Primary reviewer	45	49	48	45	60	60
Workload	193	191	200	204	193	178
Ratio (workload/primary reviewer)	4.3	3.9	4.2	4.5	3.2	3.0
Program outlays	$6,506	$6,860	$6,809	$6,447	$9,125	$8,873
Salary outlays for program FTEs	$5,384	$5,810	$5,792	$5,316	$7,262	$7,276
Primary reviewer	$2,991	$3,235	$3,233	$2,990	$4,072	$4,080
Operating expenses	$1,123	$1,051	$1,017	$1,132	$1,863	$1,597
PMA supplements						
Applications received	660	593	606	395	372	499
Panel-tracked applications filed	6	5	4	1	3	4
% filed	35%	38%	27%	10%	60%	100%
Applications pending	335	339	485	465	376	377
Active	215	206	341	346	243	226
On hold	120	133	144	119	133	151
Total decisions	919	752	636	569	584	586
Applications approved	700	480	394	354	385	435
% decisions that were approved	76%	64%	62%	62%	66%	74%
Approvable decisions	138	138	120	91	95	78
Mean days to approval	180	175	167	269	371	275
FDA time	146	131	135	213	301	209
Non-FDA time	35	44	32	56	70	66
Program FTEs	40	37	39	34	33	32
Primary reviewer	22	21	22	19	18	20
Workload	1,191	928	945	880	837	875
Ratio (workload/primary reviewer)	54.1	44.2	43.0	46.3	46.5	43.8
Program outlays	$2,919	$2,687	$2,862	$2,522	$2,672	$2,750
Salary outlays for program FTEs	$2,659	$2,443	$2,627	$2,259	$2,240	$2,380
Primary reviewer	$1,462	$1,386	$1,482	$1,262	$1,222	$1,360
Operating expenses	$260	$244	$236	$263	$432	$370

