FDA's FY 2000 Budget Request
(to close performance gaps)

- Adverse Event/Injury Reporting -- $60M
  (Lower the enormous cost in dollars and lives)

  - reduce injuries and healthcare costs by 15%

- Product Safety Assurance -- $126M

  - meet 95% of statutory inspection obligation; reduce rising industry recall rates

- Product Review -- $56M
  (Speed products to consumers; enhance industry competitiveness)
  - review 90% of product applications in statutory time frame

- Food Safety -- $49M

  - achieve a 50% reduction in food borne illness

① Size = 800 / Quilcenter

② Payments – on Phone

③ Hours;

FOOD AND DRUG ADMINISTRATION
OFFICE OF THE COMMISSIONER
200 C STREET, S.W., ROOM 6823
WASHINGTON, D.C. 20204

FDA. Wright

FACSIMILE TRANSMISSION RECORD

3 NUMBER OF PAGES (including coversheet)

TO: Tom Friedman

Facsimile Telephone No. 456-7431 Voice Telephone No.

FROM: Bill Schultz / Bill Hubbard - FDA

Facsimile Telephone No. (202) 205-4741 Voice Telephone No. (202) 205-4102

DATE: 12/4/98

MESSAGE: Per Discussion

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FDA'S YEAR 2000 FOOD SAFETY GOALS
(If funds are appropriated)

INSPECTIONS

- Establish a nationally integrated food safety system with Federal, state, and local authorities.
  - For the first time in decades, FDA will ensure that every high risk food manufacturer in the United States is inspected at least once a year.
  - For other food firms, inspections will be twice as often as today (from once every 8 years to once every 4 years).
  - For the first time ever, state and Federal inspection results will be shared, via an electronic connection, that will reduce overlapping efforts and greatly enhance the ability of those authorities to improve public health
- FDA will have an enhanced international food safety program, which will include evaluations of other countries' food safety systems and provision of technical assistance to foreign countries who import to this country (thereby continuing the shift to ensuring that foods are safely produced before they arrive at our shores).

RESEARCH

- FDA will be able to ensure the applicability and effectiveness of the new preventive control techniques used to ensure the safety of seafood, juices, eggs, fresh produce and other foods.
- New detection tests will be developed for such dangerous contaminants as Salmonella in eggs and Cyclosopora in fresh produce, and test methods for E. coli 0157:H7 in foods in which it cannot now be detected.

OUTBREAK RESPONSE

- With its increased surveillance, CDC expects an increase of 40% of foodborne illness from E. coli 0157:H7 and salmonella, and 10% for all foodborne illness. Funding is needed so that FDA will have the laboratory and staff capability to respond rapidly to those outbreaks when they occur--to track down their source and prevent further danger.
- CDC's new PulseNet contaminant tracing system will be connected to FDA's laboratories, thus enabling FDA to use this state-of-the-art disease detection system to control foodborne illness at the source.

RETAIL

- CDC estimates that one-third of foodborne illness comes from retail establishments. A majority of states will adopt FDA's model food code that raises the standards for safer handling of food in restaurants, nursing homes, hospitals, and grocery stores. If funding is available, FDA can provide the necessary training and education to state and local inspectors (as well as industry) to implement those new standards.

EDUCATION

- Targeted resources are needed so that the most vulnerable (e.g., elderly, very young, and pregnant women) will be taught how they should and can avoid contaminated food. The result will be that their behavior will begin to change so that the most severe illnesses and deaths can be prevented.

RISK ASSESSMENT

- New information will become available about how much of a contaminant must be in a food to make people sick (such as Listeria) and how certain contaminants (such as Salmonella) can best be controlled.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DETERMINED TO BE AN ADMINISTRATIVE MARKING
INITIALS: Pue DATE: 06/26/15

~~CONFIDENTIAL~~

Memorandum

CLOSE-HOLD

Date: November 27, 1998

TO: Assistant Secretary for Management and Budget

FROM: Acting Commissioner of Food and Drugs

SUBJECT: Appeals to FY2000 OMB Passback

We are encouraged by the increases noted in the FY2000 Passback, and want to express our appreciation for the efforts made on behalf of FDA by you, your staff, and other senior DHHS officials. I recognize the time you and others have taken to understand FDA's broad resource needs, and it appears that effort will now bear fruit. In addition, we appreciate the recognition in the Passback that FDA needs resources in all of its programs, and not only in targeted initiatives. At the same time, we are submitting several appeals, in the hope that additional funding can be provided to reduce the substantial gap between what we are able to do, and what Congress and the public expect us to do.

Our appeals, in priority order, include:

Restoration of Current Services costs	$ 33.4	Million
Product Safety Assurance programs	83.0	
(Including completion of Los Angeles and Arkansas laboratories)		
Premarket Review programs	36.1	
Food Safety Initiative	48.9	
Tobacco	50.0	
Bioterrorism	13.0	
	$ 264.4	Million

In addition, we are seeking to modify the user fee proposals--not the dollar amount--and offer models somewhat different from those that OMB proposed, but in the same program areas of Medical Devices and Food Additive Review. We greatly appreciate OMB's recognition that deficit-reduction user fees should not be included in our budget request, and we support new user fees that can enhance FDA's performance. In the case of food additives, we are suggesting a proposal that would collect $6 million in user fees to fully establish the new system of premarket notifications for food contact substances, as authorized by the Food and Drug Administration Modernization Act. In addition, we would propose user fees of up to $11 million to improve our existing program for our review of food additives. While these projected fees are substantially larger than the $2 million suggested by OMB, we believe these programs would provide a significant service to industry, and that therefore the industry would support such legislation. While we are requesting appropriated resources for our review of new medical devices, we are

proposing a potential third party program that would provide industry with the safety certifications they need to market in other countries. Although the medical device industry, particularly the number of smaller device companies, has been strongly opposed to user fees for new product review, we believe the industry would support this new effort to facilitate the U.S. device industry to compete in international markets.

I believe the request for current services funding is particularly important, in view of the compounded effect of FDA's absorbing the cost of pay raises and inflation for six consecutive years -- a $165 million shortfall. Erosion of our budget to pay these costs has led directly to reductions of at least 500 FTE, jeopardizing FDA's ability to respond to new technologies and emerging problems, much less fully implement the expectations of the Food and Drug Modernization Act.

It is extremely important that the Presidential Initiatives receive total funding. The Food Safety Initiative directed at significantly reducing the number and incidence of foodborne illness; Bioterrorism focused on prevention and cure in the event of a biological attack; and the Youth Tobacco Prevention Program targeted at reducing the exposure of tobacco products to our children and adolescents represent different aspects of the Agency's mission but initiatives that are critical to the public health of the consumer.

Physicians' salaries: I encourage DHHS to appeal, for the whole Department, the issue of OMB's proposed limitation on growth of physicians' salaries. This would greatly limit our ability to recruit and retain highly specialized Medical Officers, and depending how it were implemented, could jeopardize our ability to fill vacancies as they occur. In addition to the increases allowed in the Passback, the continued project growth in drug review under PDUFA will require increased recruitment of physicians in many different specialties; limiting our ability to provide competitive compensation could jeopardize that program and become a new bottleneck in the review process. Moreover, we believe the issue should be treated equitably not only among the DHHS agencies, but Government-wide.

