## FOOD AND DRUG ADMINISTRATION

### Appeal Item #1) Restore Base Resources & Eliminate Unauthorized User Fees (Dollars in Millions)

| | 1996 Enacted | 1997 Enacted | 1998 Amended Request | 1998 OMB | 1998 Appeal #1 |
|---|---|---|---|---|---|
| BA | $876.9 | $887.6 | $1,104.1 | $727.1 | +$167.1 |
| Prog. Level | $979.9 | $995.9 | $1,235.2 | $1,015.1 | -$167.1 |
| Outlays | $875.3 | $923.9 | $1,046.1 | $758.8 | $127.5 |

Description of OMB Passback: OMB is proposing user fees beyond the $131.1M FDA has already included in its budget request. These new user fees are **not directly linked to any specific program enhancement or industry benefit** as required by the general user fee statute and are meant to offset budget authority (BA) reductions made to our base resources. The resulting program level of $1,015.1M (which includes BA plus user fees) is held constant through FY 2002, but BA is further reduced by about another 2.2% per year and replaced with additional user fees.

Description of Appeal: FDA is appealing for $167.1M to restore the BA eliminated by these proposed user fees in order to maintain our funding at the FY 1997 enacted level. **This is not the user fee model that OMB itself recognizes as successful.** If the appeal is not upheld, it would be catastrophic for FDA.

OMB's proposal runs counter to Congressional direction, and therefore would dramatically effect current negotiations with the Congress on FDA reform and PDUFA reauthorization. This proposal will force the kind of FDA reform long opposed by the Administration. If we send a budget to the hill with a $170 million gap to be filled by new user fees, Congress may instead choose to make it up by giving product review responsibility to third parties. This will jeopardize the quality of FDA's review of products, and in turn, threaten the public health.

We have worked hard for several years to convince industry that user fees should be supported. The industry has been split down the middle as to whether to accept such fees. The drug industry has finally accepted them, for new reviews, and is paying millions of dollars. There is optimism that other industries can be brought along for licensing fees to get new products on the market. However, if we push for user fees for enforcement, industry will see it as purely a tax, which they have adamantly opposed. That approach might well unify industry against all user fees, undermine the negotiations with the drug industry on reauthorizing prescription drug user fees, and negate any hope of getting other industries to accept such fees.

Given Congress' and the industry's opposition, the likelihood of enacting legislation for non-additive user fees in the coming Congress is virtually zero. If Congress is forced to fill the $170M gap from appropriated funds, it will greatly harm the Administration's chances to add new funding in high priority areas such as tobacco and food safety.

The magnitude and risk of the reduced appropriation levels contained in the OMB passback would lead to an overall reduction of 20% for FDA core public programs in FY 1998. These cuts would cripple the Agency and destroy its ability to protect the public health. Given the lack of support for these kinds of user fees in the past, FDA would be forced to plan for the worst-case scenario, absorbing the 20% reduction in funding. **Beginning in FY 1997**, we would be forced to implement draconian and dangerous cuts to programs and personnel, eliminating essential programs and drastically cutting others. Some examples of the negative public health consequences follow:

-- The safety of the Nation's blood supply would be jeopardized. Blood bank inspections would be reduced and resources available to review and approve blood license applications would plummet.
-- Frequency and effectiveness of food safety evaluations and establishment inspections would be reduced, leading to increased incidence of microbiological and chemical hazards. Over the past 10 years, the number of inspections has dropped significantly, and recalls have increased dramatically.
-- Improvements in the device review process would be negated; review times would revert to pre-FY 1995 levels which are unacceptable to Congress and the Administration.
-- Under current law, PDUFA would not be triggered. FDA could not collect fees and approval times would revert back to pre-1992 drug approval times.
-- A virtual shut-down of the Animal Drug review process would occur. The result would be increased animal drug/feed contamination -- a threat to the safety of the nation's food supply.