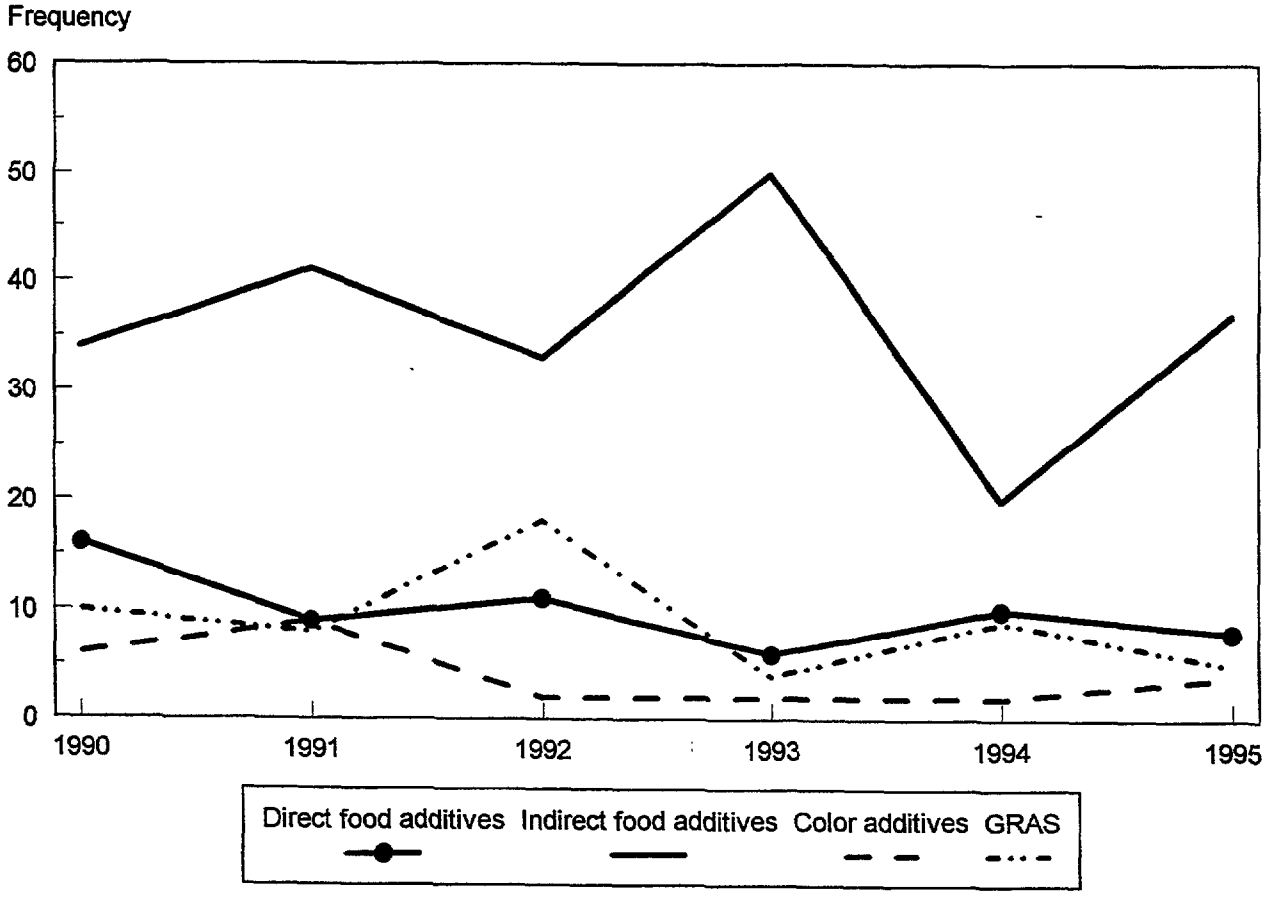
ENCLOSURE VIII

510(k)s						
Applications received	5,831	5,770	6,509	6,288	6,434	6,056
Applications pending	1,900	2,291	3,951	5,157	4,374	2,450
Active	1,174	1,402	2,599	3,822	2,414	1,486
On hold	726	889	1,352	1,335	1,960	964
Total decisions	6,197	5,367	4,862	5,073	7,135	7,948
Substantially equivalent	4,748	4,294	3,776	4,007	5,498	5,594
% decisions that were equivalent	77%	80%	78%	79%	77%	70%
Not substantially equivalent	117	122	130	135	135	101
Other	1,332	951	956	931	1,502	2,253
Mean days to decision	98	102	126	195	216	178
FDA time	78	81	102	162	184	137
Non-FDA time	20	21	24	33	32	41
Median days to decision	78	82	90	164	155	102
FDA time	71	73	88	144	134	91
Non-FDA time	7	9	2	20	21	11
Program FTEs	120	131	126	140	186	211
Primary reviewer	67	73	71	78	104	110
Workload	8,090	7,670	8,800	10,239	11,591	10,430
Ratio (workload/primary reviewer)	67.4	58.5	69.8	73.1	62.3	49.4
Ratio (decisions/primary reviewer)	51.6	41.0	38.6	36.2	38.4	37.7
Program outlays	$9,392	$9,973	$9,768	$10,728	$14,973	$15,409
Salary outlays for program FTEs	$7,976	$8,648	$8,486	$9,302	$12,624	$13,396
Primary reviewer	$4,453	$4,819	$4,782	$5,183	$7,059	$7,480
Operating expenses	$1,417	$1,325	$1,282	$1,426	$2,349	$2,013
Percent applications received						
IDEs	5.3%	4.7%	4.6%	5.1%	4.1%	4.2%
IDE supplements	30.0%	34.5%	32.1%	33.5%	29.3%	31.1%
PMAs	0.8%	0.7%	0.6%	0.4%	0.4%	0.4%
PMA supplements	6.5%	5.6%	5.3%	3.6%	3.6%	4.9%
510(k)s	57.4%	54.5%	57.3%	57.4%	62.5%	59.4%
Number of applications	10,153	10,581	11,350	10,952	10,293	10,189
Percent primary reviewers						
IDEs	15.3%	12.8%	13.4%	14.1%	9.9%	10.6%
IDE supplements	11.5%	10.7%	11.2%	11.5%	8.1%	8.5%
PMAs	24.6%	26.2%	25.7%	23.6%	27.0%	25.5%
PMA supplements	12.0%	11.2%	11.8%	9.9%	8.1%	8.5%
510(k)s	36.6%	39.0%	38.0%	40.8%	46.8%	46.8%
Number of primary reviewers	183	187	187	191	222	235

