

The State of Science at the Food and Drug Administration

By Peter Barton Hutt*

Introduction

Science at the Food and Drug Administration (FDA) today is in a precarious position. In terms of both personnel and the money to support them, the agency is barely hanging on by its fingertips. The accumulating unfunded statutory responsibilities imposed on FDA, the extraordinary advance of scientific discoveries, the complexity of the new products and claims submitted to FDA for pre-market review and approval, the emergence of challenging safety problems, and the globalization of the industries that FDA regulates -- coupled with chronic underfunding by Congress -- have conspired to place demands upon the scientific base of the agency that far exceed its capacity to respond. FDA has become a paradigmatic example of the "hollow government" syndrome -- an agency with expanded responsibilities, stagnant resources, and the consequent inability to implement or enforce its statutory mandates. For the reasons set forth in this report, Congress must commit to a two-year appropriations program to increase the FDA employees by 50 percent and to double the FDA funding, and then at least to maintain a fully burdened yearly cost-of-living increase of 5.8 percent across all segments of the agency. Without these resources the agency is powerless to improve its performance, will fall only further behind, and will be unable to meet either the mandates of Congress or the expectations of the American public.

Congress and the nation therefore have a choice. We can limp along with a badly crippled FDA and continue to take serious risks with the safety of our food and drug supply, or we can fix the agency and restore it to its former strength and stature. If Congress concludes to fix FDA, however, this cannot be done cheaply. It will be necessary to appropriate substantial personnel and funds to reverse the damage done to FDA in the past two decades.

There should be no doubt about the ability of FDA to absorb and put to good use a 50 percent increase in personnel and a 100 percent increase in funds over two years. Beginning in 1992, four of the FDA Centers have readily accommodated large increases in personnel and funds under user fee statutes and still have major neglected unfunded scientific responsibilities.

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Adequate resources -- both personnel and money -- alone will not be sufficient to repair the deteriorating state of science at FDA. Strong scientific leadership and a new vision to access applicable scientific knowledge and expertise from throughout the government and the private sector are essential to rebuilding the agency's ability to implement its scientific responsibilities effectively. While increasing the FDA staff and doubling the FDA's annual funding by itself will not achieve this objective, without adequate resources even the most creative leadership cannot hope to accomplish what must be done. In short, a substantial increase in resources is a necessary, but not sufficient, requirement to restore the science base at FDA to a level adequate to permit the agency to address its important public health mission.

This report first reviews the overall state of science at FDA in terms of the resources available to the agency as compared with the accumulating unfunded mandates imposed by Congress. It then considers the scientific personnel and resources needed in order to return FDA to a fully-functioning science-based agency in the future.

Lack of Historical Database

It must be emphasized at the outset that analyses of the FDA budget and regulatory activities over the past decades have been hindered, and in many instances have been made impossible, by the lack of a validated FDA historical database. A review of the state of science at FDA should proceed on the basis of well-documented and uniform historical data reflecting the entire spectrum of the agency's budget, personnel, and workload. Because of chronic underfunding of the agency, and the need to focus all available resources on FDA's important public health mission, the agency has never developed a consistent historical database on which adequate analyses can be undertaken. For example, under each of its four user fee statutes the funds and personnel are split among one or more Centers, the Field offices, and various FDA headquarters administrative offices, but FDA has no comprehensive compilation that breaks out these numbers by recipient. FDA's data for the years prior to 1997 do not separate the Centers from the Field force. The agency is unable to break out the personnel and funding levels for cosmetics from the numbers for the Center for Food Safety and Applied Nutrition (CFSAN). The numbers shown in Tables 4 and 5 are therefore a combination of publicly-available data and extrapolations, derived from a variety of sources. The Final Report of the Advisory Committee on the Food and Drug Administration to the Secretary of HHS (May 1991) found the same deficiencies 16 years ago (page 33). In spite of these substantial limitations, however, FDA worked hard to compile sufficient publicly available information to support the development of Tables 4 and 5.

For an agency that traces its origin to 1862 and that has had a federal statutory mandate to regulate the nation's food and drug supply since 1906, this lack of a historical database for budget, personnel, and

regulatory activities is appalling. FDA cannot be managed effectively without understanding where its funds and personnel are allocated as well as the historical trends for its regulatory responsibilities. A science-based approach to regulation requires an infrastructure that can produce adequate data to underpin regulatory planning that will most efficiently and effectively promote and safeguard the American food and drug supply. But it is also the fault of Congress, not just FDA, that such a database does not exist. Congress has failed to provide FDA with personnel and funds adequate to support the information technology and staff essential for such an effort.

Accumulating Unfunded FDA Statutory Mandates

When the Federal Food, Drug, and Cosmetic Act was originally enacted in 1938, the regulatory and compliance issues faced by FDA were comparatively simple and required far less reliance upon science. The issues of adulteration and misbranding could be handled by well-trained Field inspectors located throughout the country. The need for Ph.D.s and M.D.s was modest, and very few were employed by the agency.

There was only one exception. The 1938 Act included pre-market notification (but not pre-market approval) for the safety (but not the effectiveness) of human and animal new drugs. From that modest beginning, FDA's role as gatekeeper to new products has expanded enormously. Through the enactment of a series of landmark statutes beginning in the 1950s and extending through the 1970s, FDA was given a mandate by Congress to review and approve, prior to marketing, the safety of color additives, human food additives, and animal feed additives, and to review and approve the safety and effectiveness of human new drugs, animal new drugs, human biological products, and medical devices for human use. As a practical matter, today no new pharmaceutical product or medical technology can be marketed in the United States without FDA first determining that it is safe and effective for its intended use. In 1990, Congress added pre-market approval for disease prevention and nutrient descriptor claims for food products, and in 1994 it added pre-market review for new dietary supplement ingredients. These unprecedented new responsibilities forever transformed the nature and scope of the agency's workload.

As these and other statutory mandates accumulated, the need for adequately-trained FDA scientific personnel, and the resources appropriate to support them, increased exponentially. With the rapid advance of such scientific disciplines and techniques as analytical chemistry, food technology, recombinant DNA technology, quantitative risk assessment, modern engineering and electronics, the biological sciences, blood and tissue technology, genomics and the other "omics," and nanotechnology -- to name just a few -- FDA has struggled to recruit well-trained scientists and to keep up with new scientific developments in order to maintain a solid medical and

scientific basis for its pre-market review and approval decisions. Without congressional appropriations for increased scientific personnel and funds to support participation in professional scientific meetings and to maintain cutting-edge educational programs within the agency, FDA staff become increasingly isolated and fall behind their counterparts in academia and the regulated industry.

FDA encounters tremendous problems in implementing the burgeoning number of new statutory responsibilities imposed by Congress each year. Table 1 lists the more than 100 statutes that directly impact FDA enacted by Congress only since 1988 -- an average of more than 6 each year. These are in addition to the core provisions of the 1938 Act itself and another 90-plus statutes directly involving FDA that were enacted during 1939-1987. Each of these statutes requires some type of FDA action. Many require the development of implementing regulations, guidance, or other types of policy, and some require the establishment of entire new regulatory programs. Virtually all require some type of scientific knowledge or expertise for the agency adequately to address them. Yet none of these statutes is accompanied by an appropriation of new personnel and increased funding designed to allow adequate implementation. In the history of our country, no other Federal regulatory agency has ever faced such an onslaught of new statutory mandates without appropriate funding and personnel to implement them. Instead, the agency is expected to implement all of these new unfunded congressional mandates with resources that, in the corresponding time, represent at best a flat budget. Not surprisingly, many of the new congressional mandates languish for years or cannot be implemented at all.

For example, in 1994 Congress authorized FDA to establish good manufacturing practice (GMP) regulations for dietary supplements. It took nine years before FDA published proposed regulations in 2003, and four years later the final regulations have just now finally been promulgated. In 1997, Congress required drug manufacturers to notify FDA about the discontinuance of specified drug products. FDA proposed regulations to implement this requirement in 2000, and seven years later has just now promulgated the final regulations.

As another example, it is well-documented that contamination of railroad cars used to transport food and other FDA-regulated products can result in serious health hazards. Congress sought to address this in 1990 by authorizing the Department of Transportation to issue regulations to prevent the contamination of these important products, but DOT eventually determined in 2004 that the expertise for assuring their safety lies with FDA. Congress then enacted a new law in 2005 requiring FDA to establish regulations to assure that food is not transported under conditions that may render the food adulterated. No new personnel or money accompanied this statutory requirement. Substantial scientific resources will be needed if the agency is expected to develop and implement appropriate regulations. As of today, FDA has taken no action to develop these regulations, and has no plans to

do so, because it does not have the requisite scientific resources. This matter is not even mentioned in the 2007 list of the top 150 priorities for CFSAN.

These simple examples illustrate the problems that FDA encounters with the enactment of every one of the new statutory responsibilities embodied in the legislation listed in Table 1. Because they are unfunded mandates, they are often unimplemented mandates.

Just a short while ago, Congress once again enacted an unfunded FDA omnibus statute, the Food and Drug Administration Amendments Act of 2007, that demands substantial FDA scientific resources to analyze and implement. It consists of 11 separate titles, each of which is a comprehensive statute in and of itself, for a total of 155 pages of new regulatory responsibilities -- with no plans for additional appropriated funds or personnel to implement it. Parts of it are funded by user fees, but large parts are not. There are no personnel or funds in the proposed FDA 2008 appropriations to implement the major new programs this new statute mandates. FDA cannot manage this process by tired old slogans like "work smarter." These only insult an already overworked and very dedicated agency staff. The statutes documented in Table 1 -- and particularly the FDA Amendments Act of 2007 -- can only be implemented by diverting the agency's staff from one task to another. To meet the requirements of a new statute, in short, FDA must abandon work on an old one. That is exactly what has been happening at FDA for the past 20 years. The only way to stop the disintegration of FDA's core responsibilities and still maintain the ability to accept new mandated programs is for Congress to appropriate the personnel and funds needed to do both.

Just the congressional consideration of these new statutes through House and Senate legislative hearings -- and the related investigational hearings and letters by other committees and individual members of Congress -- siphon off substantial time of FDA scientists whose expertise is needed to assure that the agency responds fully and accurately. This is unquestionably an important part of our democratic process. But it is also an unfunded major activity that is not accounted for in the budget process even though it consumes thousands of hours of FDA personnel.