Once again, we appreciate the effort both DHHS and OMB have made to recognize and provide funding for essential FDA programs. Thank you for your consideration of our appeal, we appreciate your support of our requested increased level of funding for FY 2000.

MAFriedman

Michael A. Friedman, M.D.

Attachments

FOOD AND DRUG ADMINISTRATION
Appeal Item #1) Provide Full Funding for Current Services
(Dollars in Millions)

	1998 Enacted	1999 Enacted	2000 Request	2000 OMB	2000 Appeal
Budget Authority	$925.1	$982.2	$1,514.5	$1,080.0	+$33.4
Program Level	$1,037.8	$1,134.7	$1,680.7	$1,263.2	+$33.4
Outlays	$951.9	$964.1	$1,367.5	$1,041.8	+$26.5
FTE	9,288	9,030	10,111	9,320	NA

Description of OMB Passback: The passback to FDA included no resources to restore the loss of current services. Based on current pay assumptions, FDA expects the pay related current services costs for FY 2000 to be $31.5 million. We are appealing for the full requested amount of pay related current services, with the remaining $1.9 million to be used to absorb some of the non-pay related cost increases.

Key Arguments of Appeal: The cumulative effect of the absorption of pay and non-pay current services from FY 1994 through FY 1999 is $165 million, or 20.5 percent of the total FY 1999 S&E portion of FDA's budget.

The result of the loss to priority programs include:

- Inability to properly analyze and react in a timely manner to adverse event/injury reports.
- Drastic reduction of import program. In 1998 only 1.5 percent of imports were inspected, only 1 percent will be inspected in 2000.
- Inspection frequency declining. FDA meets only 50 percent of statutory mandate.
- Products largely unregulated – dietary supplements, cosmetics, medical products purchased overseas.
- Applications for products – longer review times.

Through FY 1999, FDA has been forced to reduce by more than 500 FTE in order to absorb inflation. Further absorption could force the loss of an additional 300 FTE from FDA's base programs. This continued absorption of inflation cannot continue.

If we do not get this support in FY 2000, FDA's leadership role in assuring high public health and consumer protection standards will be jeopardized. Without adequate support for the agency's core programs, we are facing the possibility of significantly reducing our regulatory role and transforming ourselves into a very limited monitoring and oversight body similar to the European model.

FOOD AND DRUG ADMINISTRATION

Appeal Item #2) Provide Full Funding for Product Safety Assurance

(Dollars in Millions)

	1998 Enacted	1999 Enacted	2000 Request	2000 OMB	2000 Appeal
Budget Authority	$925.1	$982.2	$1,514.5	$1,080.0	+$83.0
Program Level	$1,037.8	$1,134.7	$1680.7	$1,263.2	+$83.0
Outlays	$951.9	$964.1	$1,367.5	$1,041.8	+$65.8
FTE	9,288	9,030	10,111	9,320	+208

Description of OMB Passback: The passback included $43.2 million and 108 FTE of the $126.1 million and 316 FTE requested for activities directly ensuring the safety of FDA-regulated products for consumers, and ensuring honesty and fair dealing in the marketplace on behalf of industry.

Key Arguments of Appeal: If FDA does not receive the full amount requested, the results would be:

- Inability of FDA to establish a link to the U.S. International Trade Data System (ITDS), which would provide immediate access to accurate trade statistics and data, and knowledge to promote informed compliance with trade statutes.
- Inability of FDA to enhance the Agency's Operative and Administrative System for Import Support (OASIS) to better facilitate audits of import brokers' files on imported products.
- Inadequate research to identify high risk public health areas which would facilitate regulatory focus on those areas needing the most attention.
- A weak international inspection program to assure the safety and effectiveness of products entering the U.S. -- in FY 1997, FDA inspected 8 percent of the 3,803 foreign device manufacturers, 18 percent had violations.
- The risk of negative economic impacts to the U.S. from significant international trade barriers for U.S. products. U.S. allowing entry of products that do meet our safety/health standards due to inadequate resources to allow FDA involvement in international harmonization efforts.

- An inadequate number of highly skilled, flexibly trained employees capable of applying current science to make decisions on firms with product violations, and regulation development to ensure the safety of products.

- The inability to substantially increase inspectional coverage by training and working with states/foreign governments/others to supplement our efforts through federal-state contracts, international agreements, and other partnership efforts to ensure the overall safety of products supplied to U.S. consumers and the world.

- Lack of a capable and investigative oversight and scientific arm to ensure safety, honesty, and fair dealing. It has been found that as the number of inspections decreases the rate of violations increases, and as the time between inspections of firms increases the rate of violations increases.

- FDA would monitor increasingly fewer imported food products for safety and public health concerns -- FDA was severely criticized this year by the Governmental Affairs Permanent Subcommittee on Investigations for lack of adequate coverage of imported food products. The volume of imported shipments has more than tripled in the last five years and is expected to grow exponentially. The result is a continual declining level of FDA monitoring the safety of imports.

- Inadequate monitoring of the food supply for pesticides and other contaminants of concern.

FOOD AND DRUG ADMINISTRATION
Appeal Item #3) Provide Full Funding for Product Safety Building and Facilities
(Dollars in Millions)

	1998 Enacted	1999 Enacted	2000 Request	2000 OMB	2000 Appeal
Budget Authority	$925.1	$982.2	$1,514.5	$1,080.0	+$26.9
Program Level	$1,037.8	$1,134.7	$1,680.7	$1,263.2	+$26.9
Outlays	$951.9	$964.1	$1,367.5	$1,041.8	+$ 8.7
FTE	9,288	9,030	10,011	9,320	NA

Description of OMB Passback: The passback to FDA included only $20.4 million of the $50.3 million requested to fund construction projects for the Los Angeles Laboratory and Phase III of the Arkansas Regional Laboratory (ARL).

We are appealing for an additional $20.0 million to meet the full requested amount to construct the Los Angeles Laboratory, and the full $6.9 million needed to complete Phase III of the Arkansas Regional Laboratory.

Key Arguments of Appeal:

Los Angeles Laboratory

The Food and Drug Administration, while appreciative of OMB's expression of support for the Los Angeles area laboratory facility by virtue of the partial funding contained in the OMB passback for the FY2000 Budget Request, respectfully requests reconsideration of that OMB decision and hopes that the full funding requested by the Agency can be restored.

- The new FDA laboratory and office facility at Irvine, CA will greatly enhance the Agency's capability to guarantee the safety of imported products such as fruits, vegetables, and seafood, among others.

- The new laboratory will not only help FDA to fulfill it's Product Safety mandate, but will also enable the Agency to provide faster decisions to importers and brokers awaiting FDA clearance to distribute embargoed product.

- Construction costs in southern California are increasing somewhat faster than in other parts of the country and it would be desirable for FDA to be able to award a construction contract

for the entire facility at one time and thus lock-in the contractor's pricing at the most favorable total project cost.

- A single construction contract award based on full funding for the project will allow early completion of construction and will also result in a "seamless" project without the scheduling difficulties that can result from phased construction or the finger pointing that can occur where different construction contractors or sub contractors are involved with multi-phased construction.