ENCLOSURE IX

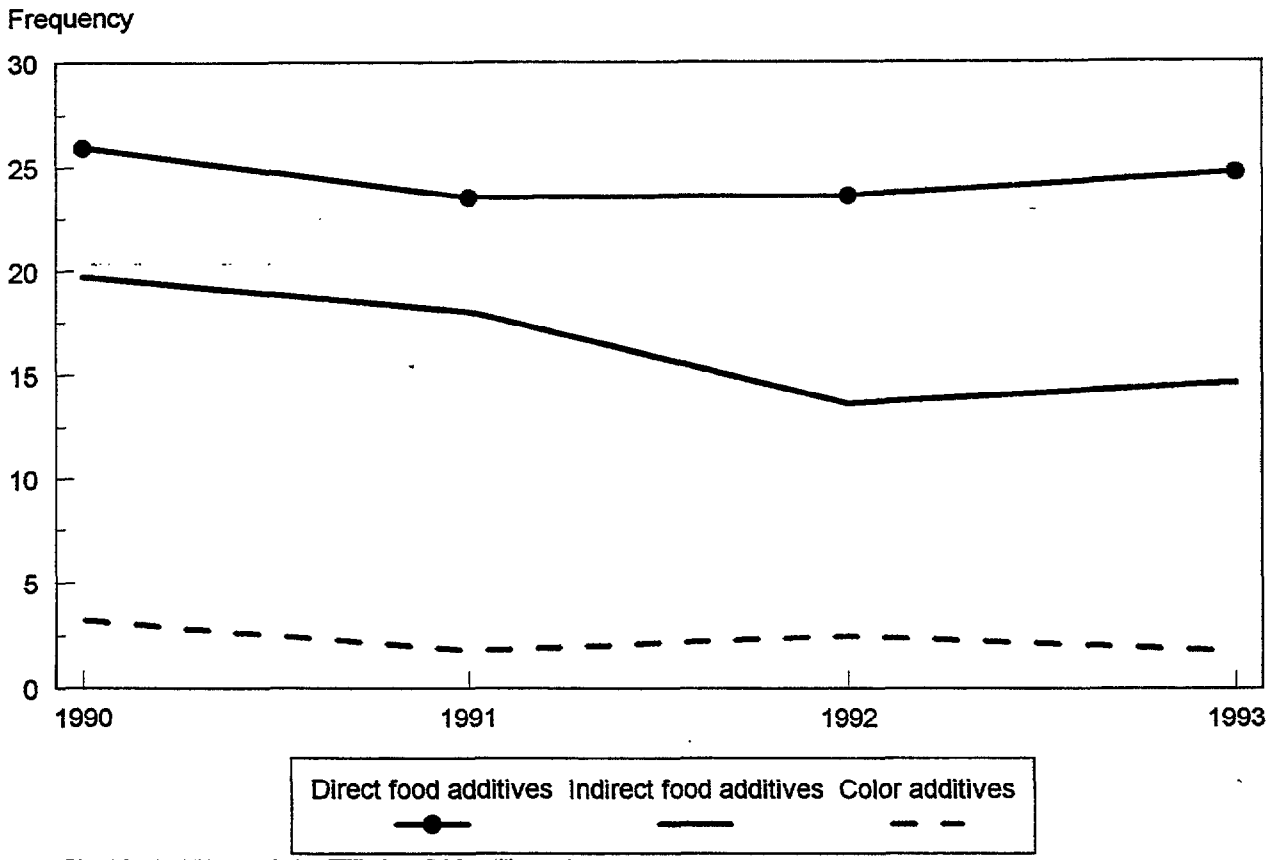
FOOD ADDITIVES FIGURES

Figure IX.1: CFSAN Petitions Received by Product Type, FY 1990-95



ENCLOSURE IX

Figure IX.2: CFSAN Direct FTEs by Product Type, FY 1990-95



Note: Direct food additives includes FTEs for GRAS petition review.