In addition to the laws listed in Table 1, which directly require FDA to take action, Congress has enacted a number of statutes of general applicability that place a large administrative burden on FDA in conducting its daily work. Representative statutes of general applicability that require substantial FDA resources for compliance are listed in Table 2. For example, in order to promulgate a regulation, FDA must at a minimum include, in the preamble, not only full consideration of all the substantive issues raised by the regulation itself, but also a cost-benefit analysis, an environmental impact discussion, a federalism evaluation, a small business impact statement, a determination whether there is an unfunded mandate

impact on state or local governments, and an analysis of paperwork obligations. The proposed and final regulations must be reviewed and approved by the Department of Health and Human Services (DHHS) and the White House Office of Management and Budget (OMB). However well-intentioned, these responsibilities place a major burden on FDA and require that scientific resources be diverted from other areas in order to assure compliance. This has led FDA to avoid rulemaking wherever possible and to substitute informal guidance or to take no action whatever on important regulatory matters.

The impact on FDA of just one of these statutes of general applicability can be readily quantified. The Freedom of Information Act requires FDA, along with other federal agencies, to provide documents in the agency's files to the public upon request. This is unquestionably a statute of major importance to the country. Because FDA is the repository of substantial information that is of interest to the regulated industry, academia, and the general public, FDA receives each year more FOI requests than any other government agency except the Federal Bureau of Investigation. Handling these requests places a substantial burden on FDA personnel and funds. To alleviate the cost to FDA, Congress included in the FDA Revitalization Act of 1990 authorization to establish a revolving fund to pay for FOI costs. This has, however, produced only a modest offset to the agency FOI costs. In 2006, FDA received a total of \$493,202 in FOI fees, compared to the overall agency FOI costs of more than \$11 million. In many instances, it is the scientists and not the support personnel at FDA who must respond to these FOI requests, in order to assure that the correct documents are being provided and that confidential information is not made public. These are the same scientific personnel who have, as their major priority, the review and approval of applications for new products and claims.

The FOI Act requires that FDA determine within 20 days whether it will provide the requested documents, and provide the documents "promptly" thereafter. Because of its lack of funds and personnel, FDA reduced its FOI staff from 123 in 1995 to 88 in 2006. As a result, its backlog of unfilled FOI requests has grown from 13,626 in 2000 to 20,365 in 2007. Some requests date back four years and even longer. The entire system is clearly broken. It cannot be fixed by admonitions that the agency should "do better." It can only be fixed by congressional appropriation of adequate resources devoted to implementing the FOI Act and providing this information to the public.

The statutes of general applicability are not the only directives that have a strong impact on FDA. Every President in the past 40 years has issued one or more Executive Orders that impose additional obligations on FDA. A representative sample is set forth in Table 3. These Executive Orders have the same binding status as a statute and can have as great or greater impact.

For example, President Bush recently issued an Executive Order delegating review of administrative agency guidance to OMB. As noted above, FDA began to issue guidance in the 1970s in order to provide useful information to the regulated industry on important regulatory policy issues, without the formality of promulgating regulations. Now the agency scientists must devote substantial time to determining which guidance fall under OMB review. For each guidance that requires OMB review, the agency must decide whether it has the resources to pursue the matter at all and, if so, what other matters must be abandoned in order to carry this one forward. This is not a criticism of this Executive Order. But Congress must realize that it entails substantial administrative burdens that require additional personnel and funds to implement.

The combined weight of these unfunded FDA statutes, statutes of general applicability, and Executive Orders is tremendous. Each includes additional responsibilities for the agency without commensurate appropriations for personnel and funds. The result is that, with relatively flat funding and a very large increase in what the country expects from the agency, FDA is falling further and further behind.

These unfunded mandates cascade down on FDA from all sides of the political spectrum. It is not a problem caused by partisan politics. The Administrations of President Clinton and President Bush have been equally unresponsive to FDA's needs. Nor does this report question the justification for these mandates. Rather, it is the undeniable fact that these mandates are unfunded, and thus that FDA lacks the capacity to implement them, that is objectionable. The country cannot withhold the requisite scientific resources from FDA and then complain that the agency is incapable of meeting our expectations.

This disparity between expectations and resources has become increasingly apparent to the public in the past five years. Daily media headlines have focused on safety problems with prescription drugs, medical devices, the food supply, and now pet food as well. Without adequate appropriations, this will not just continue but increase.

The result of this very visible deterioration in FDA resources is a sharp decline in public confidence. Three decades ago, FDA ranked among the most respected federal agencies, with a public confidence rating of about 80 percent. Today, it has plummeted to between 30 and 40 percent:

FDA Public Confidence Rating (Harris Poll)	
1970s	80%
2000	61%
2004	56%
2006	36%

As long as appropriations lag behind public expectations and new responsibilities imposed by Congress, this decline in public confidence can be expected to continue.

At the heart of the problem is the lack of adequate scientific personnel and resources. As noted above, prior to 1970 FDA was primarily a law enforcement agency. Beginning in the 1970s, however, FDA became a modern science-based regulatory agency. With the advent of pre-market review and approval requirements for FDA-regulated products, the bulk of FDA work shifted from the courts to administrative decisions made within the agency. These administrative decisions are almost always based upon science.

The reaction of Congress to the decline of FDA has been to enact further legislation, not to appropriate additional resources. This vastly misperceives the problem. The current reduced state of FDA is not the result of a lack of statutory authority and mandates to foster and protect the public health. It is the direct result of the lack of adequate appropriations of personnel and money to do the job. More statutes only exacerbate the problem.

Scientific research agencies like NIH and CDC have had substantial increases in appropriations over the past two decades but FDA has not. Since 1988, NIH appropriations have increased \$22.264 billion and CDC \$5.261 billion as compared to \$1.096 billion for FDA. The regulated industry has strongly supported higher FDA appropriations, but to no avail. Whatever the reason for this disparity, it is now time for Congress to make up the difference. Today, NIH and the pharmaceutical industry are investing more than \$60 billion annually in the search for new lifesaving pharmaceutical products. The important medical and scientific discoveries that flow from our country's preeminent research laboratories will be severely hindered from reaching the patient's bedside unless FDA is given adequate resources.

Need to Leverage Other Scientific Sources

FDA is a science-based regulatory agency, not a scientific research organization. Basic scientific research should be conducted at the National Institutes of Health (NIH), in academia, and in other basic science organizations, not at FDA. But it is vital that FDA have access to that research in order to apply it to the daily regulatory decisions with which it is charged. FDA cannot make well-reasoned decisions on the marketing of new medical technology if it does not have within the agency up-to-date expertise on the science that underpins that technology.

There are also some areas of applied science that are vital to FDA's regulatory mission, such as the development and validation of analytical methods. This form of regulatory science must continue to be supported within the agency.

FDA must take advantage of the programs in other federal agencies that complement the FDA mission and that can, with effective coordination, multiply the impact of what FDA can do alone. For example, there are food safety programs in the Centers for Disease Control and Prevention, the United States Department of Agriculture, State agencies, and the land grant universities. Yet FDA has inadequate appropriations to leverage these resources through a closely-cooperating consortium that could greatly enhance the effectiveness of all the participants.

With increasing technical specialization, FDA must focus on the core areas of scientific expertise that must reside within the agency in order to permit FDA to continue its historic mission, and those areas that can more appropriately be outsourced in order to access technical expertise. No better example of outsourcing exists than information technology. FDA cannot recruit sufficient technicians to allow the agency to design and build a state-of-the-art information technology system by itself, nor should it try to do so. But FDA still needs a core information technology staff to manage the contractors and coordinate the entire effort. To accomplish this for the entire agency will require major new appropriations.

One of the most important issues facing FDA today is the development of a modern active post-market safety surveillance network for drugs, biological products, and medical devices that will establish an early warning system by electronically linking public and private adverse event databases throughout our healthcare system. FDA has struggled with this issue for four decades, lacking both the technology and the appropriations to build an appropriate system. With the advent of current cutting-edge information technology, the technology part of the issue can now readily be addressed. But without substantial immediate appropriations FDA still cannot move forward with a program that is vitally needed to assess the continued safety of our medical products once they reach the marketplace. Congress must recognize this need and act on it promptly, or sit by and witness continuing media revelations of product safety problems.

Because congressional appropriations have failed to support the science base at FDA at an adequate level, in desperation FDA and the regulated industries have sought to fill the gap with user fees -- first for human prescription drugs and biological products, and more recently for medical devices and animal drugs. Even with these non-appropriation funding mechanisms, however, FDA has failed to keep pace with the mandates of Congress and the expectations of the public. Regulatory decisions must therefore be made by an agency that has inadequate scientific personnel and resources. It is not the fault of FDA leadership that this has occurred. It is the fault of the entire country that our most important health agency has been neglected to the extent that the science base on which virtually all of its decisions depend has substantially deteriorated. Unless something is done about it immediately, the ability of FDA to pursue its public

health mission -- to promote and protect the health of the American people -- will become even more tenuous.

Unfinished FDA Safety Programs

The lack of adequate scientific personnel and the resources to support them has had a major adverse impact on important FDA regulatory programs to assure the continued safety of marketed products. For example, on several occasions FDA has established comprehensive reviews of products after they have been marketed, either at the direction of Congress or on its own initiative. Virtually all of these reviews remain unfinished for lack of agency resources.

Color Additives. At the direction of Congress, in 1960 FDA began a review of the safety of all color additives used in food, drugs, and cosmetics since 1906. Today, 47 years later, the lakes of all color additives used in these products still have not yet been the subject of a final safety decision by FDA even though they have been used in marketed products for the past 100 years.

Prescription Drugs. The Drug Amendments of 1962 directed FDA to review the effectiveness of all drugs for which an NDA had become effective solely on the basis of safety between 1938 and 1962. This was implemented by the Drug Efficacy Study Implementation (DESI) program. Today, 45 years later, approximately 20 of these DESI drugs still remain on the market without a final determination of effectiveness.

Nonprescription Drugs. In 1972, FDA established the OTC Drug Review, to review the safety, effectiveness, and labeling of all nonprescription drugs then being marketed. Today, 35 years later, there remain several categories of OTC drugs, representing thousands of separate products, that have not yet been the subject of a final determination under the OTC Drug Review.

Biological Products. Following the transfer of responsibility for the licensing of biological products from NIH to FDA, in 1973 the agency announced that it would conduct a review of the safety, effectiveness, and labeling of all biological products marketed pursuant to licenses issued from 1902 to 1972. Today, 34 years later, the Biologics Review remains only partially completed.

Food Ingredient GRAS List Review. In 1969, President Nixon directed FDA to undertake a comprehensive review of the safety of all food ingredients listed by the agency as generally recognized as safe (GRAS) and thus as marketed without the need for FDA review and approval of safety through promulgation of a food additive regulation. After completing part of the GRAS List Review, FDA abandoned this program for lack of resources and now reviews the safety of marketed GRAS food substances only when specific issues are raised.