The Administration has commended FDA for its efforts to reduce teen smoking; for its reinvention initiatives in the areas of foods, drugs and medical devices; and, for reducing the burden on industry while improving agency efficiency. FDA has worked hard with both industry and Congress to forge FDA reform proposals that are acceptable to both parties without jeopardizing the health of American consumers. FDA has serious concerns about the inclusion of unauthorized user fees in its budget proposal to Congress. However, FDA is keenly aware of the value of additive user fees to the accomplishment of its mission. The implementation of this type of user fee in the form of PDUFA has had exemplary results. Benefits of the program are wide-spread. Industry gets a faster, more predictable process, FDA accomplishes its mission through improved performance without sacrificing quality, and consumers receive safe and effective products more quickly. Also, FDA has advanced similar user fee proposals for medical device review and the processing of imports, which have not been authorized by the Congress in the past.

## FOOD AND DRUG ADMINISTRATION

### Appeal Item #2) Provide Funding for Food Safety Inter-Agency Initiatives (Dollars in Millions)

| | 1996 Enacted | 1997 Enacted | 1998 Amended Request | 1998 OMB | 1998 Appeal #2 |
|---|---|---|---|---|---|
| BA | $876.9 | $887.6 | $1,104.1 | $727.1 | +$53.4 [1/] |
| Prog. Level | $979.9 | $995.9 | $1,235.2 | $1,015.1 | +$53.4 |
| Outlays | $875.3 | $923.9 | $1,046.1 | $758.8 | $40.7 |

Description of OMB Passback: No funding is provided for FDA's role in the Interagency Food Safety Initiative.

Description of Appeal: FDA is appealing $53.4 million and 293 FTEs for its part of the multi-agency (CDC, USDA, EPA and FDA) Food Safety Initiative. President Clinton and Vice-President Gore have begun an important and overdue restructuring of our nation's food safety programs. The President signed landmark pesticide legislation and revolutionized meat, poultry, and seafood safety regulations. These were important steps forward. Funding this initiative will help to completely fulfill their vision by providing resources to improve **coordination** between Federal and State agencies in the management of response to foodborne illness; enhance the infrastructure for **inspections** and **early warning system/surveillance** activities to strengthen regulatory capabilities; and improve **education, risk assessment**, and **research** efforts. Also, funding would be provided for premarket activities to enhance the review processes for new animal drug applications and for new food additives petitions.

> **Early Warning System/Surveillance** -- $4.680 million and 15 FTEs. Improve strategies to ensure rapid and early detection of foodborne illness outbreaks and dissemination of information to facilitate response, thereby decreasing the total number of cases of foodborne related deaths and illness by 2 percent. This funding would also create a national electronic network for comparison of bacterial "fingerprints", expand the Sentinel Site project to assure appropriate geographic diversity of the network, cover a greater portion of the nation's population and larger spectrum of foodborne pathogens, increase the number of experts to investigate and control foodborne disease outbreaks, and enhance surveillance for foodborne pathogens in food animals and feed, monitor laying hens and egg products before pasteurization for Salmonella.

1/ In addition, we are seeking $19.1 million to fund 190 HACCP FTEs which should be transferred to HHS from the Department of Commerce.

**Coordination** -- $1.000 million and 2 FTEs. Unify the considerable existing expertise of Federal, State, and local health authorities, by creating a Federal emergency response system designed to better manage outbreaks, ensure interagency collaboration, and provide advanced communications networks with the capability to speed information to experts nationwide, and enhancing infrastructure for foodborne illness surveillance and coordination at State health departments.

**Inspections** -- $27.602 million and 201 FTEs. Establish an effective infrastructure for a nationwide HACCP-based system for seafood, and expand Federal/State inspection partnerships to monitor the nation's food supply. Twenty percent of all foodborne related deaths and illness can be eliminated via this enhanced inspection partnership program. Funding would also enhance foodborne pathogen testing by all HACCP programs, provide a greater coverage of the ever-increasing imported food-product supply, and upgrade food inspection programs by transferring 190 inspectors from the National Marine Fisheries Service.

**Education** -- $7.030 million and 23 FTEs. Launches an educational campaign focused on preventive measures for improved food safety. More than 50 percent of food related deaths and illnesses may be caused by unsafe preparation practices. This portion of this initiative could reduce food related death and illness by 1 percent per year. Our focus is to improve food safety education campaigns targeted to consumers, retail, institutional and food services, veterinarians and producers, the transportation industry, and laboratory scientists in state and local health departments.