FOOD ADDITIVES TABLE: PETITIONS SUMMARY, FTEs AND SALARIES, FY 1990-95

With food additives, petitions for which no final action has been taken are defined as pending. They include petitions under active review and those for which CFSAN is waiting for data from the petitioner.

Data are available on the number of applications reviewed and we show the ratio of that number to the number of reviewers. Data for direct and indirect food additives review times have been combined. However, review time for indirect additive petitions is generally shorter than review time for direct additives and should be calculated separately.

Direct FTEs refer to resources devoted directly to petition review. Supported FTEs--support across the agency--include "computer support, data system development and management, regulation development and processing, compliance and enforcement activities, and secretarial and management support." FTEs and salary for GRAS petition reviews are included in direct food petition reviews.

Dollars are constant dollars in thousands.

ENCLOSURE X

FOOD ADDITIVES TABLE: PETITIONS SUMMARY, FTEs AND SALARIES, FY 1990-95

	1990	1991	1992	1993	1994	1995
Direct food additives						
Petitions received	16	9	11	6	10	8
Petitions pending	65	67	63	52	50	46
Petitions reviewed	10	7	15	17	12	12
Petitions approved	4	2	7	10	9	10
% approved	40%	29%	47%	59%	75%	83%
Supported FTEs	49.2	44.7	44.8	46.9	na	na
Direct FTEs	25.9	23.5	23.6	24.7	na	na
Workload	75	74	78	69	62	58
Ratio (workload/direct FTE)	1.5	1.7	1.7	1.5	na	na
Ratio (decisions/direct FTE)	0.2	0.2	0.3	0.4	na	na
Salary outlays for program FTEs	$3,901	$3,501	$3,650	$3,908	na	na
Direct FTEs	$2,054	$1,841	$1,923	$2,058	na	na
Indirect food additives						
Petitions received	34	41	33	50	20	37
Petitions pending	122	141	140	161	141	143
Petitions reviewed	37	22	34	29	40	35
Petitions approved	30	15	25	16	36	26
% approved	81%	68%	74%	55%	90%	74%
Supported FTEs	37.4	34.2	25.8	27.7	na	na
Direct FTEs	19.7	18.0	13.6	14.6	na	na
Workload	159	163	174	190	181	178
Ratio (workload/direct FTE)	4.3	4.8	6.7	6.9	na	na
Ratio (decisions/direct FTE)	1.0	0.6	1.3	1.0	na	na
Salary outlays for program FTEs	$2,965	$2,679	$2,102	$2,308	na	na
Direct FTEs	$1,562	$1,410	$1,108	$1,216	na	na
Time to approval: direct and indirect food additives						
Mean months to approval	29	25	44	46	66	43
Median months to approval	23	25	38	32	36	35
Range	6-170	3-54	10-102	9-124	4-340	4-222
Color additive petitions						
Petitions received	6	9	2	2	2	4
Petitions pending	20	23	25	19	13	14
Petitions reviewed	5	6	0	8	8	3
Petitions listed	4	1	0	6	6	2
% listed	80%	17%	0%	75%	75%	67%
Supported FTEs	6.1	3.4	4.8	3.4	na	na
Direct FTEs	3.2	1.8	2.5	1.8	na	na
Workload	25	29	25	27	21	17
Ratio (workload/direct FTE)	4.1	8.5	5.2	7.9	na	na
Ratio (decisions/direct FTE)	1.0	2.6	0.4	0.6	na	na
Salary outlays for program FTEs	$483	$266	$391	$284	na	na
Direct FTEs	$254	$141	$204	$150	na	na