Human Food Ingredient GRAS Affirmation. In 1972, FDA established a procedure under which food ingredient manufacturers who marketed their products as GRAS could obtain affirmation from FDA of the safety of these ingredients. Because of a lack of resources FDA abandoned this procedure in 1997 and substituted for it a simple notification procedure under which the agency issues letters stating that the agency has "no questions" but makes no affirmative determination of safety. Today, ten years later, the proposed regulation for this new policy has not yet been promulgated in final form even though the new policy has been fully implemented for human food ingredients.

Animal Feed Ingredient GRAS Affirmation. The 1997 proposed GRAS notification procedure applied to animal feed ingredients as well as human food ingredients. Because of a lack of resources, the Center for Veterinary Medicine (CVM) not only abandoned the GRAS affirmation procedure but declined to implement the new GRAS notification process as well. On request, CVM issues letters stating that the agency has "no objections" but makes no affirmative determination of safety. On the basis of these letters the regulated industry then handles all feed ingredient GRAS issues through the Association of American Feed Control Officials (AAFCO) and individual State agencies.

Review of Pre-1976 Class III Medical Devices. Under the Medical Device Amendments of 1976, all pre-1976 medical devices that are classified by FDA as requiring pre-market approval for safety and effectiveness (Class III) are required to be the subject of a regulation promulgated by the agency either calling for the submission of a pre-market approval (PMA) application or reclassifying the device. Today, 31 years later, up to 15 of these categories of pre-1976 devices -- including post-1976 devices determined to be substantially equivalent -- remain on the market under Class III without an FDA review and decision on their safety and effectiveness.

Food Additive Regulations. In 1977, FDA announced that it would undertake a cyclic review of all food additive regulations to assure that past food safety decisions remained currently justified. Because of a lack of resources FDA abandoned this program in the early 1980s and now reviews the safety of marketed food additives only when specific issues are raised.

Unapproved New Drugs. The DESI program required by the Drug Amendments of 1962, for new drugs that were covered by an NDA between 1938 and 1962, did not extend to drugs that had been marketed without an NDA on the basis of an independent determination by the manufacturer that they were GRAS and thus exempt from the requirement for an NDA. After one of these unapproved new drugs caused serious adverse events that required a nationwide recall, FDA committed to Congress in 1984 that it would review the safety and effectiveness of these products

and take appropriate action. Because FDA has taken action against fewer than ten of these types of drugs since 1984, thousands of unapproved drugs are now being marketed without any type of FDA review of safety or effectiveness and are estimated to represent approximately two percent of all prescriptions.

These represent only a few examples of numerous FDA programs that languish for lack of adequate scientific personnel and funding. They illustrate the problems that the agency faces when congressional appropriations are inadequate to permit FDA to devote scarce resources to important product safety programs.

Lack of Adequate FDA Appropriations

No one outside FDA has enough information about the agency to conduct a zero-based budget analysis for FDA. It is likely that FDA itself has numerous materials that would bear upon such an analysis, but the agency states that it is not able to make those public.

This report therefore pursues a different approach. Attached are tables that present a partial statistical history of the congressional appropriations for FDA personnel and funds for the past 20 years, compiled from publicly-available sources. Tables 4 and 5 cover the 20-year period of 1988 - 2007 (or, where these figures are not available, the most recent years for which they are available). As the last column in Table 5 shows, from 1988 to 1994 FDA's appropriated personnel and funding kept even with its increasing responsibilities and exceeded inflation. The agency's appropriated personnel increased from 7,039 to 9,167 (a gain of 2,128 people) and its funding from \$477.504 million to \$875.968 million (a gain of \$398.464 million). In 1994, however, FDA hit a brick wall. From 1994 to 2007 the agency's appropriated personnel decreased from 9,167 to 7,856 (a loss of 1,311 people), returning it almost to the same level that was appropriated 20 years earlier. FDA's appropriated funding during this time increased by \$698.187 million, but this was only about two-thirds the funding needed to keep up with FDA's fully burdened cost-of-living increase of 5.8 percent, compounded yearly. Thus, over the entire 20 years FDA gained only 817 employees -- an increase of 12 percent -- and lost more than \$300 million to inflation, while faced with implementing the new statutes listed in Table 1 and the agency's substantial other core responsibilities under the 1938 Act. Confronted with a burgeoning industry as documented in Table 6, it became increasingly impossible for FDA to maintain its historic public health mission.

This report concludes that a substantial increase in appropriations is essential to halt the disintegration of FDA and to allow the agency to regain its former strength and vitality. A 50 percent increase in personnel (FTE) and a 100 percent increase in funds, over a two-year period, is necessary in order to rescue FDA from its current precarious condition.

The FDA appropriations for 2007 provide for 7,856 employees. The recommendation of this report would raise this appropriated level to 9,820 employees in 2008 -- just slightly more than the 9,352 employed by the agency in 1994. The appropriated number of employees would then rise to 11,794 in the following year. This represents only a 64 percent increase from the 7,210 employees appropriated for FDA in 1988, 20 years earlier. Considering just the enormous workload created by the new 100-plus statutes enacted by Congress during this time, this increase is quite modest.

Doubling the funds appropriated for FDA is essential to rebuild regulatory programs that have been decimated over the past 20 years. The recommendation of this report would raise the appropriated funds for FDA from \$1.574 billion today to \$2.361 billion in 2008 and to \$3.148 billion in the following year. Applying FDA's fully burdened cost-of-living factor for the agency of 5.8 percent, compounded annually, for the past 20 years means that \$1.475 billion in FDA funding is required just to restore the agency to the same level today as in 1988 (\$477.504 million), without consideration of the additional burdens imposed on the agency under the new statutes listed in Table 1. But we need to do much more than just that. For example, substantial funds are needed to construct a nationwide adverse event warning system for medical products and new inspection programs for both domestic and imported products, just three current high priority new programs for the agency. Together just these programs will cost well over \$500 million to plan, implement, and maintain. These new funds are vitally needed to make up for years of neglect. The cumulative gap between the funds FDA has needed all these years, and the amount actually appropriated, far exceeds the funding this report is recommending. This recommendation will be sufficient, however, to lift the agency from its present state of disrepair and to allow the rebuilding process to begin.

It must be emphasized that this is not a one-time quick fix. Appropriations for FDA personnel and funding must have indexed increases each year, to prevent another sustained period of deterioration.

The 3,928 new employees that will be hired, and the \$1.574 billion in new funds, over this two-year period should primarily be allocated to functions not presently supported by user fees. As discussed in greater detail below, user fees have completely distorted the current FDA budget. The applications review functions for human drugs, biological products, medical devices, and animal drugs have been supported by both indexed appropriations and user fees, while the rest of FDA has stagnated. Accordingly, most of the increased appropriations that we recommend should be allocated to the functions of FDA that have not been supported by user fees, such as CFSAN and the Field force.

FDA regulates an estimated 25 percent of each individual's personal consumption in our country. Each citizen presently pays only \$5.21 per year -- about 1.5 pennies per day -- to support the agency. Our proposal would raise this to \$10.42 per year, or 3 cents per day. Considering that the products that FDA regulates are essential to sustain life itself, this is a bargain.

Destructive Impact of User Fees

FDA and industry have resorted to user fees to prop up the agency since 1992 only because the pre-market review and approval functions of the agency would collapse without them. In the long run, however, funding FDA by a tax on the regulated industry is not an appropriate solution to the agency's needs and should be abandoned. This approach has clearly contributed to the decline in FDA's public credibility. This report agrees with the Institute of Medicine that Congress should return to providing personnel and funds to FDA by appropriations, not by user fees.

The advent of user fees for prescription drugs and biologics has, in fact, shielded the serious deterioration of FDA science from public view. In 2007 the agency obtained \$352 million and 1,519 staff through user fees for new drugs and biological products. But these new resources are specifically limited to the review process for new drug applications (NDAs) and biological license applications (BLAs) and to related safety functions. For example, they do not support the review and promulgation of OTC drug monographs; or the review and decisions relating to DESI and non-DESI unapproved new drugs; or the Critical Path initiative; or post-market compliance review of product labeling and advertising; or the regulation of generic drugs; or Field post-market compliance action to assure the enforcement of FDA GMP requirements; or action relating to counterfeit or illegal internet and imported drugs; or numerous other activities that make important contributions to FDA regulation of pharmaceutical products. Because user fees have focused narrowly on the NDA/BLA review function and the user fee statutes require an annual cost-of-living increase for this function only, the appropriations for the rest of the regulatory process for drugs and biological products have stagnated. Thus, CDER and CBER today are divided into two parts -- the rich (supported by both indexed appropriations and user fees) and the poor (supported by flat or reduced appropriations). This intolerable disparity fails to recognize the importance of all of the parts of these Centers that contribute to the regulation of drugs and biological products.

A close analysis of how user fees actually work reveals an even more pernicious impact on the rest of the FDA budget. Each of the user fee statutes requires that Congress maintain its normal appropriations for the same function, indexed for inflation. At first blush, this makes sense. User fees are intended to add to congressional appropriations, not to replace them. Thus, funding and personnel for the functions of pre-market review and approval of new drugs, biological products,

medical devices, and new animal drugs receive a guaranteed cost-of-living increase each year as well as the user fees. But the impact on FDA as an institution is highly destructive. This system not only creates rich and poor functions within the four Centers that have user fees, but it leaves the remaining two Centers, CFSAN and NCTR, and the FDA Field force absolutely destitute.

This can be illustrated using the FDA budget figures for 2002 and 2005. FDA's total program funding (including user fees) was \$1.37 billion in 2002 and \$1.62 billion in 2005, broken down in pertinent part as follows:

Total FDA Program Funding (\$ Millions)		
	2002	2005
Total FDA Program	1,370.000	1,620.000
Total Review Functions	344.930	637.551
User Fees	181.553	305.288
User Fee Indexing	163.377	332.263
Total Core Functions	854.185	604.035

As a result of user fees the review functions increased substantially, at the expense of the Agency's core functions:

Percent of Total FDA Program Funding		
	2002	2005
Review Functions	25%	39%
Core Functions	62%	37%

In these three years alone, the core functions of FDA -- all of its basic responsibilities for implementing the 1938 Act and its hundreds of amendments -- lost \$250 million in funding, an incredible reduction of 29 percent. The core functions dropped precipitously from 62 percent to 37 percent of the total FDA program funding. And since 2005, it has only become worse. This is the real impact of user fees. It documents the systematic dismantling of the FDA's core mission.