**Risk Assessment** -- $10.330 million and 21 FTEs. Develop methodology to evaluate surveillance plans, risk reduction strategies, implementation of HACCP practices, and research programs. The result is a more focused critical control point and far less costly than the current "scattershot" approach. Further, funding would establish an interagency risk assessment consortium to further develop and strengthen food safety risk assessment research and methods development, ensure development of high-quality, high-priority biological data and develop/validate exposure data and models, initiate research on the use of biomarkers of exposure and effect, and initiate research on target-dose toxicokinetics.

**Bioscience Research** --$13.870 million and 31 FTEs. Enhance research science capabilities to develop new and improved methods for rapid testing of microbial and chemical contaminants, and better understanding of antibiotic resistance. Research activities are pivotal to the success of the Inspection and Risk Assessment parts of the initiative. Funding would also strengthen scientific programs to achieve a more comprehensive collaborative food safety program, improve methods to detect, control, reduce and eliminate foodborne pathogens, and develop data for strategies to counter development of antibiotic resistance in pathogens.

**Premarket Activities** -- $8 million. Enhance activities required to process applications for new food animal drugs and for petitions for new food additives.

Americans rightly expect to have the world's safest food supply. Although it is among the safest, it is not safe enough. There is a growing risk that a serious outbreak of food-borne illness such as the one that recently made thousands ill across Japan could strike the U.S. The Centers for Disease Control and Prevention (CDC) estimates that 9,000 deaths and 33 million illnesses in the U.S. each year are food-related.

The 21st century will present new and greater challenges. Novel pathogens are emerging. Long-understood pathogens are growing resistant to the treatments we have relied upon. Lowering of trade barriers has led to record levels of food imports. Rapid delivery services routinely move food from the furthest reaches of the world to the American meal table overnight. These changing circumstances require greatly strengthened systems of prevention, surveillance, research, targeted illness reduction, coordination, and education.

More than 30 million U.S. citizens are considered to be at high risk for diseases from foodborne microorganisms. Every hour of every day, one American dies from *preventable* foodborne diseases. These 'high-risk' individuals include the portion of the population age 65 or older, and those who are chronically ill. Full implementation of the Food Safety Initiative can save up to the lives of 2,600 American citizens every year, and reduce the number of foodborne illness by 8.8 million every year.

## FOOD AND DRUG ADMINISTRATION

### Appeal Item #3) Provide Funding for the President's Tobacco Initiatives (Dollars in Millions)

| | 1996 Enacted | 1997 Enacted | 1998 Amended Request | 1998 OMB | 1998 Appeal #3 |
|---|---|---|---|---|---|
| BA | $876.9 | $887.6 | $1,104.1 | $727.1 | +$55.0 |
| Prog. Level | $979.9 | $995.9 | $1,235.2 | $1,015.1 | $55.0 |
| Outlays | $875.3 | $923.9 | $1,046.1 | $758.8 | $42.0 |

Description of OMB Passback: The FDA passback provided $5M to fund the President's tobacco initiatives.

Description of Appeal: On August 23, 1996, President Clinton announced his Administration's plan for the regulation of nicotine-containing tobacco products. FDA is appealing $55M and 54 FTEs for the costs associated with implementing, and enforcing the final rule on this regulation.

The President is committed to a goal of decreasing young people's use of tobacco 50% over seven years. In four years, at the end of his term, the President will be judged on how well this goal was achieved. Even under the best circumstances, this goal is ambitious and will be difficult to reach. However, without these resources, we will not be able to even begin moving toward the goal.

Every year, another 1 million young people become regular smokers, and one-third of them will eventually die prematurely as a result of their smoking. Smoking is the leading preventable cause of death in the United States. Tobacco products are responsible for more than 400,000 deaths annually due to cancer, respiratory illness, heart disease, and other health problems. According to CDC, health care costs associated with smoking soared to more than $50 billion in 1993.

FDA's continued investments in promoting and protecting the health of our youth is essential to the future of our nation's well-being, and will be accomplished through reduced availability and appeal of tobacco products to children and teenagers, and education of young people about the health risks of tobacco use. FDA plans to carry out a major portion of this initiative through State contracts amounting to about $30M.