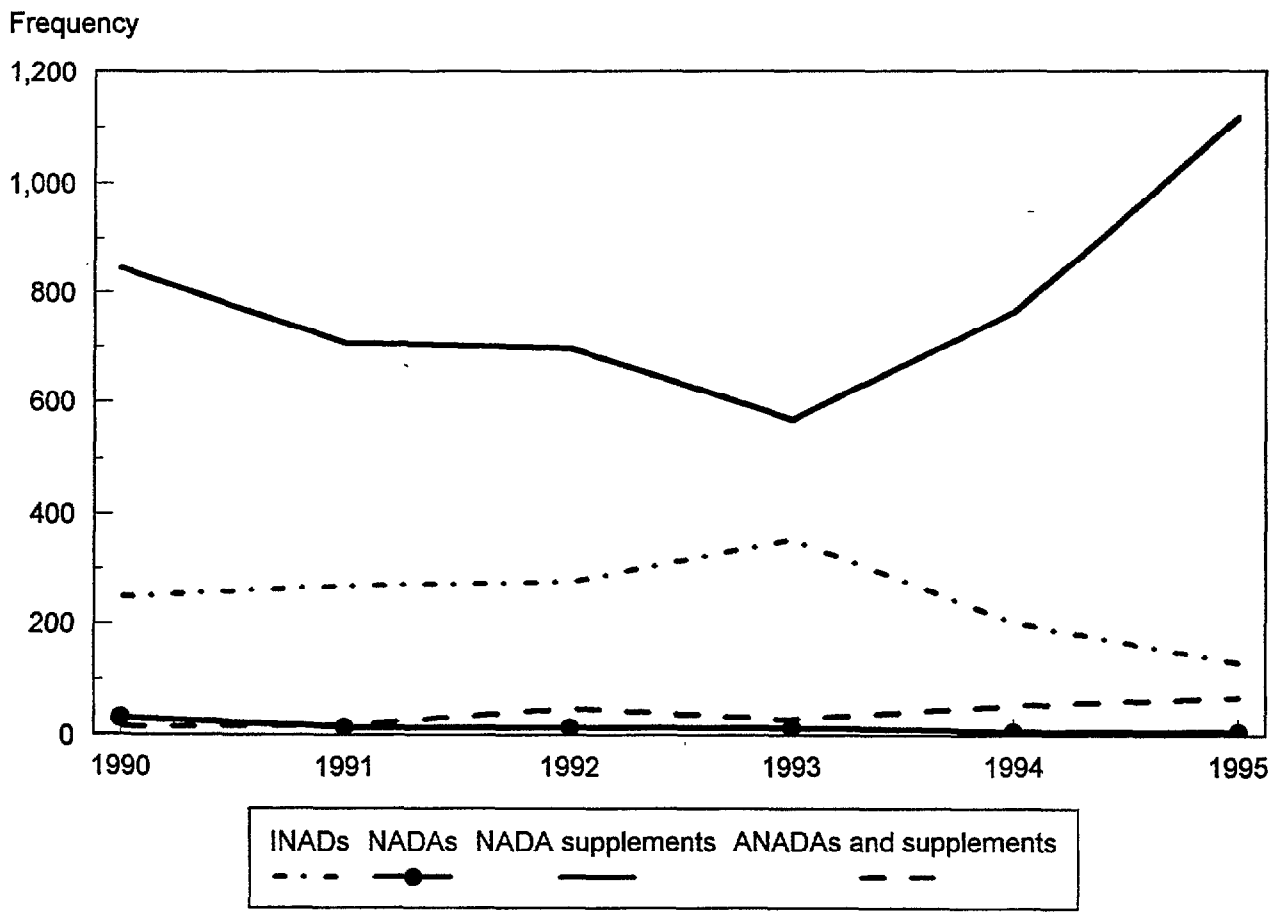
ENCLOSURE X

GRAS petitions						
Petitions received	10	8	18	4	9	5
Petitions pending	66	72	81	69	73	95
Petitions reviewed	6	2	9	16	5	3
Petitions affirmed	2	0	3	3	1	1
% affirmed	33%	0%	33%	19%	20%	33%
Workload	72	74	90	85	78	78
Percent petitions received						
Direct food additives	24%	13%	17%	10%	24%	15%
Indirect food additives	52%	61%	52%	81%	49%	69%
Color additives	9%	13%	3%	3%	5%	7%
GRASs	15%	12%	28%	6%	22%	9%
Number of petitions	66	67	64	62	41	54
Percent direct FTEs						
Direct food additives	53%	54%	59%	60%	na	na
Indirect food additives	40%	42%	34%	36%	na	na
Color additives	7%	4%	6%	4%	na	na
Number of FTEs	48.8	43.3	39.7	41.1	na	na
Resources for food additives						
Total food additive cost	$9,107	$8,079	$8,255	$8,311	$8,556	$9,400
FTE cost	$7,346	$6,445	$6,148	$6,497	$7,270	$7,720
Extramural contracts	$1,761	$1,634	$2,107	$1,814	$1,285	$1,680
Supported FTEs	92.7	82.3	75.4	78.0	84.2	86.7
Direct FTEs	48.8	43.3	39.7	41.1	44.3	46.2