Lack of Adequate FDA Personnel

Nor is money alone the answer to the current crisis in FDA science. FDA needs a major increase in scientific personnel and support staff if it is to regain its former strength and stature. Indeed, FDA's most serious deficit during the past 20 years has been the steady erosion in its human capital. Table 5 shows that the total appropriated personnel level in 1988 was 7,039. Today, 20 years later, the appropriated FTE level is 7,856, an increase of only 817 positions, or 12 percent -- and a

loss of 1,311 positions, or 14 percent, since 1994. The avalanche of laws documented in Table 1, together with the increase shown in Table 6 in the FDA-regulated industry, justify the attention of a substantial increase in the agency's scientific personnel.

One example will illustrate this problem. Each year FDA receives an increasing number of reports of adverse events associated with prescription drugs that are submitted by health care practitioners through MedWatch or by the NDA or BLA holder as expedited (for adverse events that are both serious and unexpected) or periodic (quarterly, annually, or at FDA's request):

Total Adverse Event Reports Submitted to FDA			
1996	191,865	2002	322,691
1997	212,978	2003	370,898
1998	247,607	2004	423,031
1999	278,266	2005	464,068
2000	266,978	2006	471,679
2001	285,107		

Even with the 146 percent increase in these reports from 1996 to 2006, FDA has had no increase in personnel to review and evaluate these reports. Simple mathematics shows that in 2006 FDA reviewers spent 40 percent of the time on each report that they spent in 1996. Higher appropriations would not have changed this result. Only a greater number of scientific personnel can return FDA to a more adequate handling of product safety evaluations.

The same scientific deficit occurred with the submission of medical device reports (MDRs) to the Center for Devices and Radiological Health (CDRH). CDRH received 184,222 MDRs in 2005 and 325,742 MDRs in 2006 -- a 77 percent increase in only one year, with no increase in scientific personnel to review and evaluate them.

Science-trained personnel are also essential to audit the conduct of clinical trials submitted to FDA to support applications for FDA-regulated products and claims that require pre-market notification or pre-market approval -- such widely divergent products as artificial sweeteners, automatic defibrillators, new dietary supplement ingredients, blood products, and cancer and AIDS drugs. This biomedical monitoring function of FDA serves the dual purposes of protecting human subjects and verifying the validity of the clinical trial results. Because of its budget constraints, FDA currently conducts only a partial audit of about 1 percent of these trials.

It is a tragedy that, when Congress, other government agencies, and the press uncover deficiencies in FDA regulation, they blame the agency for the problem, not the actual root cause of the agency's

inaction -- the failure of Congress to provide adequate funding and staff to handle the matter. For example, the HHS Inspector General's recent report excoriating FDA for inadequate monitoring of clinical trials drew a headline on the front page of the New York Times that read "Report Assails F.D.A. Oversight of Clinical Trials." Neither the Inspector General nor the New York Times sought to trace the problem to its source and thus to place the blame on Congress, where it really belongs. Every report urging greater FDA action on a particular program should be required to specify what program the agency should discard in order to take on the new one.

Training and mentoring FDA scientific personnel -- both within the agency and through independent professional and academic programs here and abroad -- is an acute need. Application reviewers throughout the agency run the risk of inconsistent or uninformed decisions absent continuing education, coordination, and collaboration. For example, Bayesian statistical techniques are encouraged at CDRH but discouraged at CDER. FDA needs a strategic and sustained program of agency-wide in-depth intellectual engagement with its reviewers, not to satisfy idle curiosity but to equip them with the knowledge to confront current issues in health and disease as they are presented in the applications submitted to the agency. Although the explosion of scientific knowledge over the past 20 years seems daunting enough, it promises to be even more overwhelming in the next 20 years. FDA must prepare for it. Without the personnel and funds to develop and implement such a program FDA reviewers and their decisions will be poorly informed and the public health will be poorly served.

Attracting and retaining qualified scientists is a serious problem at FDA. The regulated industry almost always offers higher pay and benefits than FDA for entry level personnel. And once FDA trains its scientists, their expertise in FDA regulatory practice and policy makes them even more valuable to the industry. Confronted with frustration from the working conditions at FDA -- too few personnel and too little money -- and the opportunity for higher pay and better working conditions in industry, it is not surprising that FDA's attrition rates for scientists are higher than in other federal scientific agencies. This can be addressed by FDA only through congressional appropriations of additional personnel and funds.

The type of project planning undertaken by scientific research organizations cannot be rigorously implemented by FDA. In addition to its routine regulatory responsibilities, FDA is a crisis management organization. At any moment, FDA scientists both in Washington and in the Field must be prepared to ignore their established priorities and statutory deadlines in order to confront safety issues raised by food contaminated with pathogens, animal feed and pet food with chemical contaminants, fish with antibiotics, malfunctioning medical devices, serious adverse events associated with prescription drugs, BSE in cattle, and a host of other problems for which the agency is responsible. Because these issues are broadcast instantly throughout

the country through the electronic media, Congress and the public expect immediate answers and action from FDA. It is essential that the agency always have a critical mass of scientific expertise adequate to respond knowledgeably and effectively. It is also essential for the country to understand that there are some questions for which there are no quick and easy answers and that this is no reflection on the dedication or ability of the FDA scientists. But to handle these communication crises, FDA has an inadequate staff throughout the agency.

Disintegration of CFSAN

The science functions within the FDA Center for Food Safety and Applied Nutrition (CFSAN) have been hit particularly hard. In the 15 years from 1992 to 2007, CFSAN suffered a reduction in force of 138 people, from 950 to 812, or 15 percent of its staff. During the same period, Table 1 shows that Congress enacted new legislation creating large new responsibilities for CFSAN, all of which required substantial scientific expertise for implementation. CFSAN has been expected to implement such complex statutes as the Nutrition Labeling and Education Act of 1990, the Dietary Supplement Health and Education Act of 1994, the FDA Modernization Act of 1997, the Food Safety and Security Amendments of 2002, the Food Allergen Labeling and Consumer Protection Act of 2004, and the Sanitary Food Transportation Act of 2005, and most recently the Dietary Supplement Adverse Event Reporting Act of 2006 and the Food Safety Amendments of 2007 -- to name just the most important unfunded food statutes enacted during this period -- while facing a loss of 138 people.

This disintegration of the FDA food regulation function has continued unabated over the past quarter century. Sixteen years ago the Final Report of the Advisory Committee on the Food and Drug Administration to the Secretary of HHS (May 1991) identified the same problems (Appendix D, page 1):

There are deep concerns about the viability of the foods program and the lack of agency priority for food issues. Decline in resources and program initiatives during the past 10-15 years indicate a lack of agency management attention and interest in this area, although public interest in, and concern for, an effective food program remain high.

The status of CFSAN today is far worse than it was in 1991.

Dietary supplements receive far too little attention within CFSAN, because of the lack of adequate funding for scientific personnel. Following the enactment of the Dietary Supplement Health and Education Act of 1994, the dietary supplement industry has experienced a major increase in sales. From 1990 to 2005, the annual sales of dietary supplements increased from \$5 billion to over \$20 billion. Because the manufacturers of these products are authorized by law to petition FDA for approval of disease prevention claims, and

to make claims relating to the impact of their products on the structure or function of the human body without requesting FDA approval, it is essential that CFSAN employ physicians and scientists who can monitor these claims and recommend regulatory action where the claims are not justified. But during the time that these claims were becoming more prevalent and prominent following enactment of the Nutrition Labeling and Education Act of 1990 and the Dietary Supplement Health and Education Act of 1994, and the landmark First Amendment case of Pearson v. Shalala in 1999, Congress reduced the personnel responsible for reviewing and regulating these claims by 145 people. It is impossible for CFSAN to fulfill its statutory obligations under these conditions. The scientific personnel at CFSAN cannot "do more with less." They can only do less with less, and that is in fact what has happened.

Within CFSAN, the Office of Cosmetics has suffered even more than CFSAN itself. At one time, the cosmetic regulation function within CFSAN was funded adequately and had a robust regulatory program. These were the appropriations during 1972 - 1977 for the regulation of cosmetics:

Appropriations for Regulation of Cosmetics (\$ Millions)	
1972	\$1.308
1973	\$1.991
1974	\$2.425
1975	\$2.286
1976	\$2.581
1977	\$2.790

Approximately 60 FTE were engaged in the regulation of cosmetics at CFSAN during this period. By 1980, however, the appropriations were reduced to \$1.855 million and CFSAN had 39 personnel devoted to cosmetics. In 1997, this was reduced to 26 personnel. In 2007, there are only 14 staff employed at CFSAN to regulate cosmetics, supported by a minimal \$3.5 million in funding.

FDA has long stated that cosmetics are the safest products that the agency regulates. Nonetheless, there are important regulatory issues relating to cosmetics that deserve adequate attention by FDA. A total of 14 staff personnel is clearly insufficient for a credible regulatory program for cosmetics, an industry with more than \$60 billion in annual sales. Just to keep up with inflation since 1977, the appropriations for cosmetics must be at least \$10 million in 2007, instead of the \$3.5 it has received, and the personnel level must be restored accordingly

Deterioration of the FDA Field Force

The review and approval of product applications is not the only FDA function that requires scientific knowledge and training. FDA inspectors in the Field force -- in both domestic and foreign manufacturing establishments and at our ports of entry -- must daily make scientific evaluations of the FDA-regulated products that they encounter. In the past 35 years, however, the decrease in FDA funding for inspection of our food and drug supply has forced FDA to impose a major reduction in the number of inspections. For example, the following table documents the decline in Field inspections of food establishments:

FDA Inspection of Foreign and Domestic Food Establishments			
1973	34,919	1995	5,741
1975	22,471	2000	7,204
1980	29,355	2005	9,038
1985	12,850	2006	7,783
1990	7,077		

This represents a 78 percent reduction in food inspections, at a time when Table 6 documents that the food industry has been rapidly expanding. FDA conducted twice the number of foreign and domestic food establishment inspections in 1973 (34,919) than it did for all FDA-regulated products in 2006 (17,641). This is what happens when Congress fails to authorize sufficient personnel and appropriations for FDA adequately to implement the agency's core statutory mandates.

The reduction in FDA establishment inspections has hit hardest at food and cosmetics. The law requires that FDA inspect every drug and medical device establishment in the United States at least once every two years. Although FDA repeatedly violates this unfunded statutory mandate, the agency does inspect drug and medical device manufacturers more frequently than food and cosmetic manufacturers. FDA estimates that the Field inspects food manufacturers at most once every ten years and cosmetic manufacturers less frequently. The agency conducts no inspections of retail food establishments and only limited inspections of food-producing farms, except in emergencies.