THE FOOD AND DRUG ADMINISTRATION

Food Safety

QUESTION:

Why can't this initiative be done using user fees? Especially seafood?

ANSWER:

- User fees of this type are not the type which are authorized under the general User Fee statute. This statute authorizes regulations to collect fees for product approvals, but not general public benefit activities such as inspections and other activities which are intended to be funded from appropriations at large.

- We have worked hard for several years to convince industry that user fees should be supported. The industry has been split down the middle as to whether to accept such fees. The drug industry has finally accepted them, for new reviews, and is paying millions of dollars. There is optimism that other industries can be brought along for licensing fees to get new products on the market. However, if we push for user fees for enforcement, industry will see it as purely a tax, which they have adamantly opposed. That approach might well unify industry against all user fees, undermine the negotiations with the drug industry on reauthorizing prescription drug user fees, and negate any hope of getting other industries to accept such fees.

- For seafood, the Commerce Department's National Marine Fisheries Service offers a "voluntary" inspection program on processed seafood. This voluntary, fee for service program in which only about 20 percent of seafood processors participate, is perceived by the regulated industry as fundamentally different than the mandatory public health seafood inspection program performed by the FDA.

THE FOOD AND DRUG ADMINISTRATION

Food Safety

QUESTION:

Why is it important to do the Food Safety Initiative now?

ANSWER:

- President Clinton and Vice-President Gore have begun an important and long overdue restructuring of our nation's food safety programs. The President signed landmark pesticide legislation and revolutionized meat, poultry, and seafood safety regulations.

- The 21st century will present new and greater challenges. Novel pathogens are emerging. Long-understood pathogens are growing resistant to the treatments we have relied upon. Lowering of trade barriers has led to record levels of food imports. Rapid delivery services routinely move food from the furthest reaches of the world to the American meal table overnight.

- Today, we are not ready -- We are prime for the same type of foodborne illness outbreak that hit the Japanese.

KEY INFORMATION:

- Funding this initiative will complete these initial steps by providing resources to improve **coordination** between Federal and State agencies in the management of response to food borne illness; enhance the infrastructure for **inspections** and **early warning system/surveillance** activities to strengthen regulatory capabilities; and improve **education**, **risk assessment**, and **research** efforts. Funding would be provided for premarket activities to enhance the review processes for new animal drug applications and for new food additives petitions.

- Americans rightly expect to have the world's safest food supply. Although it is among the safest, it is not safe enough. There is a growing risk that a serious outbreak of food-borne illness such as the one that recently made thousands ill across Japan could strike the U.S. The Centers for Disease Control and Prevention (CDC) estimates that 9,000 deaths and 33 million illnesses in the U.S. each year are food-related.

- More than 30 million U.S. Citizens are considered to be at high risk for diseases from food borne microorganisms. Every hour of every day, one American dies from *preventable* food borne diseases. These 'high-risk' individuals include the portion of the population age 65 or older, and those who are chronically ill. Full implementation of the Food Safety Initiatives can save the lives of 2,600 American citizens every year, and reduce the number of food borne illness by 8.8 million every year.

THE FOOD AND DRUG ADMINISTRATION

Food Safety

QUESTION:

The food safety initiative includes a request to transfer 190 FTEs (their seafood inspectors) from the Department of Commerce to HHS. Is the Department of Commerce on board with this?

ANSWER:

- We have discussed transfer of the FTEs only, not any funding for the program. In reality, since the current DOC program is based on a voluntary user fee program, there are no dollars that would transfer to pay these inspectors. Our proposal includes funding for these FTEs.

KEY INFORMATION:

- The Commerce Department's National Oceanographic and Atmospheric Administration (NOAA) oversees the National Marine Fisheries Service (NMFS). NMFS has various programs to assist and regulate marine resources, including marine laboratories and the protection of offshore fishing grounds from pollution. Another is a seafood inspection program, under which NMFS inspectors "grade" (i.e., provide a Commerce seal of quality) on processed seafood and inspect for safety (under the new HACCP safety procedures). The inspection program is a voluntary one in which about 20% of seafood processors participate. They pay a fee to NMFS for the service, which is supposed to be self-supporting.