ENCLOSURE XI

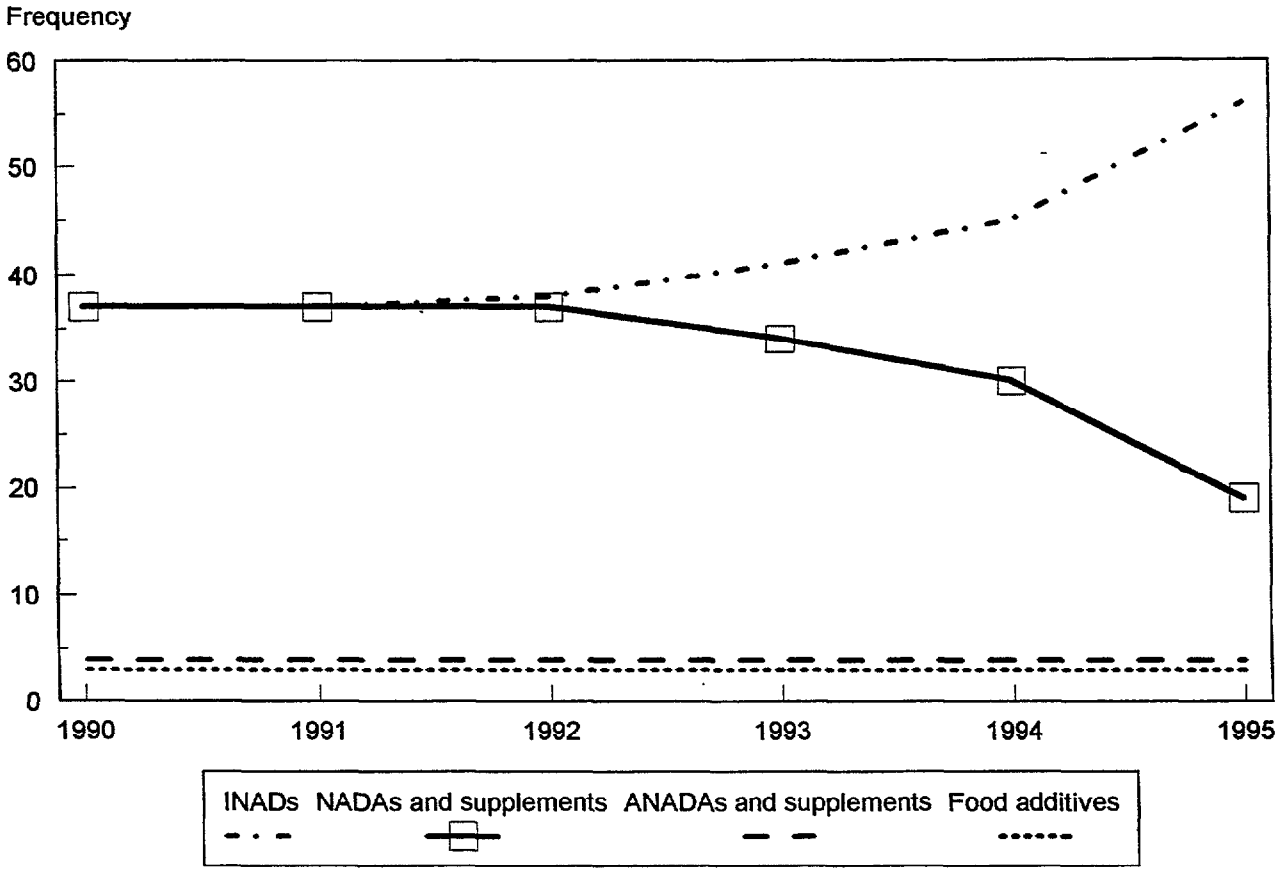
ANIMAL DRUGS FIGURES

Figure XI.1: CVM Applications Received by Product Type, FY 1990-95



ENCLOSURE XI

Figure XI.2: CVM Program FTEs by Product Type, FY 1990-95



ANIMAL DRUGS TABLE: APPLICATIONS SUMMARY, FTEs AND SALARIES, FY 1990-95

The definition CVM uses for pending applications includes only applications that are under active review and in the review queue. It does not include applications waiting for data from the sponsor.

CVM distinguishes between decisions for original applications and reactivated applications. A reactivation is a resubmission of an original application that had previously been found not approvable; therefore, the original application has a single action. Subsequent actions count toward decisions on a reactivated application. To calculate the ratio of applications reviewed to reviewer, we used the number of original applications reviewed.

Resource data are given in terms of program FTEs for NADA and NADA supplements combined. ANADA and ANADA supplement resources are also combined. Since we do not have data on review time for all product types, we cannot indicate their relative resource demands.

Dollars are constant dollars in thousands.

ANIMAL DRUGS TABLE: APPLICATIONS SUMMARY, FTEs AND SALARIES, FY 1990-95

	1990	1991	1992	1993	1994	1995
INADs						
General initial submissions	248	268	276	354	203	131