As a result of its lack of resources, the agency has recently announced that it will rely more upon State food and drug inspectors to fill the void. Because of similar budget constraints at the State level, however, and the variable number of inspectors in the individual States, this policy will produce useful assistance only in a few large States and is not an adequate substitute for regular FDA inspections throughout the country. For that reason, FDA Field officials recently truthfully and accurately testified before Congress that the agency is failing to meet its statutory obligations and is doing a poor job in

implementing the current law. They are to be commended for their candor and honesty.

At the same time, importation of food into the United States has been exploding. During 1990-2005, imports of FDA-regulated products increased from 2 million to 15 million lines per year -- an extraordinary 650 percent increase -- the majority of which are food. We now import more than 15 percent of our food supply. To meet this crushing tide of food imports, along with inspections of the domestic food industry, Congress appropriated only a 13 percent increase in Field personnel. With inadequate resources to handle these burgeoning imports, FDA now conducts a brief visual review of less than one percent of imports and conducts an actual physical examination for less than a tenth of one percent.

Realizing that this was untenable, in 2002 FDA proposed a science-based plan to reinvent food import regulation through use of scientific risk assessment and risk management techniques. Because it was estimated to cost \$80 million, however, the proposal did not make it through the Federal budget process. The resulting crises in adulterated and misbranded imported food during the past year have been the direct result of that decision. The \$80 million price tag for a new science-based import program -- which will cost at least \$100 million today -- is dwarfed by the hundreds of millions of dollars lost as a result of the failure to implement this program.

In his recent Executive Order announcing an Interagency Working Group on Import Safety, President Bush stated that the current system must be fixed "within available resources." The truth is that the system cannot be fixed "within available resources," but this answer is not politically correct and thus undoubtedly will not make it through the political process. Unless we are willing as a country to appropriate at least \$100 million for the scientific personnel and analyses needed to devise and implement a new food import system, we will retain the antiquated version we have now and will continue to witness the crises that we have seen in the past year.

FDA needs to develop the same type of science-based inspection program for domestic establishment inspections that it developed (but was not allowed to implement) for import inspections. Implementation of an adequate domestic inspection program would, of course, cost substantially more than the projected cost of the import inspection program. Without such a science-based plan, and the means to implement it, the country will continue to experience increased food safety problems -- such as the episodes of pathogens in spinach, lettuce, tomatoes, and peanut butter, and botulism in canned food, during the past year.

Imports of legitimate products are not the only problem confronting FDA's Field staff. The import of counterfeit drugs -- as well as the manufacture of counterfeit drugs at domestic establishments posing as compounding pharmacies -- are overwhelming the Field inspection personnel. For example, Field inspectors had to trace the source of a million ineffective counterfeit diabetes test strips from the affected patients through 700 pharmacies, eight wholesalers, and two importers, to their ultimate source in China. A substantial increase in the FDA Field force is needed just to handle the growing number of counterfeit products.

Following the attacks on September 11, 2001, Congress appropriated increased funds and personnel for 2002, which allowed FDA to hire 673 new employees to improve its capacity to respond to the potential for terrorist threats and attacks regarding all FDA-regulated products. More than 60 percent of this supplemental appropriation was allocated to food. By 2006, however, all of this funding and personnel had disappeared from FDA appropriations. The number of Field personnel regularly performing inspections of imports fell from 531 in 2003 to 380 in 2006. There are 326 ports in the United States through which FDA-regulated products can enter the country. Obviously, FDA must deploy larger numbers of inspectors in the busiest of these ports, such as New York and San Francisco. Thus, there are many ports where FDA has no inspectors at all.

Because of its increasing responsibilities and its stagnant number of personnel, as well as a lack of travel funds, FDA cannot afford to send many inspectors abroad to investigate problems at their source. In 2000, FDA inspected 887 foreign establishments. By 2006, this was reduced to 738, a cut of 17 percent. Although approximately 80 percent of the active pharmaceutical ingredients used in our prescription drugs are imported from abroad, and foreign imports of drugs and active pharmaceutical ingredients were valued at more than \$42 billion in 2006, FDA conducted only 361 foreign drug and biological product establishments in 2006. Only 32 Field inspections were made in India and 15 in China, the two largest sources of pharmaceutical exports to the United States. Millions of shipments of FDA-regulated products are imported into the country each year from foreign facilities that have never been inspected by FDA and, with current appropriations, never will be.

Because of the reduced resources available to the FDA Field force, court enforcement actions have dwindled:

FDA Court Enforcement Cases			
	Seizure	Criminal	
		Injunction	Prosecution
1991	168	21	43
1992	183	31	52

FDA Court Enforcement Cases			
	Seizure	Criminal	
		Injunction	Prosecution
1993	117	23	26
2004	10	13	0
2005	20	15	0
2006	17	17	0
2007	6	12	0

Administrative compliance actions have suffered the same fate:

FDA Warning Letters	
1991	832
1992	1,712
1993	1,788
2004	725
2005	535
2006	538
2007	467

A weakened FDA inevitably leads to weak compliance with the law.

Conclusion

We must all recognize that FDA can increase its attention to high priority issues, or take on entirely new responsibilities, only in the following two ways. First, FDA can divert personnel from other priorities, thus leaving those other areas neglected. This is what happened with contaminated pet food, one of the many areas which have been neglected because of a lack of agency resources. Second, Congress can determine to provide adequate funding for all of the responsibilities that the country expects FDA to implement. But it is clear that, unless Congress adopts this second approach, FDA will of necessity be forced to follow the first.

Science is at the heart of everything that FDA does. Without a strong scientific foundation, the agency will founder and ultimately fail. The scientific resources needed by FDA to carry out its statutory mission cannot be sustained on a minimal budget. Congress must commit to doubling the current FDA funds, together with a 50 percent increase in authorized personnel, within the next two years. From then on, it is essential that the FDA budget at least keep up with inflation and perhaps even more. Another report should be prepared in five years to offer advice on the state of science at FDA at that time and the resource needs that remain.

Table 1 – Statutory History of FDA Regulatory Jurisdiction and Authority 1988–2007

The following compilation of 1988–2007 federal statutes includes only those for which the Food and Drug Administration (FDA) has been specifically delegated administrative responsibility by the Secretary of Health and Human Services and those that specifically direct the Commissioner of Food and Drugs or the agency to participate in federal action. It excludes those statutes that merely renumber the sections in the United States Code or rename the appropriate officials or agencies involved, as well as statutes of general applicability that apply to all federal agencies and are not specifically delegated to FDA. For omnibus statutes that cover more than one FDA-regulated product category (such as the FDA Modernization Act of 1997, the Bioterrorism Act of 2002, and the FDA Amendments Act of 2007), the major components are listed separately.

Year	Statute
1988	Orphan Drug Amendments of 1988 102 Stat. 90 (April 18, 1988)
	Prescription Drug Marketing Act of 1987 102 Stat. 95 (April 22, 1988)
	Pesticide Monitoring Improvements Act of 1988 102 Stat. 1411 (August 23, 1988)

Year	Statute
	Clinical Laboratory Improvement Amendments of 1988 102 Stat. 2903 (October 31, 1988)
	AIDS Amendments of 1988 102 Stat. 3062 (November 4, 1988)
	Food and Drug Administration Act of 1988 102 Stat. 3120 (November 4, 1988)
	Generic Animal Drug and Patent Term Restoration Act 102 Stat. 3971 (November 16, 1988)
	Veterinary Prescription Drug Amendment 102 Stat. 3983 (November 16, 1988)
	Anabolic Steroid and Human Growth Hormone Amendments 102 Stat. 4230 (November 18, 1988)
1989	
1990	National Nutrition Monitoring and Related Research Act of 1990 104 Stat. 1034 (October 22, 1990)
	Sanitary Food Transportation Act of 1990 101 Stat. 1213 (November 3, 1990)
	Congressional Access to FDA Trade Secret Information Amendment 104 Stat. 1388-210 (November 5, 1990)
	Nutrition Labeling and Education Act of 1990 104 Stat. 2353 (November 8, 1990)
	Good Samaritan Food Donation Act 104 Stat. 3183 (November 16, 1990)
	Amtrak Waste Disposal Act 104 Stat. 3185 (November 16, 1990)
	Agricultural Products National Laboratory Accreditation Standards Act 104 Stat. 3562 (November 28, 1990)
	Organic Foods Production Act of 1990 104 Stat. 3935 (November 28, 1990)
	Safe Medical Devices Act of 1990 104 Stat. 4511 (November 28, 1990)
	Combination Products Amendment 104 Stat. 4526 (November 28, 1990)
	Food and Drug Administration Revitalization Act 104 Stat. 4583 (November 28, 1990)
	FDA Freedom of Information Act Fee Retention Amendments 104 Stat. 4584 (November 28, 1990)
	Anabolic Steroids Control Act of 1990 104 Stat. 4851 (November 29, 1990)
	Human Growth Hormone Amendment 104 Stat. 4853 (November 29, 1990)
1991	Nutrition Labeling and Education Act Technical Amendments 105 Stat. 549 (August 17, 1991)
1992	American Technology Preeminence Act of 1991 106 Stat. 7 (February 14, 1992)
	Generic Drug Enforcement Act of 1992 106 Stat. 149 (May 13, 1992)

Year	Statute
	Medical Device Amendments of 1992 106 Stat. 238 (June 16, 1992)
	Methadone Maintenance Amendment 106 Stat. 412 (July 10, 1992)
	American Technology Preeminence Act Amendments 106 Stat. 847 (August 3, 1992)
	Prescription Drug Amendments of 1992 106 Stat. 941 (August 26, 1992)
	Mammography Quality Standards Act of 1992 106 Stat. 3547 (October 27, 1992)
	Prescription Drug User Fee Act of 1992 106 Stat. 4491 (October 29, 1992)
	Dietary Supplement Act of 1992 106 Stat. 4500 (October 29, 1992)
1993	FDA Employee Education Loan Repayment Amendments 107 Stat. 210 (June 10, 1993)
	Nutrition Labeling and Education Act Amendments of 1993 107 Stat. 773 (August 13, 1993)
1994	Nutrition Labeling and Education Act Amendment of 1994 108 Stat. 705 (May 26, 1994)
	Animal Medicinal Drug Use Clarification Act of 1994 108 Stat. 4153 (October 22, 1994)
	Maple Syrup Preemption Amendment 108 Stat. 4154 (October 22, 1994)
	Dietary Supplement Health and Education Act of 1994 108 Stat. 4325 (October 25, 1994)
1995	Edible Oil Regulatory Reform Act 109 Stat. 546 (November 20, 1995)
1996	National Technology Transfer and Advancement Act of 1995 110 Stat. 775 (March 7, 1996)
	Repeal of Saccharin Notice Requirement 110 Stat. 882 (April 1, 1996)
	Repeal of the Tea Importation Act of 1897 110 Stat. 1198 (April 9, 1996)
	FDA Export Reform and Enhancement Act of 1996 110 Stat. 1321-313 (April 26, 1996)
	Export of Partially Processed Biological Products Amendments of 1996 110 Stat. 1321-320 (April 26, 1996)
	Food Quality Protection Act of 1996 110 Stat. 1513 (August 3, 1996)
	Prescription Drug Medication Guide Amendment 110 Stat. 1593 (August 6, 1996)
	Saccharin Study and Labeling Act Extension Amendment of 1996 110 Stat. 1594 (August 6, 1996)
	Import for Export Amendment 110 Stat. 1594 (August 6, 1996)
	Bottled Drinking Water Standards Amendments 110 Stat. 1684 (August 6, 1996)