- Although the NMFS inspection program is structured to pay for itself through user fees, it has been unable to recruit enough "customers" to do so, and the program began its first Reduction-in-Force this year. As a result, NOAA has offered the program to both FDA and USDA, neither of which had excess FTEs to absorb the approximately 190 FTEs that operate the program. However, those inspectors are skilled seafood experts who could carry out FDA's seafood inspection program, freeing up FDA inspectors to inspect other commodities that are currently under-inspected (e.g., canned goods, fruit juices, dairy products and many others).

- NOAA officials have had repeated conversations with FDA relative to FDA's absorption of these inspectors, and NOAA has seen a draft of our food safety report. Their response thus far is that they have no objection to the proposal, although they have not sought an official concurrence from the Secretary of Commerce.

THE FOOD AND DRUG ADMINISTRATION

Tobacco

QUESTION:

Why can't this initiative be done using user fees?

ANSWER:

- The implementation and enforcement activities planned by FDA for tobacco are not the type for which fees are authorized under the general User Fee statute. This statute authorizes regulations to collect fees for product approvals, but not general public benefit activities such as inspections, outreach, enforcement, and education, which are intended to be funded from appropriations at large.

- Also, it is not clear to whom such user fees would be assessed. Tobacco producers, retailers and users would view any such fee as a tax.

THE FOOD AND DRUG ADMINISTRATION

Tobacco

QUESTION:

Why does this cost so much? When we began discussing this, we didn't believe it would cost so much.

ANSWER:

- In terms of potential lives saved and the reduction in medical costs, this proposal is very inexpensive.
- The scope of the problem is enormous and successfully dealing with it is costly.
- Additionally, the original figure was a mere placeholder because FDA had not yet devised its implementation and enforcement plan for the final rule.

KEY INFORMATION:

- Our final rule is aimed at tackling the leading preventable cause of death and disease in the United States. Annual health care costs associated with treating tobacco-related diseases is around $50 billion. Even if we reduce this by one percent -- a conservative estimate -- we have avoided health care costs of $500 million, nearly 10 times the amount of our proposed investment of $60 million investment.
- Half of the request is for funds that go directly to the states for implementation and enforcement of the final rule. To effectively enforce this rule, we need to have coverage across the nation and have enough of a presence to provide a deterrence effect.

THE FOOD AND DRUG ADMINISTRATION

Tobacco

QUESTION:

Why are we doing this?

ANSWER:

➤ The President is committed to a goal of decreasing young people's use of tobacco 50% over seven years. Without these resources, we will not be able to even begin moving toward the goal. We need to fund this initiative to support the President's courageous stand taken shortly before the election.

KEY INFORMATION:

➤ The tobacco initiative is one of the President's major domestic accomplishments. But there is unfinished business. We now have a final rule to implement and enforce. In four years the President needs to be able to point at his accomplishments in reducing young people's tobacco use. The only way he will be able to do that is by adequately funding the implementation and enforcement of FDA's final rule starting right now.

THE FOOD AND DRUG ADMINISTRATION

User Fees

QUESTION:

Even if the OMB plan is ambitious, why not send it up to let Congress fix the budget problem, like in past years?

ANSWER:

- The OMB plan runs counter to Congressional direction and strong opposition to deficit reduction user fees to fund FDA's core programs. It dilutes the credibility of the budget and threatens the public health.

- This plan places Congress in the position of robbing Peter to pay Paul, thus exacerbating an already cumbersome process.

- This proposal jeopardizes the current FDA reform negotiations underway with industry and Congress.

- This passback will alienate industry negotiators working with FDA to reauthorize PDUFA.

KEY INFORMATION:

- Reducing FDA's base and promoting deficit user fees is neither reasonable nor feasible. Based on the voice of Congress, this is a failed strategy that threatens funding for important public health programs if reduced appropriations occur, but user fee legislation does not pass.