Submissions pending	59	74	112	70	80	47
Submissions reviewed	233	230	318	344	236	146
Program FTEs	37	37	38	41	45	56
Workload	na	327	350	466	273	211
Ratio (workload/program FTE)	na	8.8	9.2	11.4	6.1	3.8
Ratio (decisions/program FTE)	6.7	7.2	7.3	8.6	4.5	2.3
Salary outlays for program FTEs	$2,563	$2,560	$2,553	$3,002	$3,193	$3,881
NADAs						
Applications received						
Originals	31	14	13	13	6	7
Reactivations	93	72	73	44	26	17
(Amendments)	153	122	162	124	79	54
Applications pending						
Originals	15	35	18	13	8	1
Reactivations	57	45	39	34	22	12
(Amendments)	93	68	69	59	46	27
Applications reviewed						
Originals	12	31	18	18	13	4
Reactivations	104	78	78	56	36	16
(Amendments)	174	121	174	138	99	67
Applications approved	23	4	14	14	11	8
% approved	20%	4%	15%	19%	22%	40%
Mean months to approval	51	47	42	44	44	39
Workload	na	29	48	31	19	15
NADA supplements						
Applications received						
Originals	844	707	696	567	764	1,117
Reactivations	291	274	266	262	209	204
(Amendments)	130	148	138	154	209	312
Applications pending						
Originals	270	296	310	277	259	361
Reactivations	57	102	76	62	70	90
(Amendments)	17	24	37	23	39	65
Applications reviewed						
Originals	817	693	726	586	662	1,044
Reactivations	246	300	279	254	189	207
(Amendments)	109	138	158	140	183	289
Applications approved	605	462	518	445	514	760
% approved	57%	47%	52%	53%	60%	61%
Mean months to approval	na	na	na	na	na	na
Workload	na	977	992	877	1,041	1,376