- The FY 1999 increase for the Food Safety Initiative will go far to support much needed expansion of imported product entry review at the border, and will provide much needed resources for increased imported food sampling and laboratory analysis. A great part of this workload will occur in southern California; the new laboratory facility in Los Angeles is critical if the agency is to keep up with increased imports and associated microbiological hazards.

Arkansas Regional Laboratory, Phase III

- The omission of the $6.9 million for the completion of the Arkansas Regional Laboratory from FDA's Building and Facilities budget request for FY 2000 will leave the overall project 20 percent short of completion with 17 percent of the floor space unusable.

- Congress appropriated $3 million in FY 1999 to begin construction of Phase III of this $42 million project. This enabled FDA to maintain the current contractor and continue on the original completion schedule. Without the $6.9 million Congress expects us to request in FY2000, the contractor will exhaust all current funds and we will be forced to terminate the contract.

- If the remaining funds are made available at a later date, the completion of the project will have to be re-competed and the new contractor would have to remobilize all necessary equipment and personnel at a much higher cost than the current estimate of $6.9 million.

- This project began in FY 1995 with the funding of $2.5 for the Architectural and Engineering design of the facility. Once that was completed, funding for the construction of the project has been provided each fiscal year since. The requested funding for FY 2000 will complete this project and allow FDA to continue with its consolidation plans for the 21st century.

FOOD AND DRUG ADMINISTRATION

Appeal Item #4) Provide Full Funding for Premarket Application Review

(Dollars in Millions)

	1998 Enacted	1999 Enacted	2000 Request	2000 OMB	2000 Appeal
Budget Authority	$925.1	$982.2	$1,514.4	$1,080.0	+$36.1
Program Level	$1,037.8	$1,134.7	$1,680.7	$1,263.2	+$36.1
Outlays	$951.9	$964.1	$1,367.5	$1,041.8	+$28.7
FTE	9,288	9,030	10,111	9,320	+226

Description of OMB Passback: OMB provided $20.0 million for Premarket Application Review activities. The Agency is appealing the remaining $36.1 million and 226 FTE, the unfunded amount for Premarket Application Review.

Key Arguments of Appeal: FDA has successfully initiated a number of innovative approaches and improvements which have improved our performance. However, the FDA is rapidly reaching the point where further improvements toward our statutory goals cannot occur without an infusion of additional resources. The passback is proposing a number of reductions from our proposal which will severely impede the ability of FDA to conduct complete, timely premarket application reviews. The full $56.1 million is needed to meet both the public and industry expectation of FDA for the review of medical devices, human & generic drugs, blood and tissue products, animal drugs and food additives, in order to meet the specific performance goals in each category as stated our request to OMB. The lack of total funding will yield the following results:

- Delay transition to full electronic review of abbreviated new drug applications, and retard information system maintenance for electronic reviews and database for submissions for the Entry Validation Application program for structured submission of bioequivalence data that accompany generic drug applications; hinder communication of regulatory requirements to industry.

- Delays in getting new products on the market can postpone treatment to patients and access for the health care system of products.

- Delays in product approvals causing longer returns on investments, encouragement to move research and development overseas, and a general chilling of investment in those industries.

- Limited reengineering and automation of the premarket application review process to maximize efficiency; hinder productive interactions with industry, including up-to-date review guidance, industry education, and reviewer training; limited target laboratory work

on emerging technologies and decreased regulatory uncertainty; and limited on-time, science-base interactive reviews.

- Further erosion of our science base. FDA needs to restore this critical science base to be able to lead the way in regulating complex new technologies, conduct independent laboratory analysis, update standards and review guidance.

FOOD AND DRUG ADMINISTRATION
Appeal Item #5) Additive User Fees
(Dollars in Millions)

	1998 Enacted	1999 Enacted	Request	2000 OMB	Appeal
Budget Authority	$925.1	$982.2	$1,514.4	$1,080.0	0.0
Program Level	$1,037.8	$1,134.7	$1,680.7	$1,263.2	0.0**
Outlays	$951.9	$964.1	$1,367.5	$1,041.8	0.0
FTE	9,288	9,030	10,111	9,320	??

** FDA is not appealing the dollar amount of proposed additive user fees, but is proposing alternative fee proposals, within the same two program areas -- Medical Devices and Food Additive review.

Description of OMB Passback: Proposes $17.0 million in new additive user fees for medical device reviews/postmarket activities ($15.0 million) and for the review of food additive petitions ($2.0 million). Represents a policy shift from BA-reducing user fees and responds to the HHS/FDA arguments that additive fees, especially when accompanied by increases in the base, can be accepted by industry and gain approval by Congress.

Key Arguments of Appeal: While in total agreement with this shift in philosophy, FDA is nonetheless appealing for the substitution of two different user fees proposals-- the inclusion, instead, of $6 million in new additive user fees for premarket notifications for food contact substances, combined with up to $11 million for review of Food Additive Petitions, and a pilot program for a third-party based program, possibly off-budget, for providing medical device manufacturers with the safety certifications they need to market in the European Market and elsewhere.

- Using PDUFA as an example, industry support is critical for any kind of additive user fee to be successful. For medical device additive user fees, certain segments of the industry are adamantly opposed. To include a proposal without first developing support would create ill-will or mistrust and possibly prohibit any future development.

- Industry support is generally evident for additive user fees for food additive petitions. However, this support is currently being built informally. FDA believes that there is a real chance for success, since the industry has discussed this issue with Congress.

- The FDAMA amends section 409 of the FD&C Act to establish a premarket notification (PMN) program for food contact substances which will make it easier to introduce products to market. FDAMA includes funding provisions, however, that must be met before the program can be implemented, which have not been met so far. Industry support is clear and strong for this program to become operational. User fees to cover the projected costs of $6 million are viewed as an effective and viable way of achieving this. Implementation is possible for fiscal year 2000.

- In addition, FDA proposes a user fee program of up to $11 million to strenthen and enhance the existing program for review of Food Additive Petitions. This would include a means of dividing these Petitions into tiers based on the relative complexity of different types of additives and the time it takes FDA to review their safety. The agency believes the industry would also support this type of user fee, subject to negotiations with industry and with Congress on the amount of the fees and the performance expected of FDA under an enhanced program.

- FDAMA's emphasis on a harmonized United States - European Union (U.S.-E.U). regulatory environment places a special sensitivity on the funding of inspections for medical devices. A substantial segment of U.S. medical device manufacturers are now obliged to pay for inspections by E.U. third parties in order to participate in the $7 billion export market to the E.U. While these fees are tolerated by the U.S. industry as a necessary cost of doing business with Europe, the industry's steadfast objection to FDA fee-funded inspections impeded FDA from providing these inspection services without denigrating its already sub-statutory performance on the frequency of domestic inspections. The eventual solution to this situation will likely require a U.S. based third party inspection system with a capability to satisfy both FDA and EU requirements. This system would almost certainly need to be both voluntary and "off-budget". Any traditional budget proposal for user fees would likely complicate development of a consensus towards this solution.

FDA is opposed to the Medical Device User Fee Proposal in the OMB Passback because:

- The Food and Drug Administration Modernization Act of 1997 (FDAMA) outreach meetings with FDA stakeholders documented strong industry opposition, for multiple reasons. We think it is unwise to do something that is pre-doomed to certain failure.