- FDA is working hard with both industry and Congress to forge an FDA reform that is acceptable to both parties without jeopardizing the health of the American consumers. The Administration and Congress have commended FDA for its efforts to reduce teen smoking, for its reinvention initiatives in the area of foods, drugs, and medical devices, and reducing the burden on industry while improving agency efficiency. Investment resources provided by PDUFA have resulted in the U.S. approving products as fast or faster than any country in the world. The user fee proposal runs the risk of diminishing these innovative models for improvements and undermines the work already accomplished with industry and Congress -- instead it provides a further opportunity for FDA opponents who would rather bash the Agency than engage in a meaningful dialogue on ways to improve FDA's performance.

- Should Congress accept the reduced appropriation levels contained in the OMB passback for FDA, it will mean an overall reduction of 21% for FDA core programs. These cuts will cripple the Agency and destroy its ability to protect the public health.

-- The safety of the Nation's blood supply would be jeopardized, blood bank inspections would be reduced and resources available to review and approve blood license applications will be reduced.

-- Evaluations and establishment of inspections for food safety would be dramatically lessened, thus increasing the incidence of microbiological and chemical hazards.

-- Improvements in the device review process would be eliminated and review times would revert to pre-FY 95 levels which are unacceptable to Congress.

-- Under current law PDUFA would not trigger, thereby disallowing FDA from collecting fees and reverting back to the exceedingly long pre-1992 approval times.

THE FOOD AND DRUG ADMINISTRATION

User Fees

QUESTION:

Why does everything have to be additive, this is a difficult budget year if we are going to balance the budget. Don't we have to look ahead to make industry pay for these services?

ANSWER:

- A guiding principal of PDUFA, and key to industry and Congressional support, is the additive nature of the user fee resources. This model improved public health programs, while at the same time yielded economic benefits to the regulated industry in the form of improved and predictable performance. OMB's user fee passback runs counter to the lessons of PDUFA.

- We believe the user fee passback will bolster industry's long held suspicion that additive user fees lead to deficit reduction user fees. Industry will merely step up its opposition to any user fee proposal, even additive user fees.

- The passback would have the immediate effect of alienating industry negotiators working with FDA to reauthorize PDUFA.

KEY INFORMATION:

- Negotiations currently underway with industry to reauthorize PDUFA indicate they are adamant about maintaining the additive nature of the fees and the current proportion to total program costs (36% industry, 64% FDA). Industry is only supportive of additional user fees for increased performance -- not the agency's base. Industry would immediately oppose such fees in Congress, endangering the success FDA and industry have achieved over the last 5 years.

- If PDUFA is not reauthorized, FDA would be forced to eliminate 700 FTE which would quickly return the program to 30 month review times. Backlogs would reappear and many of the innovative initiatives and incentives created under PDUFA would erode.

- Industries' opposition to replacing base resources with user fees, is the same whether it's the Pharmaceutical companies, food manufacturers, device manufacturers or animal drug manufacturers::

  -- The food industry has consistently opposed the idea of paying user fees. This position is reflected in a statement issued by the Grocery Manufacturers of America (GMA),

Inc., on February 16, 1994, where GMA and 21 other FDA regulated industries rejected the Administration's proposal to fund part of FDA's FY 95 budget through the imposition of user fees. This position was reiterated as recently as December 11, 1996, bu a representative of the GMA in a presentation before the Food and drug Law Institute's annual conference.

-- About 80 percent of the U.S. device industry that submit device marketing applications to FDA are small businesses. These firms have said consistently in the past that user fees to support a program about half the size of the one proposed would put them out of business or force them to relocate jobs overseas, thereby hurting the competitiveness of small business.

-- The main reason behind industry support for device user fees in the past was that they thought user fees would be structured incrementally so they could pay more for better performance. However, the main reason why device user fees were not successfully enacted in the past was the suspicion that the user fees would be used to offset the base. Given their concern, industry would vehemently oppose this proposal. The additive user fees proposed by FDA in the FY1998 budget would be the best approach to enact viable user fees for medical devices.

-- Under the OMB passback, the Animal Drug industry would pay 26 million for services they already receive. While the animal drug and feed industry might be willing to pay user fees for <u>additive</u> services, they would be unlikely to support such fees just to maintain the services they have now. Under this plan, FDA would not be able to improve its processes to help accelerate review of products. It is expected that there would be a decrease in service because of the cost of design and implementation would be covered by the user fees.