Year	Statute
	Health Insurance Portability and Accountability Act of 1996 110 Stat. 1936 (August 21, 1996)
	Good Samaritan Food Donation Act 110 Stat. 3011 (October 1, 1996)
	Repeal of Cardiac Pacemaker Registry Requirement 110 Stat. 3031 (October 2, 1996)
	Electronic Freedom of Information Act Amendments of 1996 110 Stat. 3048 (October 2, 1996)
	Comprehensive Methamphetamine Control Act of 1996 110 Stat. 3099 (October 3, 1996)
	Animal Drug Availability Act of 1996 110 Stat. 3151 (October 9, 1996)
	Drug-Induced Rape Prevention and Punishment Act of 1996 110 Stat. 3807 (October 13, 1996)
1997	Food and Drug Administration Modernization Act of 1997 111 Stat. 2296 (November 21, 1997)
	Prescription Drug User Fee Amendments of 1997 111 Stat. 2298 (November 21, 1997)
	Pediatric Drug Testing and Labeling Act of 1997 111 Stat. 2305 (November 21, 1997)
	The Prescription Drug Modernization Act of 1997 111 Stat. 2309 (November 21, 1997)
	The Biological Products Modernization Act of 1997 111 Stat. 2323 (November 21, 1997)
	The Medical Device Modernization Act of 1997 111 Stat. 2332 (November 21, 1997)
	The Food Modernization Act of 1997 111 Stat. 2350 (November 21, 1997)
	The General Provisions Modernization Act of 1997 111 Stat. 2356 (November 21, 1997)
1998	Food Safety Research and National Conference Amendments 112 Stat. 606 (June 23, 1998)
	Biomaterials Access Assurance Act of 1998 112 Stat. 1519 (August 13, 1998)
	Mammography Quality Standards Reauthorization Act of 1998 112 Stat. 1864 (October 9, 1998)
	Animal Drug Combination Ingredient Amendment 112 Stat. 2681-30 (October 21, 1998)
	Methamphetamine Trafficking Penalty Enhancement Act of 1998 112 Stat. 2681-759 (October 21, 1998)
	Antimicrobial Regulation Technical Corrections Act of 1998 112 Stat. 3035 (October 30, 1998)
	Repeal of Annual Report on Radiation Control for Health and Safety Program 112 Stat. 3285 (November 10, 1998)
1999	Healthcare Research and Quality Act of 1999 113 Stat. 1653 (December 6, 1999)

Year	Statute
2000	Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000 114 Stat. 7 (February 18, 2000) Autoimmune Diseases Amendments 114 Stat. 1153 (October 17, 2000) Research in Children Amendment 114 Stat. 1167 (October 17, 2000) Drug Addiction Treatment Act of 2000 114 Stat. 1222 (October 17, 2000) Methamphetamine Production, Trafficking, and Abuse Act of 2000 114 Stat. 1228 (October 17, 2000) Rapid HIV Tests Amendment 114 Stat. 1354 (October 20, 2000) Medicine Equity and Drug Safety Act of 2000 114 Stat. 1549A-35 (October 28, 2000) Prescription Drug Import Fairness Act of 2000 114 Stat. 1549A-40 (October 28, 2000) Needlestick Safety and Prevention Act 114 Stat. 1901 (November 6, 2000) Human Papillomavirus Education Amendments 114 Stat. 2763A-72 (December 21, 2000) Condom Labeling Amendment 114 Stat. 2763A-73 (December 21, 2000) Repeal of Saccharin Study and Labeling Act 114 Stat. 2763A-73 (December 21, 2000)
2001	Animal Disease Risk Assessment, Prevention, and Control Act of 2001 115 Stat. 11 (May 24, 2001)
2002	Best Pharmaceuticals for Children Act 115 Stat. 1408 (January 4, 2002) Toll Free Number in Drug Labeling Amendment 115 Stat. 1422 (January 4, 2002) Catfish and Ginseng Labeling Amendments 116 Stat. 526 (May 13, 2002) Food Pasteurization Amendment 116 Stat. 530 (May 13, 2002) Food Irradiation Labeling Amendment 116 Stat. 531 (May 13, 2002) Accelerated Approval of Priority Bioterrorism Countermeasures Amendment 116 Stat. 613 (June 12, 2002) Food Safety and Security Amendments 116 Stat. 662 (June 12, 2002) Drug Safety and Security Amendments 116 Stat. 675 (June 12, 2002) Prescription Drug User Fee Amendments of 2002 116 Stat. 687 (June 12, 2002) Drug Postmarketing Studies Amendments 116 Stat. 693 (June 12, 2002)

Year	Statute
	Medical Device User Fee and Modernization Act of 2002 116 Stat. 1588 (October 26, 2002)
	Rare Diseases Orphan Product Development Act of 2002 116 Stat. 1992 (November 6, 2002)
2003	United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 117 Stat. 711 (May 27, 2003)
	Blood Safety Report Amendments 117 Stat. 902 (August 15, 2003)
	Animal Drug User Fee Act of 2003 117 Stat. 1361 (November 18, 2003)
	Defense Biomedical Countermeasures Amendments 117 Stat. 1680 (November 24, 2003)
	Emergency Use of Medical Products Amendments 117 Stat. 1690 (November 24, 2003)
	Pediatric Research Equity Act of 2003 117 Stat. 1936 (December 3, 2003)
	Abbreviated New Drug Application Amendments 117 Stat. 2448 (December 8, 2003)
	Importation of Prescription Drugs Amendment 117 Stat. 2464 (December 8, 2003)
	Report on Importation of Drugs Amendment 117 Stat. 2469 (December 9, 2003)
2004	Medical Devices Technical Corrections Act 118 Stat. 572 (April 1, 2004)
	Project BioShield Act of 2004 118 Stat. 835 (July 21, 2004)
	Minor Use and Minor Species Animal Health Act of 2004 118 Stat. 891 (August 2, 2004)
	Food Allergen Labeling and Consumer Protection Act of 2004 118 Stat. 905 (August 2, 2004)
	Anabolic Steroid Control Act of 2004 118 Stat. 1661 (October 22, 2004)
	Mammography Quality Standards Reauthorization Act of 2004 118 Stat. 1738 (October 25, 2004)
2005	Patient Safety and Quality Improvement Act of 2005 119 Stat. 424 (July 29, 2005)
	Medical Device User Fee Stabilization Act of 2005 119 Stat. 439 (August 1, 2005)
	Methadone Treatment Amendments 119 Stat. 591 (August 2, 2005)
	Sanitary Food Transportation Act of 2005 119 Stat. 1911 (August 10, 2005)
	Contact Lens Amendment 119 Stat. 2119 (November 9, 2005)
	Stem Cell Therapeutic and Research Act of 2005 119 Stat. 2550 (December 20, 2005)

Year	Statute
	Public Readiness and Emergency Preparedness Act 119 Stat. 2818 (December 30, 2005)
2006	Combat Methamphetamine Epidemic Act of 2005 120 Stat. 256 (March 9, 2006)
	Biomedical Advanced Research and Development Act 120 Stat. 2865 (December 19, 2006)
	Dietary Supplement and Nonprescription Drug Consumer Protection Act 120 Stat. 3469 (December 22, 2006)
	Pandemic and All-Hazards Preparedness Act 120 Stat. 2831 (December 19, 2006)
2007	Food and Drug Administration Amendments Act of 2007 121 Stat. 823 (September 27, 2007)
	Prescription Drug User Fee Amendments of 2007 121 Stat. 825 (September 27, 2007)
	Medical Device User Fee Amendments of 2007 121 Stat. 842 (September 27, 2007)
	Medical Device Amendments of 2007 121 Stat. 852 (September 27, 2007)
	Pediatric Medical Device Safety and Improvement Act of 2007 121 Stat. 859 (September 27, 2007)
	Pediatric Research Equity Act of 2007 121 Stat. 866 (September 27, 2007)
	Best Pharmaceuticals for Children Act of 2007 121 Stat. 876 (September 27, 2007)
	Reagan-Udall Foundation for the Food and Drug Administration Act of 2007 121 Stat. 890 (September 27, 2007)
	Conflicts of Interest Amendments of 2007 121 Stat. 900 (September 27, 2007)
	Clinical Trial Databases Amendments of 2007 121 Stat. 904 (September 27, 2007)
	Postmarket Safety of Drugs Amendments of 2007 121 Stat. 922 (September 27, 2007)
	Food Safety Amendments of 2007 121 Stat. 962 (September 27, 2007)
	Food and Drug Administration Miscellaneous Amendments of 2007 121 Stat. 971 (September 27, 2007)

Table 2 – Representative Statutes of General Applicability that Have a Direct Major Impact on FDA 1935–2006

The following statutes do not specifically name FDA and have not specifically been delegated to FDA for implementation, but they have a substantial impact on the Agency.