- FDA can offer no tangible value to firms from FDA inspections paid for by user fees. Establishments that aren't inspected or get free inspections under Budget Authority funds would have same market advantage as those paying for inspections.

- The most affected firms -- those which FDA does not already inspect for free -- would be small firms with less than 20 employees. There are obvious implications of a "small business tax " no matter how skillfully it is packaged.

- This is inherently, a regressive tax, we may call it an inspection fee, but the result is the same. Small firms would pay a greater percentage of their relatively small profits for these inspections than large firms would pay from their comparatively large profits.

FOOD AND DRUG ADMINISTRATION

Appeal Item #6) Provide Full Funding for the Food Safety Initiative

(Dollars in Millions)

	1998 Enacted	1999 Enacted	Request	2000 OMB	Appeal
Budget Authority	$925.1	$982.2	$1,514.4	$1,080.0	+$48.9
Program Level	$1,037.8	$1,134.7	$1,680.7	$1,263.2	+$48.9
Outlays	$951.9	$964.1	$1,367.5	$1,041.8	+$38.8
FTE	9,288	9,030	10,111	9,320	+152

Description of OMB Passback: Provides zero funding for the next installment of the President's Food Safety Initiative for FDA or CDC. Inexpicably, USDA, on the other hand, received 163 percent of their FY 2000 request.

Key Arguments of Appeal: The fiscal year 2000 request builds upon the many accomplishments already achieved.

- Foodborne illness is still a problem that affects between 6.5 and 33 million consumers at a cost in related medical costs and lost wages of between $7.0 and $37.0 billion a year.
- As a result of these activities we now have more rapid identification of foodborne illness and containment of outbreaks, better coordination among food safety agencies, faster response times to Foodborne Outbreaks, the start of a seamless food safety system, preventive controls, and outreach to industry and consumers
- We have documented cases where we shortened the time to identify and respond to outbreaks, as well as prevent potential ones. This directly benefits consumers and provides phenomenal "bang for the buck".
- The fiscal year 1999 request focuses resources on imports, particularly fresh produce, and provides specific research targeted toward antibiotic resistance, and builds on 1998. However, Congress did not fully fund the President's FY 1999 FSI request, leaving much still to be accomplished. The FY 2000 request would provide funding to respond to the new data generated from initiatives begun in 1998 and 1999.

Funding for 2000 will continue to build on these foundations and will allow for :

- Increased outbreak response work, tracing back through the food distribution and production chain to find the source of contamination that caused an outbreak. This type of work will increase as the FoodNet system matures and the data becomes more reliable.

- Focus on antimicrobial resistance. The identification and containment of resistance as a result of the monitoring programs will help ensure the continued effectiveness of both human and veterinary drugs, and aid in increasing the availability and distribution of effective drugs.

- Increased food production preventive controls systems work, including development of additional industry guidance and HACCP where appropriate.

- Work with states to achieve adoption of the Food Code by states, develop performance standards for food service workers, and provide education and training to support Food Code adoption and change unsafe behaviors since available data indicates that foods prepared by retail food service are the source of a large number of outbreaks.

- To develop a vertically integrated national food inspection system, resources will be devoted to provide state inspectors with resources and training to conduct complementary inspections and provide a nationwide, uniformly applied food safety system.

- Inspections on high-risk areas (such as seafood) will be conducted once per year.

- Work in the area of imported foods will expand to cover additional products or practices.

- Work will also continue in the major areas to address the food safety issues identified in the original Food Safety Initiative and the more recently developed Fresh Produce Initiative.

- Research and risk assessment provides a cornerstone for targeting scarce resources to those areas that yield the most benefits, and will be needed to support these activities.

FOOD AND DRUG ADMINISTRATION
Appeal Item # 7) Provide Full Funding for Youth Tobacco Prevention
(Dollars in Millions)

	1998 Enacted	1999 Enacted	2000 Request	2000 OMB	2000 Appeal
Budget Authority	$925.1	$982.2	$1,514.5	$1,080.0	+$50.0
Program Level	$1,037.8	$1,134.7	$1,680.7	$1,263.2	+$50.0
Outlays	$951.9	$964.1	$1,367.5	$1,041.8	+$39.7
FTE	9,288	9,030	10,111	9,320	25

Description of OMB Passback: The passback to FDA included no resources additional resources for the Youth Tobacco Prevention program. FDA is appealing for $50.0 million and 25 FTE.

Key Arguments of Appeal: Smoking is the leading preventable cause of death in the United States. Every year, another one million young people become regular smokers, and one-third of them will eventually die prematurely as a result of their smoking. The average teenage smoker starts smoking at 14 ½ years of age and becomes a daily smoker by the age of 18. Reducing young people's use of tobacco is an enormous undertaking with potential for great public health outcomes.

Tobacco products are responsible for more than 400,000 deaths annually due to cancer, respiratory illness, heart disease, and other health problems. According to the CDC, health care costs associated with smoking soared to more than $50 billion in 1993.

It is estimated that between 500,000 and a million retailers may sell tobacco in the United States. Although several states do have license records for retailers, many states have either inadequate or nonexistent lists.

Without the requested funding increase:

- FDA would be unable to expand significantly on the outreach and enforcement activities initiated during FY 1998.
- FDA would be unable to further limit children's access to tobacco. Were we able to further limit access, this would will reduce the toll of lost lives, lost productivity, impaired health and increased health care costs.
- FDA will only be able to conduct a limited amount of unannounced compliance checks each month of tobacco product retailers.

- FDA will continue it's Tobacco program activities at the FY 1998 level.
    - Instead of an expanded compliance outreach effort, it will have a modest continuation of FY 1998 activities.
    - While FDA will have an enforcement presence in all 50 states, it will be a minimal one, not an increasingly effective, robust presence.

FOOD AND DRUG ADMINISTRATION
Appeal Item #8) Provide Full Funding for Bioterrorism
(Dollars in Millions)

	1998 Enacted	1999 Enacted	2000 Request	2000 OMB	2000 Appeal
Budget Authority	$925.1	$982.2	$1,514.4	$1,080.0	+$13.0
Program Level	$1,037.8	$1,134.7	$1,680.7	$1,263.2	+$13.0
Outlays	$951.9	$964.1	$1,367.5	$1,041.8	+$13.0
FTE	9,288	9,030	10,111	9,320	+42

Description of OMB Passback: The OMB passback included $6.4 million for FDA's portion of the President's Bioterrorism Initiative. FDA is appealing the remaining $13.0 million.