NADAs and NADA supplements						
Original applications received	875	721	709	580	770	1,124
Original applications pending	285	331	328	290	267	362
Original and reactivations reviewed	1,179	1,102	1,101	914	900	1,271
Originals reviewed	829	724	744	604	675	1,048
Program FTEs	37	37	37	34	30	19
Workload	na	1,006	1,040	908	1,060	1,391
Ratio (workload/program FTE)	na	27.2	28.1	26.7	35.3	73.2
Ratio (decisions/program FTE)	22.4	19.6	20.1	17.8	22.5	55.2
Salary outlays for program FTEs	$2,563	$2,560	$2,485	$2,456	$2,129	$1,294
ANADAs						
Applications received						
Originals	15	18	48	26	24	13
Reactivations	1	13	24	71	52	38
(Amendments)	4	10	44	29	60	29
Applications pending						
Originals	3	12	8	21	16	11
Reactivations	0	1	6	8	38	27
(Amendments)	1	3	2	14	15	21
Applications reviewed						
Originals	6	22	35	31	29	14
Reactivations	0	8	22	43	61	55
(Amendments)	2	11	32	28	54	42
Applications approved	0	0	2	7	21	23
% approved	0	0	4%	9%	23%	33%
Mean months to approval	na	na	na	21	29	31
Workload	na	21	60	34	45	29
ANADA supplements						
Applications received						
Originals	0	0	1	3	30	56
Reactivations	0	0	0	0	4	5
(Amendments)	0	0	1	1	2	13
Applications pending						
Originals	0	0	0	1	0	16
Reactivations	0	0	0	0	0	3
(Amendments)	0	0	0	0	0	1
Applications reviewed						
Originals	0	0	0	4	14	49
Reactivations	0	0	0	0	1	6
(Amendments)	0	0	0	0	1	11
Applications approved	0	0	0	3	8	37
% approved	0	0	0	75%	53%	67%
Mean months to approval	na	na	na	na	na	na
Workload	na	0	1	3	31	56

ANADAs and ANADA supplements						
Original applications received	15	18	49	29	54	69
Original applications pending	3	12	8	22	16	27
Original and reactivations reviewed	6	30	57	78	105	124
Originals reviewed	6	22	35	35	43	63
Program FTEs	4	4	4	4	4	4
Workload	na	21	61	37	76	85
Ratio (workload/program FTE)	na	5.3	15.3	9.3	19.0	21.3
Ratio (decisions/program FTE)	1.5	5.5	8.8	8.8	10.8	15.8
Salary outlays for program FTEs	$278	$269	$261	$271	$275	$276
Food additive petitions						
Petitions received						
Originals	2	7	2	1	3	3
Reactivations	4	5	10	3	2	7
(Amendments)	0	3	4	6	4	6
Petitions pending						
Originals	1	1	2	3	2	1
Reactivations	2	3	1	3	0	1
(Amendments)	0	0	1	3	4	1
Petitions reviewed						
Originals	2	6	1	4	2	3
Reactivations	3	7	8	4	3	4
(Amendments)	0	2	2	5	7	1
Program FTEs	3	3	3	3	3	3
Workload	na	8	3	3	6	5
Ratio (workload/program FTE)	na	2.7	1.0	1.0	2.0	1.7
Ratio (decisions/program FTE)	0.7	2.0	0.3	1.3	0.7	1.0
Salary outlays for program FTEs	$208	$208	$202	$202	$207	$207
Percent applications received						
INADs	21.8%	26.4%	26.6%	36.7%	19.7%	9.9%
NADAs	2.7%	1.4%	1.3%	1.3%	0.6%	0.5%
NADA supplements	74.0%	69.7%	67.2%	58.8%	74.2%	84.2%
ANADAs	1.3%	1.8%	4.6%	2.7%	2.3%	1.0%
ANADA supplements	0.0%	0.0%	0.1%	0.3%	2.9%	4.2%
Food additive petitions	0.2%	0.7%	0.2%	0.1%	0.3%	0.2%
Number of applications	1,140	1,014	1,036	964	1,030	1,327
Percent program FTEs						
INADs	45.7%	45.7%	46.3%	50.0%	54.9%	68.3%
NADAs and NADA supplements	45.7%	45.7%	45.1%	41.5%	36.6%	23.2%
ANADAs and ANADA supplements	4.9%	4.9%	4.9%	4.9%	4.9%	4.9%
Food additive petitions	3.7%	3.7%	3.7%	3.7%	3.7%	3.7%
Number of FTEs	81	81	82	82	82	82

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