Year	Statute
1935	Federal Register Act 49 Stat. 500 (July 26, 1935)
1946	Administrative Procedure Act 60 Stat. 237 (June 11, 1946)
1958	Small Business Act 72 Stat. 384 (July 18, 1958)
1966	Animal Welfare Act 80 Stat. 350 (August 24, 1966)
1967	Freedom of Information Act 81 Stat. 54 (June 5, 1967)
1970	National Environmental Policy Act of 1969 83 Stat. 852 (January 1, 1970)
1972	Federal Advisory Committee Act 86 Stat. 770 (October 6, 1972)
1974	Freedom of Information Act Amendments of 1974 88 Stat. 1561 (November 21, 1974)
	Privacy Act of 1974 88 Stat. 1896 (August 21, 1974)
1976	Government in the Sunshine Act 90 Stat. 1241 (September 13, 1976)
	Freedom of Information Act Amendments of 1976 90 Stat. 1247 (September 13, 1976)
1978	Carcinogen Testing and Listing Amendments 92 Stat. 3434 (November 9, 1978)
1980	Regulatory Flexibility Act 94 Stat. 1164 (September 19, 1980)
	Stevenson-Wydler Technology Innovation Act of 1980 94 Stat. 2311 (October 21, 1980)
	Paperwork Reduction Act of 1980 94 Stat. 2812 (December 11, 1980)
	Bayh-Dole Act 94 Stat. 3019 (December 12, 1980)
1981	Equal Access to Justice Act 95 Stat. 598 (August 13, 1981)
1982	Federal Managers Financial Integrity Act of 1982 96 Stat. 814 (September 8, 1982)
1984	Competition in Contracting Act of 1984 98 Stat. 1175 (July 19, 1984)

Year	Statute
1986	Federal Technology Transfer Act of 1986 100 Stat. 1785 (October 20, 1986)
	Freedom of Information Reform Act of 1986 100 Stat. 3207-48 (October 27, 1986)
1990	Chief Financial Officers Act of 1990 104 Stat. 2838 (November 15, 1990)
	Negotiated Rulemaking Act of 1990 104 Stat. 4969 (November 29, 1990)
1993	Government Performance and Results Act of 1993 107 Stat. 285 (August 3, 1993)
1995	Unfunded Mandates Reform Act of 1995 109 Stat. 49 (March 22, 1995)
	Paperwork Reduction Act of 1995 109 Stat. 163 (May 22, 1995)
	Federal Reports Elimination and Sunset Act of 1995 109 Stat. 707 (December 21, 1995)
1996	Information Technology Management Reform Act of 1996 110 Stat. 679 (February 10, 1996)
	Health Insurance Portability and Accountability Act of 1996 110 Stat. 1936 (August 21, 1996)
	Economic Espionage Act of 1996 110 Stat. 3488 (October 11, 1996)
	National Information Infrastructure Protection Act of 1996 110 Stat. 3491 (October 11, 1996)
1998	Government Paperwork Elimination Act 112 Stat. 2681-749 (October 21, 1998)
	Federal Reports Elimination Act of 1998 112 Stat. 3280 (November 10, 1998)
1999	Federal Financial Assistance Management Improvement Act of 1999 113 Stat. 1486 (November 20, 1999)
2000	Truth in Regulating Act of 2000 114 Stat. 1248 (October 17, 2000)
	Technology Transfer Commercialization Act of 2000 114 Stat. 1742 (November 1, 2000)
	Data Quality Act 114 Stat. 2763A-153 (December 21, 2000)
2002	Customs Border Security Act of 2002 116 Stat. 972 (August 6, 2002)
	E-Government Act of 2002 116 Stat. 2899 (December 17, 2002)

Table 3 – Representative Executive Orders of General Applicability that Have a Direct Major Impact on FDA 1969–2007

The following Executive Orders do not name FDA and have not specifically been delegated to FDA for implementation, but they have a very large impact on the Agency.

President	Executive Order
Nixon	Executive Order No. 11490 (Assigning Emergency Preparedness Functions to Federal Departments and Agencies) 34 Fed. Reg. 17567 (October 30, 1969)
Ford	Executive Order No. 11821 (Inflation Impact Statements) 39 Fed. Reg. 41501 (November 29, 1974)
	Executive Order No. 11921 (Emergency Preparedness Functions) 41 Fed. Reg. 24294 (June 15, 1976)
Carter	Executive Order No. 12044 (Improving Government Regulations) 43 Fed. Reg. 12661 (March 24, 1978)
	Executive Order No. 12174 (Paperwork) 44 Fed. Reg. 69609 (December 4, 1979)
Reagan	Executive Order No. 12291 (Federal Regulation) 46 Fed. Reg. 13193 (February 19, 1981)
	Executive Order No. 12372 (Intergovernmental Review of Federal Programs) 47 Fed. Reg. 30959 (July 16, 1982)
	Executive Order No. 12498 (Regulatory Planning Process) 50 Fed. Reg. 1036 (January 8, 1985)
	Executive Order No. 12512 (Federal Real Property Management) 50 Fed. Reg. 18453 (May 1, 1985)
	Executive Order No. 12600 (Predisclosure Notification Procedures for Confidential Commercial Information) 52 Fed. Reg. 23781 (June 25, 1987)
	Executive Order No. 12612 (Federalism) 52 Fed. Reg. 41635 (October 26, 1987)
George H.W. Bush	Executive Order No. 12689 (Debarment and Suspension) 54 Fed. Reg. 34131 (August 18, 1989)
	Executive Order No. 12770 (Metric Usage in Federal Government Programs) 56 Fed. Reg. 35801 (July 29, 1991)
Clinton	Executive Order No. 12861 (Elimination of One-Half of Executive Branch Internal Regulations) 58 Fed. Reg. 48255 (September 14, 1993)
	Executive Order No. 12862 (Setting Customer Service Standards) 58 Fed. Reg. 48257 (September 14, 1993)
	Executive Order No. 12866 (Regulatory Planning and Review) 58 Fed. Reg. 51735 (October 4, 1993)
	Executive Order No. 12875 (Enhancing the Intergovernmental Partnership)

President	Executive Order
	58 Fed. Reg. 58093 (October 28, 1993)
	Executive Order No. 12988 (Civil Justice Reform) 61 Fed. Reg. 4729 (February 7, 1996)
	Executive Order No. 13011 (Federal Information Technology) 61 Fed. Reg. 37657 (July 19, 1996)
	Executive Order No. 13083 (Federalism) 63 Fed. Reg. 27651 (May 19, 1998)
	Executive Order No. 13100 (President's Council on Food Safety) 63 Fed. Reg. 45661 (August 25, 1998)
	Executive Order No. 13132 (Federalism) 64 Fed. Reg. 43255 (August 10, 1999)
George W. Bush	Executive Order No. 13327 (Federal Real Property Asset Management) 69 Fed. Reg. 5897 (February 6, 2004)
	Executive Order No. 13422 (Further Amendment to Executive Order 12866 on Regulatory Planning and Review) 72 Fed. Reg. 2763 (January 23, 2007)
	Executive Order No. 13439 (Establishing an InterAgency Working Group on Import Safety) 72 Fed. Reg. 40053 (July 20, 2007)

**Table 4 – FDA Appropriations and User Fees Part I
FY 1988–FY 2007 (\$ Millions)**

Fiscal Year	Human Drugs		Biologics		Medical Devices		Animal Food & Drugs	
	Center	Field	Center	Field	Center	Field	Center	Field
1988								
\$ Approp.	89.020	28.110	43.160	8.220	52.440	22.470	17.780	7.630
FTE Approp.	1,359	583	467	117	884	398	287	154
1989								
\$ Approp.	99.720	31.495	51.020	9.450	54.920	23.540	17.116	7.336
FTE Approp.	1,339	574	539	135	871	392	269	145
1990								
\$ Approp.	111.350	35.17	61.520	11.720	62.560	26.810	21.470	9.200
FTE Approp.	1,418	608	620	155	919	413	285	153
1991								
\$ Approp.	134.070	42.330	69.790	13.300	73.340	31.440	24.680	10.580
FTE Approp.	1,584	679	659	165	1,023	459	314	169
1992								
\$ Approp.	150.890	47.650	76.050	14.480	81.710	35.020	27.300	11.700
FTE Approp.	1,572	674	718	180	1,107	497	329	177
1993								
\$ Approp.	154.052	48.645	82.560	15.721	91.608	37.417	26.612	11.405
FTE Approp.	1,714*	735*	735	194	1,161	522	315	170
\$ User Fees	6.800*	2.150*	N.A	N.A	N.A	N.A	--	--
FTE User Fees	N.A.	N.A	N.A	N.A	N.A	N.A	--	--
\$Total	160.852	50.795	82.560	15.721	91.608	37.417	26.612	11.405
FTE Total	1,714	735	775	194	1,161	522	315	170

"N.A." (Not Available) means that there is a number for this category but FDA is unable to provide it.

"--" means that there is no number for this category.

"**" means that this number for the category of Human Drugs includes funds or personnel obtained by user fees that were shared with the Center for Biologics Evaluation and Research, the Field, and other parts of FDA but FDA is unable to provide a further breakdown into these categories.

For 1988-1996, the breakdown between the Center and the Field is based on extrapolation from historical data.

1994								
\$ Approp.	150.490	47.522	107.180	20.411	111.551	47.808	28.223	12.095
FTE Approp.	1,743	747	882	221	1,169	630	322	173
\$ User Fees	30,360*	9.591*	N.A	N.A	N.A	N.A	--	--
FTE User Fees	N.A	N.A	N.A	N.A	N.A	N.A	--	--
\$Total	180.850	57.113	107.180	20.411	111.551	47.808	28.223	12.095
FTE Total	1,743	747	882	221	1,169	630	322	173

Fiscal Year	Human Drugs		Biologics		Medical Devices		Animal Food & Drugs	
	Center	Field	Center	Field	Center	Field	Center	Field
1995								
\$ Approp.	109.350	34.526	87.450	16.663	111.485	45.536	29.178	12,506
FTE Approp.	1,277	548	763	191	1,263	568	304	164
\$ User Fees	56.290*	17.774*	N.A	N.A	N.A	N.A	--	--
FTE User Fees	317*	136*	N.A	N.A	N.A	N.A	--	--
\$Total	165.640	52.300	87.450	16.663	111.485	45.536	29.178	12,506
FTE Total	1,594	684	763	191	1,263	568	304	164
1996								
\$ Approp.	153.540	48.484	73.340	13.975	100.600	35.945	25.810	11.061
FTE Approp.	1,476	632	643	161	1,106	497	262	141
\$ User Fees	38.660	12.203	25.190	4.801	5.990	5.733	--	--
FTE User Fees	246	105	165	41	30	13	--	--
\$Total	192.200	60.687	98.530	18.776	106.590	45.684	25.810	11.061
FTE Total	1,722	737	808	202	1,136	510	262	141
1997								
\$ Approp.	139.201	61.878	78.858	17.398	103.207	44.165	25.588	10.628
FTE Approp.	1,287	782	640	221	1,058	561	247	135
\$ User Fees	48.764	4.572	25.986	398	4.598	7.851	--	--
FTE User Fees	386	60	204	5	32	16	--	--
\$Total	187.965	66.450	104.844	17.496	107.805	52.016	25.588	10.628
FTE Total	1,673	842	844	226	1,090	577	247	135
1998								
\$ Approp.	139.201	57.378	78.35	17.744	104.311	39.175	29.375	12.598
FTE Approp.	1,241	784	644	231	1,030	493	264	164
\$ User Fees	56.499	5.924	26.095	511	8.653	5.158	--	--
FTE User Fees	404	69	187	5	32	19	--	--
\$Total	198.649	63.999	104.668	18.344	107.202	48.503	29.375	12.598
FTE Total	645	853	831	236	1,062	512	264	164
1999								
\$ Approp.	139.685	60,738	77.822	17.201	105.553	40.237	30.668	12.585
FTE Approp.	1,130	716	592	199	966	466	254	139
\$ User Fees	71.767	6,109	29.031	.311	4.957	8.261	--	--
FTE User Fees	551	59	195	3	32	16	--	--
\$Total	211.452	66.847	106.853	17.512	110.510	48.498	30.668	12.585
FTE Total	1,681	775	787	202	998	482	254	139
2000								
\$ Approp.	152.194	63.344	87.451	18.592	116.015	41.644	36.471	13.122
FTE Approp.	1,168	670	576	204	988	438	271	135
\$ User Fees	88.187	7.509	33.750	834	4.478	8.123	--	--
FTE User Fees	604	67	204	7	30	16	--	--
\$Total	240.381	70.853	121.291	19.426	120.493	49.764	36.471	13.122
FTE Total	1,772	737	780	211	1,018	454	271	135