Key Arguments of Appeal: The Agency is appealing denial of $13.0 million, the amount unfunded for Bioterrorism. The lack of total funding will yield the following results:

- Delay licensure of new vaccines for anthrax and botulinum.
- Restrict the availability of FDA experts who would expedite the licensing process of these and other potential vaccines.
- Limit FDA participation in planning and coordinating the health and medical response of the federal government in the aftermath of terrorist acts involving chemical or biological agents.
- Impede development and approval of new drugs and new uses for existing drugs. These drugs are needed to treat the medical conditions caused by exposure to biological agents.
- Impair second response capability to a potential biohazard event with adequately trained and equipped investigators.
- Groundwork research for the design of new types of vaccines for anthrax, botulinum, tularemia, Q-fever, and other potential toxins will be hindered. FDA will be unable to conduct a feasibility study for the establishment of a biosafety-level 4 (BL-4) laboratory for use in the research and approval of vaccines.
- Reduce premarket review research on and the subsequent approval of diagnostic products that can be used to identify biological agents that are used in potential terrorist activities.
- Prohibit development of techniques for the rapid detection of biological agents and to develop techniques to detect genetic modifications of microorganisms.

FOOD AND DRUG ADMINISTRATION
All Purpose Table -- BUDGET AUTHORITY
(Dollars in Thousands)

Project	FY 1998 Enacted		FY 1999 Enacted		FY 2000 Request to OMB		FY 2000 OMB Passback		FY 2000 Appeal Total		FY 2000 Appeal +/- OMB	
	FTE	$	FTE	$	FTE	$	FTE	$	FTE	$	FTE	$
Foods	2,218	$203,830	2,363	$231,580	2,729	$360,008	2,414	$241,820	217	$86,481	2,631	$328,311
CFSAN	809	87,599			1,020	158,577						
Field Activities	1,409	116,231			1,709	191431						
Human Drugs	2,094	$199,305	1,985	$200,305	2,213	$256,985	2,023	$215,177	60	$20,902	2,083	$236,079
CDER	1,310	139,006			1,397	186,200						
Field Activities	784	60,299			816	70,785						
Biologics	875	$96,279	815	$96,279	1,023	$129,870	870	$111,979	71	$13,293	941	$125,272
CBER	644	78,535			788	105,463						
Field Activities	231	17,744			255	24,417						
Animal Drugs & Feeds	428	$41,973	383	$41,973	553	$88,379	380	$48,873	77	$11,077	457	$59,150
CVM	264	29,375			362	47,094						
Field Activities	164	12,598			191	18,285						
Device & Radiological Products	1,523	$143,488	1,393	$145,736	1,771	$202,385	1,469	$164,136	156	$32,620	1,625	$196,756
CDRH	1,030	104,311			1,227	147,408						
Field Activities	493	39,175			544	54,947						
NCTR	225	$31,079	225	$31,579	239	$39,225	227	$34,179	12.85	$5,046	240	$40,225
Tobacco	25	$34,000	25	$34,000	75	$184,155	25	$34,000	25	$50,155	50	$84,155
Other Activities:	931	$81,694	931	$80,694	1,004	$103,581	947	$84,094	34	$13,828	981	$97,922
Office of the Commissioner	131	11,710	131	11,710	141	14,095	133	12,200	4	1,992	137	14,192
Office of Policy	34	2,867	34	2,867	38	3,595	36	2,993	4	512	40	3,506
Office of External Affairs	188	15,061	188	15,061	206	19,341	189	15,688	4	2,552	193	18,240
Office of Oper'ns/Orphan Grants Adm	34	3,559	34	3,559	37	4,206	35	3,709	2	612	37	4,321
Office of Management & Systems	544	39,964	544	38,964	582	52,711	554	40,619	20	6,733	574	47,353
Central Services	0	8,533	0	8533	0	9,613	0	8,884	0	1,426	0	10,310
Other Rent & Rent-related Activ	0	$25,855	0	$25,855	0	$27,505	0	$25,855	0	0	0	$25,855
Rental Payments			0	$82,866			0	$94,537	0	0	0	$94,537
Total, Salaries & Expenses	8,319	$857,501	8,090	$970,867	9,607	$1,359,043	8,355	$1,084,650	653	$234,412	9,008	$1,289,062
Non-Field Activities	5,238	811,454			6,092	999,178						
Field Activities	3,081	246,047			3,515	359,865						
Rental Payments	0	$46,294			0	$94,537						
Buildings & Facilities	0	$21,350	0	$11,350	0	$80,950	0	$31,750	0	$26,900	0	$58,650
Total, Budget Authority	8,319	$925,145	8,090	$982,217	9,607	$1,514,530	8,355	$1,086,400	653	$261,312	9,008	$1,347,712

NOTE: The Budget Authority increase from FY 1999 to FY 2000 includes $127,717 thousand and 1,183 FTE associated with the restoration of FY 1999 proposed user fees to FY 2000 budget authority. The adjusted budget authority increase is $416,712 thousand.

FOOD AND DRUG ADMINISTRATION
All Purpose Table – USER FEES
(Dollars in Thousands)

User Fees	FY 1998 Enacted		FY 1999 Enacted		FY 2000 Request to OMB		FY 2000 OMB Passback		FY 2000 Appeal Total		FY 2000 Appeal +/- OMB	
	FTE	$	FTE	$	FTE	$	FTE	$	FTE	$	FTE	$
Existing User Fees												
PDUFA:	700	$117,121	735	$132,273	879	$145,434	879	$145,434	0	$0	879	$145,434
Human Drugs	467	84,648	510	91,676	612	101,459	612	101,459	0	0	612	101,459
Center Activities	398	78,724			524	94,094	524	94,094	0	0	524	94,094
Field Activities	69	5,924			88	7,365	88	7,365	0	0	88	7,365
Biologics	192	28,606	175	28,816	208	30,457	208	30,457	0	0	208	30,457
Center Activities	187	26,095			202	29,819	202	29,819	0	0	202	29,819
Field Activities	5	511			6	638	6	638	0	0	6	638
Other Activities	41	5,867	50	6,353	59	7,875	59	7,875	0	0	59	7,875
Office of the Commissioner	1	105	3	113	1	143	1	143	0	0	1	143
Off of Oper'ns/Orphan Grants Adm	0	0	2	101	0	29	0	29	0	0	0	29
Office of Management & Systems	40	5,762	45	6,139	58	7,703	58	7,703	0	0	58	7,703
GSA Rent	0	0	0	5,428	0	5,643	0	5,643	0	0	0	5,643
MQSA	53	13,986	60	14,386	63	14,817	63	14,817	0	0	63	14,817
Center Activities	32	8,653	32	9,026	32	9,180	32	9,180	0	0	32	9,180
Field Activities	19	5,158	16	5,200	19	5,473	19	5,473	0	0	19	5,473
Other Activities–Offc of Mgmt & Syst	2	154	2	159	2	164	2	164	0	0	2	164
Subtotal, Existing User Fees	783	$131,086	785	$0	932	$160,251	932	$160,251	0	$0	932	$160,251
Center Activities	660	119,493			819	146,775	819	146,775	0	0	819	146775
Field Activities	93	11,593			113	13,476	113	13,476	0	0	113	13476
Proposed User Fees												
Foods	0	0	0	0	0	0	0	2,000	0	15,000	0	17,000
Additive Petitions (Center)	0	0	0	0	0	0	0	2,000	0	15,000	0	17000
Import Reviews (Field)	0	0	0	0	0	0	0	0	0	0	0	0
Postmarket Surveillance (Field)	0	0	0	0	0	0	0	0	0	0	0	0
Human Drugs	0	0	0	0	0	0	0	0	0	0	0	0
Generic Drugs Reviews (Center)	0	0	0	0	0	0	0	0	0	0	0	0
Import Reviews (Field)	0	0	0	0	0	0	0	0	0	0	0	0
Postmarket Surveillance (Field)	0	0	0	0	0	0	0	0	0	0	0	0
Biologics	0	0	0	0	0	0	0	0	0	0	0	0
Import Reviews (Field)	0	0	0	0	0	0	0	0	0	0	0	0
Postmarket Surveillance (Field)	0	0	0	0	0	0	0	0	0	0	0	0
Animal Drugs	0	0	0	0	0	0	0	0	0	0	0	0
Premarket Reviews (Center)	0	0	0	0	0	0	0	0	0	0	0	0
Import Reviews (Field)	0	0	0	0	0	0	0	0	0	0	0	0
Postmarket Surveillance (Field)	0	0	0	0	0	0	0	0	0	0	0	0
:al Devices	0	0	0	0	0	0	0	15,000	0	(15,000)	0	0
Premarket Reviews (Center)	0	0	0	0	0	0	0	15,000	0	(15,000)	0	0
Import Reviews (Field)	0	0	0	0	0	0	0	0	0	0	0	0
Postmarket Surveillance (Field)	0	0	0	0	0	0	0	0	0	0	0	0
Subtotal, Proposed User Fees	0	0	0	0	0	0	0	17,000	0	0	0	17,000
Center Activities	0	0	0	0	0	0	0	17,000	0	0	0	17000
Field Activities	0	0	0	0	0	0	0	0	0	0	0	0
Other User Fees:	72	$8,654	75	$5,794	72	$5,968	72	$5,968	0	$0	72	$5,968
Export Certification	8	2,000	8	1,000	8	1,030	8	1,030	0	0	8	1,030
Certification Fund	36	3,654	35	3,764	36	3,877	36	3,877	0	0	36	3,877
FOIA	0	1,000	0	1,030	0	1,061	0	1,061	0	0	0	1,061
Reimbursable Activities (FTEs)	28		32		28		28		0	0	28	0
Total, User Fees	825	$137,740	860	$5,794	1,004	$166,219	1,004	$183,219	0	$0	1,004	$183,219
Center Activities	732	126,147			891	152,743	891	169,743	0	0	891	169,743
Field Activities	93	11,593			113	13,476	121	14,506	0	0	113	13,476

FOOD AND DRUG ADMINISTRATION
All Purpose Table -- TOTAL PROGRAM LEVEL
(Dollars in Thousands)

Project	FY 1998 Enacted		FY 1999 Enacted		FY 2000 Request to OMB		FY 2000 OMB Passback		FY 2000 Appeal		FY 2000 Appeal +/- OMB	
	FTE	$	FTE	$	FTE	$	FTE	$	FTE	$	FTE	$
Foods	2,218	$203,830	2,363	$231,580	2,729	$360,008	2,414	$243,820	217	$101,491	2,631	$345,311
CFSAN	809	87,599			1,020	158,577						
Field Activities	1,409	116,231			1,709	191,431						
Human Drugs	2,561	$283,863	2,495	$291,981	2,825	$388,444	2,635	$316,836	60	$20,902	2,695	$337,538
CDER	1,708	217,730			1,921	280,294						
Field Activities	853	66,223			904	78,150						
Biologics	1,067	$122,885	990	$125,095	1,231	$160,327	1,078	$142,436	71	$13,293	1,149	$155,729
CBER	831	104,630			970	135,272						
Field Activities	236	18,255			261	25,055						
Animal Drugs & Feeds	428	$41,973	353	$41,973	663	$65,379	380	$48,873	77	$11,077	457	$59,950
CVM	264	29,375			362	47,094						
Field Activities	164	12,598			191	18,285						
Device & Radiological Products	1,574	$157,297	1,443	$160,121	1,822	$217,008	1,620	$193,789	156	$17,620	1,676	$211,409
CDRH	1,062	112,964			1,259	156,588						
Field Activities	512	44,333			563	60,420						
NCTR	225	$31,079	225	$31,579	239	$39,225	227	$34,179	13	$6,046	240	$40,125
Tobacco	25	$34,000	25	$34,000	75	$184,155	25	$34,000	25	$50,155	50	$84,155
Other Activities	974	$87,715	981	$86,946	1,065	$111,600	1,008	$92,133	34	$13,828	1,042	$105,161
Office of the Commissioner	132	11,815	134	11,823	142	14,238	134	12,343	4	1,992	138	14,335
Office of Policy	34	2,867	34	2,867	38	3,595	36	2,993	4	512	40	3,506
Office of External Affairs	188	15,061	188	15,061	206	19,341	189	15,688	4	2,552	193	18,240
Office of Oper'ns/Orphan Grants Adm	34	3,559	36	3,559	37	4,235	35	3,738	2	612	37	4,350
Office of Management & Systems	586	45,880	589	45,103	642	60,578	614	48,486	20	6,733	634	55,220
Central Services	0	8,533	0	8,533	0	9,613	0	8,884	0	1,426	0	10,310
Other Rent & Rent-related Activities	0	$28,855	0	$25,855	0	$27,505	0	$25,855	0	$0	0	$25,855
Rental Payments to GSA			0	$88,294			0	$100,180	0	$0	0	$100,180
Total, Salaries & Expenses	9,072	$988,587	8,875	$1,117,424	10,539	$1,513,651	9,287	$1,231,901	653	$234,412	9,940	$1,466,313
Non-Field Activities	5,898	730,947			6,911	1,140,310						
Field Activities	3,174	257,640			3,628	373,341						
Rental Payments	0	$46,294			0	$100,180						
Buildings & Facilities	0	$21,350	0	$11,350	0	$60,950	0	$31,750	0	$26,900	0	$58,650
Other User Fees:	72	$6,864	75	$5,794	72	$5,968	72	$5,968	0	$0	72	$5,968
Export Certification	8	2,000	8	1,000	8	1,030	8	1,030	0	0	8	1,030
Certification Fund	36	3,654	35	3,764	36	3,877	36	3,877	0	0	36	3,877
FOIA	0	1,000	0	1,030	0	1,061	0	1,061	0	0	0	1,061
Reimbursable Activities (FTEs)	28	0	32	0	28	0	28	0	0	0	28	0
Total, Program Level	9,144	$1,062,885	8,950	$1,134,568	10,611	$1,680,749	9,359	$1,269,819	653	$261,312	10,012	$1,530,931

1/ FY 1998 does not include a comparability adjustment for $900,000 and 9 FTEs to be tranferred to SAMSHA in FY 1999 for the Methadone Program.

2/ Committee action incorporated GSA Rental Payments into S&E account.