Fiscal Year	Human Drugs		Biologics		Medical Devices		Animal Food & Drugs	
	Center	Field	Center	Field	Center	Field	Center	Field
2001								
\$ Approp.	151.468	67.047	86.215	22.088	121.972	43.334	48.440	15.630
FTE Approp.	1,140	684	561	225	986	442	290	152
\$ User Fees	96.995	6.970	36.217	2.710	3.900	8.359	--	--
FTE User Fees	644	67	248	7	30	15	--	--
\$Total	248.463	74.017	122.432	24.798	125.872	51.693	48.440	15.630
FTE Total	1,784	751	809	232	1,016	457	290	152
2002								
\$ Approp.	178.017	76.683	111.054	27.551	131.466	48.496	55.727	29.916
FTE Approp.	1,122	695	657	237	965	442	323	247
\$ User Fees	104.093	5.551	38.287	878	4.919	8.776	--	--
FTE User Fees	658	42	246	7	32	15	--	--
\$Total	282.110	82.234	149.311	28.531	136.385	57.272	55.727	29.916
FTE Total	1,780	737	894	242	997	457	323	247
2003								
\$ Approp.	188.837	85.236	117.391	27,927	140.429	52.921	57.115	30.544
FTE Approp.	1,159	761	701	246	968	464	341	255
\$ User Fees	125.103	4.672	47.116	1.002	14.692	9.243	--	--
FTE User Fees	742	34	274	8	35	18	--	--
\$Total	313.940	89.908	164.507	28.929	155.121	62.164	57.115	30.544
FTE Total	1,901	795	975	254	1,003	482	341	255
2004								
\$ Approp.	210.828	81.290	96.265	26.089	141.059	50.085	54.430	28.928
FTE Approp.	1,218	725	559	233	971	441	346	246
\$ User Fees	162.653	4.821	43.607	1.055	2.879	9.483	1.083	--
FTE User Fees	972	34	247	8	90	13	3	--
\$Total	373.481	86.111	139.872	27.144	161.938	59.568	55.513	28.928
FTE Total	2,190	759	797	241	1,061	454	349	246
2005								
\$ Approp.	210.481	85.003	96,595	26,514	163.292	51.670	55.360	35.124
FTE Approp.	1,171	666	553	215	970	397	330	241
\$ User Fees	185.555	5.095	46.435	1,140	19.865	9.945	7.538	--
FTE User Fees	1,049	32	265	8	134	15	39	--
\$Total	396.036	86.098	143.030	27.654	183.157	61.125	62.898	35.124
FTE Total	2,220	698	818	223	1,104	412	369	241
2006								
\$ Approp.	217.792	79.919	111.443	27.075	165.207	55.356	53.824	34.756
FTE Approp.	1,176	665	533	197	929	399	321	217
\$ User Fees	205.279	5.911	57.466	6.725	24.622	9.856	9.264	--
FTE User Fees	1,100	36	239	10	156	14	54	--
\$Total	423.071	85.834	168.909	28.800	189.829	65.212	63.088	34.756
FTE Total	2,276	701	772	207	1,085	413	375	217

Fiscal Year	Human Drugs		Biologics		Medical Devices		Animal Food & Drugs	
	Center	Field	Center	Field	Center	Field	Center	Field
2007								
\$ Approp.	230.757	84.381	116.005	28.542	172.258	58.425	58.355	36.394
FTE Approp.	1,186	604	592	190	935	386	324	209
\$ User Fees	248.350	6.888	62.069	3.669	29.503	12.734	9.537	--
FTE User Fees	1,134	37	251	11	163	15	54	--
\$Total	479.107	91.269	178.074	32.211	201.761	71.159	67.892	36.394
FTE Total	2,320	641	843	201	1,098	401	378	209

Table 5 – FDA Appropriations Part II FY 1988–FY 2007 (\$Millions)

Fiscal Year	Food		Cosmetics		NCTR	Total FDA Budget Authority
	Center	Field	Center	Field		
1988						
\$ Approp.	53.090	73.310	N.A.	N.A.	24.291	477.504
FTE Approp.	708	1,438	N.A.	N.A.	241	7,039
1989						
\$ Approp.	59.310	81.902	N.A.	N.A.	25.545	542.343
FTE Approp.	792	1,585	N.A.	N.A.	239	7,228
1990						
\$ Approp.	67.652	93.430	N.A.	N.A.	27.269	600.979
FTE Approp.	841	1,669	N.A.	N.A.	235	7,629
1991						
\$ Approp.	77.239	106.660	N.A.	N.A.	31.407	688.392
FTE Approp.	897	1,786	N.A.	N.A.	230	8,267
1992						
\$ Approp.	88.421	117.883	N.A.	N.A.	31.097	761.830
FTE Approp.	950	1,782	N.A.	N.A.	239	8,792
1993						
\$ Approp.	85.970	118.720	N.A.	N.A.	32.986	805.818
FTE Approp.	913	1,782	N.A.	N.A.	257	8,939
1994						
\$ Approp.	89.466	123.548	N.A.	N.A.	34.989	875.968
FTE Approp.	910	1,765	N.A.	N.A.	249	9,167
1995						
\$ Approp.	90.887	125.511	N.A.	N.A.	38.349	869.230
FTE Approp.	871	1,719	39	N.A.	247	8,811

Fiscal Year	Food		Cosmetics		NCTR	Total FDA Budget Authority
	Center	Field	Center	Field		
1996						
\$ Approp.	84.395	116.546	N.A.	N.A.	30.774	889.527
FTE Approp.	809	1,539	N.A.	N.A.	232	8,459

"NA" (Not Available) means that there is a number for this category but FDA is unable to provide it.

1997						
\$ Approp.	78.133	113.050	N.A.	N.A.	31.929	880.743
FTE Approp.	790	1,436	26	8	223	8,354
1998						
\$ Approp.	87.758	118.491	N.A.	N.A.	32.189	931.883
FTE Approp.	784	1,455	N.A.	N.A.	218	8,083
1999						
\$ Approp.	99.891	135.277	N.A.	N.A.	32.109	985.279
FTE Approp.	784	1,555	N.A.	N.A.	223	7,851
2000						
\$ Approp.	124.589	155.115	N.A.	N.A.	36.522	1,048.149
FTE Approp.	830	1,556	N.A.	N.A.	217	7,728
2001						
\$ Approp.	125.888	161.616	N.A.	N.A.	36.248	1,009.311
FTE Approp.	879	1,556	N.A.	N.A.	206	7,805
2002						
\$ Approp.	143.178	250.078	N.A.	N.A.	39.259	1,354.366
FTE Approp.	924	1,810	30	11	221	8,311
2003						
\$ Approp.	147.304	259.520	N.A.	N.A.	40.403	1,398.350
FTE Approp.	950	2,217	29	14	226	8,940
2004						
\$ Approp.	144.366	262.686	N.A.	N.A.	39.652	1,401.214
FTE Approp.	910	2,172	29	15	207	8,567
2005						
\$ Approp.	152.260	283.257			40.206	1,452.274
FTE Approp.	884	2,059	28	14	187	8,181
2006						
\$ Approp.	153.470	285.251	N.A.	N.A.	40.739	1,493.580
FTE Approp.	812	1,962	27	11	190	7,893
2007						
\$ Approp.	159.114	297.991	N.A.	N.A.	42.056	1,574.155
FTE Approp.	812	1,896	14	13	190	7,856

Table 6 – Regulated Industry Sales Statistics FY 1988–FY 2007

Fiscal Year	FDA Appropriations (\$ Millions)	Sales (\$ Billions)						Total FDA Products
		Human Food	Rx & OTC Drugs	Biological Products	Cosmetics	Animal Feed & Drugs	Medical Devices	
1988	477.504	563.520	40.848	N.A.	31.800	20.060	29.009	685.237
1989	542.343	600.375	45.055	N.A.	33.900	29.938	31.160	740.428
1990	600.979	649.094	50.683	N.A.	36.000	29.356	33.675	798.808
1991	688.392	677.414	54.870	N.A.	36.900	28.657	35.061	832.902
1992	761.830	682.912	58.159	N.A.	37.900	33.283	35.829	848.083
1993	805.818	710.825	61.675	N.A.	40.300	27.086	37.426	877.312
1994	875.968	742.565	65.086	N.A.	43.200	36.687	38.911	926.449
1995	869.230	766.761	71.760	7.707	45.900	32.090	40.948	957.459
1996	889.527	797.517	79.520	8.743	48.900	44.933	43.406	1,014.278
1997	880.743	838.927	88.753	10.049	51.600	41.255	45.767	1,066.302
1998	931.883	876.419	99.785	12.905	52.500	35.724	46.948	1,111.476
1999	985.279	924.534	115.978	17.136	53.900	36.192	48.755	1,179.359
2000	1,048.149	968.639	132.202	21.130	55.000	35.406	49.496	1,240.743
2001	1,009.311	1,011.876	150.064	26.627	54.400	35.708	49.944	1,302.992
2002	1,354.366	1,050.742	169.552	32.658	54.400	39.334	51.609	1,365.638
2003	1,398.350	1,098.961	186.899	39.239	56.000	44.038	54.733	1,440.631
2004	1,401.214	1,157.534	201.532	46.390	58.200	44.484	55.889	1,517.639
2005	1,452.274	1,230.793	212.520	54.846	61.700	43.177	58.072	1,606.262
2006	1,493.580	N.A.	N.A.	64.009	N.A.	38.303	N.A.	N.A.
2007	1,574.155	--	--	--	--	--	--	--