FOOD AND DRUG ADMINISTRATION
All Purpose Table – S U M M A R Y
(Dollars in Thousands)

Project	FY 1998 Enacted FTE	FY 1998 Enacted $	FY 1999 Enacted FTE	FY 1999 Enacted $	Request to OMB FTE	Request to OMB $	FY 2000 OMB Passback FTE	FY 2000 OMB Passback $	Appeal to OMB FTE	Appeal to OMB $	Appeal +/- OMB FTE	Appeal +/- OMB $
Foods	2,218	$203,830	2,363	$231,580	2,729	$350,008	2,414	$241,820	217	$86,491	2,631	$328,311
Human Drugs	2,094	199,305	1,985	200,305	2,213	256,985	2,023	215,177	60	20,902	2,083	236,079
Biologics	875	96,279	815	96,279	1,023	129,870	870	111,979	71	13,293	941	125,272
Animal Drugs & Feeds	428	41,973	353	41,973	553	65,379	380	48,873	77	11,077	457	59,950
Devices & Radiological Products	1,523	143,486	1,393	145,736	1,771	202,355	1,469	164,136	156	32,620	1,625	196,756
NCTR	225	31,079	225	31,579	239	39,225	227	34,179	13	6,046	240	40,225
Tobacco	25	34,000	25	34,000	75	184,155	25	34,000	25	50,155	50	84,155
Other Activities	931	81,694	931	80,694	1,004	103,561	947	84,094	34	13,828	981	97,922
Other Rent & Rent-related Activities	0	25,855	0	25,855	0	27,505	0	25,855	0	0	0	25,855
GSA Rental Payments	0	46,294	0	82,866	0	94,537	0	94,537	0	0	0	94,537
Total Salaries & Expenses	**8,319**	**$903,795**	**8090**	**$970,867**	**9,607**	**$1,453,580**	**8,355**	**$1,054,650**	**653**	**$234,412**	**9,008**	**$1,289,062**
Buildings & Facilities	0	21,350	0	11,350	0	60,950	0	31,750	0	26,900	0	58,650
Total Budget Authority	**8,319**	**$925,145**	**8090**	**$982,217**	**9,607**	**$1,514,530**	**8,355**	**$1,086,400**	**653**	**$261,312**	**9,008**	**$1,347,712**
USER FEES:												
Export Certification	8	2,000	8	1,000	8	1,030	8	1,030	0	0	8	1,030
Certification Fund	36	3,654	35	3,764	36	3,877	36	3,877	0	0	36	3,877
FOIA	0	1,000	0	1,030	0	1,061	0	1,061	0	0	0	1,061
Reimbursable Activities (FTEs)	28		32		28		28		0		28	0
PDUFA:	700	117,121	735	132,273	879	145,434	879	145,434	0	0	879	145,434
Human Drugs	(467)	(84,648)	(510)	(91,676)	(612)	(101,459)	(612)	(101,459)	0	0	(612)	(101,459)
Biologics	(192)	(26,606)	(175)	(28,816)	(208)	(30,457)	(208)	(30,457)	0	0	(208)	(30,457)
Other Activities	(41)	(5,867)	(50)	(6,353)	(59)	(7,875)	(59)	(7,875)	0	0	(59)	(7,875)
GSA Rent	0	0	0	(5,428)	0	(5,643)	0	(5,643)	0	0	0	(5,643)
MQSA:	53	13,965	50	14,385	53	14,817	53	14,817	0	0	53	14,817
Devices & Radiological Products	(51)	(13,811)	32	9,026	(51)	(14,653)	(51)	(14,653)	0	0	(51)	(14,653)
Other Activities	(2)	(154)	2	159	(2)	(164)	(2)	(164)	0	0	(2)	(164)
Proposed User Fees	0	0	0	0	0	0	0	17,000	0	0	0	17,000
Total User Fees	**825**	**$137,740**	**860**	**$152,452**	**1,004**	**$166,219**	**1,004**	**$183,219**	**0**	**$0**	**1,004**	**$183,219**
Total, Program Level	**9,144**	**$1,062,885**	**8,950**	**$1,134,669**	**10,611**	**$1,680,749**	**9,359**	**$1,269,619**	**653**	**$261,312**	**10,012**	**$1,530,931**

Notes:

Per committee direction, in FY 1999 GSA rent is incorporated in the S&E appropriation.

FY 1998 does not include a comparability adjustment for $900,000 and 9 FTEs to be tranferred to SAMSHA in FY 1999 for the transfer of the Methadone program.

Includes Export Certification fees, Certification Fund and FOIA.

SU ARY FDA FY 2000 BUDGET PASSBACK APPEAL

11/30/98

	FDA REQUEST	OMB REQUEST	DECISION REQUEST	APPEAL REQUEST
GAP INITIATIVES				
CURRENT SERVICES – PAY	**$26,841**	**$33,384**	**$0**	**$33,384**
CURRENT SERVICES – NON-PAY	**$10,509**	**$0**	**$0**	
TOTAL	**$36,350**	**$33,384**	**$0**	**$33,384**
INJURY REPORTING	**$84,600**	**$80,357**	**$16,300**	**$0**
CFSAN	$3,300	$3,000	$1,200	$0
CDER	$31,100	$30,090	$7,900	$0
CBER	$6,600	$5,900	$1,600	$0
CVM	$3,800	$2,928	$800	$0
CDRH	$8,900	$8,800	$2,600	$0
ORA	$5,600	$4,800	$0	$0
OA	$5,200	$4,839	$1,200	$0
PRODUCT SAFETY ASSURANCE	**$136,810**	**$128,129**	**$43,172**	**$79,957**
CFSAN	$9,120	$8,900	$0	$8,900
CDER	$6,980	$8,800	$2,672	$4,128
CBER	$1,940	$2,000	$2,000	$0
CVM	$810	$1,000	$1,000	$0
CDRH	$4,670	$4,900	$800	$4,100
ORA	$49,080	$47,471	$16,300	$31,171
OA	$5,910	$4,758	$0	$4,758
B&F (LA Lab & ARL Phase III)	$58,300	$50,300	$20,400	$26,900
PREMARKET APPLICATION REVIEWS	**$66,600**	**$56,122**	**$20,000**	**$36,122**
CFSAN	$7,080	$3,900	$1,400	$2,500
CDER	$5,310	$4,800	$1,700	$3,100
CBER	$8,135	$6,800	$2,500	$4,300
CVM	$4,437	$3,900	$1,600	$2,300
CDRH	$27,284	$24,327	$9,000	$15,327
ORA	$1,444	$1,000	$0	$1,000
NCTR	$5,310	$4,811	$1,600	$3,211
OA	$7,500	$6,584	$2,200	$4,384
PRESIDENTIAL INITIATIVES				
Integratting NOAA Seafood PBO	**$0**	**$0**	**$3,000**	**$0**
FOOD SAFETY INITIATIVE	**$60,000**	**$48,873**	**$0**	**$48,873**
CFSAN	$22,900	$19,593	$0	$19,593
CVM	$6,300	$5,900	$0	$5,900
NCTR	$3,000	$1,000	$0	$1,000
ORA	$26,800	$21,400	$0	$21,400
OA	$1,000	$980	$0	$980
YOUTH TOBACCO INITIATIVE	**$81,000**	**$49,955**	**$0**	**$49,955**
BIOTERRORISM	**$26,115**	**$19,421**	**$6,400**	**$13,021**
CFSAN	$5,000	$3,900	$0	$3,900
CDER	$0	$400	$0	$400
CBER	$13,500	$9,696	$5,400	$4,296
CDRH	$1,500	$1,000	$0	$1,000
NCTR	$2,000	$1,000	$1,000	$0
ORA	$4,115	$3,425	$0	$3,425
USER FEES	**$13,593**	**$13,593**	**$13,593**	**$0**
PDUFA	$13,161	$13,161	$13,161	$0
MQSA	$432	$432	$432	$0
ADDITIVE USER FEES				
FOOD ADDITIVE PETITIONS			$17,000	$0
EXPORTS/CERT/FOIA			$174	$0
GSA RENTAL PAYMENTS	**$11,671**	**$11,671**	**$11,671**	**$0**
BUILDINGS & FACILITIES	**$2,300**	**$2,300**	**$0**	**$0**
COLLEGE PARK	**$8,600**	**$8,600**	**$4,640**	**$0**
TOTAL INCREASE	**$507,439**	**$430,305**	**$134,950**	**$261,312**

RECIPIENT NAME	RECIPIENT FAX #	PKLN RM. #
TO: Larry Tidmore, OFACS	FAX: 301-443-3690	5630 BLDG
TO: Bill Bristow, OIRM	FAX: 301-443-3470	16B-44
TO: Julie Carlston, OMS	FAX: 301-827-0199	16B-06
Susan Baer, ORA	FAX: 301-443-7212	12-38
Lisa Barclay, OP	FAX: 301-594-6777	14-101
Francis Benedict, CVM	FAX: 301-594-4512	16-70**
Maggie Bierwith, OLA	FAX: 301-443-2567	15-55
Butch Bosin, OPE	FAX: 301-827-5225	11B-04
Charlene Cherry, CDER	FAX: 301-827-0509	12A-38
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Denise Riley, CFSAN	FAX: 202-205-5922	16-70**
Robert Steeves, OOPD	FAX: 301-443-4915	8-73
Marge Waskewich, CDRH	FAX: 301-827-2930	16-70**
Carrie Smith-Hanley, OEA	FAX: 301-594-0113	14C-03
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FROM: Jim Donahue, OFM

Date: December 1, 1998

Number of pages including coversheet: 24

SUBJECT: Appeals to FY 2000 OMB Passback

Attached is the copy of the FDA Appeal to the FY 2000 OMB Passback. The information contained in this package is CONFIDENTIAL -- please treat it as such.

Please forward the attached fax to the person(s) indicated above immediately. If you do not receive all pages, please contact Linda Ware immediately at 301-827-5003. Thank you.

NOTE: The following material is privileged, confidential and intended only for the addressee(s) listed above. If this fax is received in error, please destroy immediately and advise/contact Linda Ware at 301-827-5003.

cc: Bob Miller, OFM
Bob MacLeod, OFM/DBFE
Formulation Team
File

S:\BUDGET\FORM\2000\OMB\APPEAL\EVERYONE.FAX Revised as of: November 30, 1998

FAX TRANSMISSION

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TO: Sharon Smith-Holston, OEA	FAX: 301-443-5930	14-95
TO: William Schultz, OP	FAX: 301-443-5930	14-81
TO: Bill Hubbard, OP	FAX: 301-594-6777	14-101
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TO: Lorrie McHugh-Wytkind, OPA	FAX: 301-443-3819	15-05
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TO: Bernard Schwetz, NCTR	FAX: 1-870-543-7576 *[PKLN-7-3042,17-53]	
TO: Steve Sundlof, CVM	FAX: 301-594-1830	16-70**
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TO: Mary Babcock, OHRMS	FAX: 301-443-6684	7-59
TO: Paul Coppinger, OPE	FAX: 301-827-5298	10-61

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PRIORITY PRIORITY

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PRIORITY PRIORITY

TO: MR. GABRIEL

FAX NO. 456-6027
NO. OF PAGES 3

FROM: JANICE F. OLIVER

DATE: 12/4/98

Comments: THIS IS A FOLLOW-UP OF WHAT WE SPOKE ABOUT EARLIER TODAY. I APPRECIATE ANY FEEDBACK YOU MIGHT HAVE. PLEASE CALL IF YOU HAVE ANY QUESTIONS. THANK YOU.

DRAFT

FDA'S YEAR 2000 FOOD SAFETY GOALS
(If funds are appropriated)

INSPECTIONS

- Establish a nationally integrated food safety system with Federal, state, and local authorities.
  - For the first time in decades, FDA will ensure that every high risk food manufacturer in the United States is inspected at least once a year.
  - For other food firms, inspections will be twice as often as today (from once every 8 years to once every 4 years).
  - For the first time ever, state and Federal inspection results will be shared, via an electronic connection, that will reduce overlapping efforts and greatly enhance the ability of those authorities to improve public health
- FDA will have an enhanced international food safety program, which will include evaluations of other countries' food safety systems and provision of technical assistance to foreign countries who import to this country (thereby continuing the shift to ensuring that foods are safely produced before they arrive at our shores).

RESEARCH

- FDA will be able to ensure the applicability and effectiveness of the new preventive control techniques used to ensure the safety of seafood, juices, eggs, fresh produce and other foods.
- New detection tests will be developed for such dangerous contaminants as Salmonella in eggs and Cyclosopora in fresh produce, and test methods for E. coli 0157:H7 in foods in which it cannot now be detected.

OUTBREAK RESPONSE

- With its increased surveillance, CDC expects an increase of 40% of foodborne illness from E. coli 0157:H7 and salmonella, and 10% for all foodborne illness. Funding is needed so that FDA will have the laboratory and staff capability to respond rapidly to those outbreaks when they occur--to track down their source and prevent further danger.
- CDC's new PulseNet contaminant tracing system will be connected to FDA's laboratories, thus enabling FDA to use this state-of-the-art disease detection system to control foodborne illness at the source.

DRAFT

RETAIL

- CDC estimates that one-third of foodborne illness comes from retail establishments. A majority of states will adopt FDA's model food code that raises the standards for safer handling of food in restaurants, nursing homes, hospitals, and grocery stores. If funding is available, FDA can provide the necessary training and education to state and local inspectors (as well as industry) to implement those new standards.

EDUCATION

- Targeted resources are needed so that the most vulnerable (e.g., elderly, very young, and pregnant women) will be taught how they should and can avoid contaminated food. The result will be that their behavior will begin to change so that the most severe illnesses and deaths can be prevented.

RISK ASSESSMENT

- New information will become available about how much of a contaminant must be in a food to make people sick (such as Listeria) and how certain contaminants (such as Salmonella) can best be controlled.

FDA budget

1. HACCP for small plants:

2. FDA
 - flat line budget core

 - line

 - PDUFA -

3. Meat & poultry User fees → · history
 · where to find money
 · budget measure

 - [illegible]

 → industry owns safety issue

 USDA - user fees

 → not an essential

① States Goals

Consumer TY
1 sh

FDA -
→ responsible
→ inspections
→ [illegible] - [illegible]
→ imported

CDC

→ $13 mill.

→ get this info to public

Substitute?
USDA

GW → FDA – budget

	Ask	→	Got	Appeal
Current Services	33	→	∅	33
~~FDA~~ ADR repairs	60.3	→	15.3	no appeal
Product Safety inspection	126.	→	43.2 (10 CA labs	– 83
Permit approval	56		20	36
Food Plant building	–			
Food	49		0	49
No bulk	57		0	50
biotherapeutics	13			