Significant Items in Appropriations Committee Reports

FDA's execution of all the significant items identified below is subject to the requirements in the final FY 2007 appropriations act for FDA.

House Significant Items

NOTE: Unless otherwise indicated, page numbers refer to House Report 109-463.

Item

Personnel -- The Committee directs that within the amount provided for food safety and counterterrorism activities, priority should be given to maintaining existing personnel and operations that are critical to ensuring the safety of domestic and imported food, rather than funding new functions, grants, or agreements. (Page 114)

Action Taken or to be Taken

As in FY 2006, FDA will ensure that existing personnel and operations critical to ensuring the safety of domestic and imported food are maintained before funding new functions, grants, or agreements.

Item

Expedited filing -- The Committee directs the Commissioner to expedite and support the filing, review, and final action on any new drug application, or supplement to a new drug application seeking approval or a reformulated and active ingredient previously-approved as safe and effective, or of a combination of active ingredients previously-approved as safe and effective, that would replace or provide a therapeutic alternative to a currently-marketed drug product that contains an active ingredient that currently is the subject of diversion and/or abuse outside regulated channels of commerce. (Page 115-116)

Action Taken or to be Taken

There are several provisions in the Act and regulations that already authorize FDA to expedite the review of certain drug applications (e.g., fast track products in section 506 of the Act and accelerated approval under21 CFR 314.500). FDA may exercise flexibility in applying these statutory standards of safety and effectiveness to expedite the development, evaluation, and marketing of new drugs intended for life-threatening or severely-debilitating diseases. FDA will take that flexibility into consideration when faced with a therapeutic alternative to a currently-marketed drug product that contains an active ingredient that currently is the subject of diversion and/or abuse outside of regulated channels of commerce.

Item

Orphan products -- The Committee directs that no less than $14,696,000 be available for grants and contracts awarded under section 5 of the Orphan Drug Act, an increase of $147,000 above the amount available in fiscal year 2006. (Page 116)

Action Taken or to be Taken
Expenditures on orphan product grants and contracts are subject to the requirements in the final appropriations act for FDA.

Item
Financial management -- The Committee directs that no more than $9,389,000, the same amount as fiscal year 2006, is available for UFMS, and requires a quarterly report on the expenditures. The Committee reiterates that any additional costs for this purpose, either direct or by transfer, are subject to approval by the Committee. (Page 116)

Action Taken or to be Taken
FDA plans to limit fiscal year 2007 spending for UFMS to the fiscal year 2006 level of $12,896,000. This number reflects a 1 percent rescission under Public Law 109-148 applied to $13,026,000, the amount specified in the FY 2006 Appropriations Public Law 109-148. FDA will prepare quarterly spending reports will be prepared and submitted one month after the end of each quarter. Any significant changes to these estimates will be addressed through an official request. The above statements in response to this significant item are subject to the requirements in the final appropriations act for FDA.

Item
Food Safety -- The Committee recognizes the contributions which the National Center for Food Safety and Technology (NCFST) is making toward ensuring the security of the nation's food supply. The Committee directs that FDA provide the fiscal year 2006 funding level to NCFST through the cooperative agreement. This funding shall be exclusive of any additional initiative funds that FDA may award to NCFST. (Page 116)

Action Taken or to be Taken
A five-year renewal of the cooperative agreement with NCFST was completed in FY 2004. Subject to the requirements in FDA's FY 2007 appropriations act, FDA plans to continue to provide funding support to NCFST. The Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $3,000,000 specified in the FY 2006 Congressional report.

Item
Test method evaluation -- The Committee directs that the agency continue its contract to conduct method evaluation of rapid test methods of fresh fruits and vegetables for microbiological pathogens with New Mexico State University's Physical Science Laboratory at the fiscal year 2006 level. (Page 116)

Action Taken or to be Taken
New Mexico State University (NMSU) is evaluating rapid test methods for microbiological analyses in food samples under the Rapid Commercial Test Kit Evaluation Program. NMSU's evaluation includes the assessment of rapid test methods for a particular analyte(s) or food commodity to be measured against the FDA Bacteriological Analytical Manual. Additionally, NMSU is evaluating new methods including screening, technologies, instrumentation, and data analysis for toxic chemical

analyses in various food or other FDA regulated product matrices. NMSU will examine the use of these rapid test methods in the arena of Food Defense. Interim counter terrorism methods have been developed for the rapid identification of agents of bioterrorism, but require further evaluation against food matrices of interest. NMSU serves to provide the validation of these counterterrorism methods. The FY 2007 amount for NMSU is subject to the requirements in the final appropriations act for FDA.

Item
DNA UV Molecular Filters -- The Committee directs the FDA to survey potential new methods of protection from UV induced DNA damage and to provide a report to the Committee by July 1, 2007 that describes new technologies and potential ways for the FDA to assist in bringing forth such additional methods of preventing skin cancer. (Page 116)

Action Taken or to be Taken
The FDA recognizes the public health importance of new methods of protection from UV induced DNA damage and is working on a report to Congress. FDA expects to meet the July 1, 2007 deadline.

Item
Consolidation -- The Committee directs DHHS to include all future consolidations that impact FDA in the President's budget request submitted to Congress. (Page 117)

Action Taken or to be Taken
FDA will submit all planned consolidations that impact the President’s budget request to the Committee.

Item
Fees -- The Committee directs that none of the funds made available to FDA in this bill be for any assessments, fees, or charges by DHHS or any other Department or Office unless such assessments, fees, or charges are identified in the FDA budget justification and expressly provided by Congress, or approved by Congress in the official reprogramming process as required in the General Provisions of this bill. (Page 117)

Action Taken or to be Taken
The Committee directs that none of the funds made available to FDA in this bill be for any assessments, fees, or charges by DHHS or any other Department or Office unless such assessments, fees, or charges are identified in the FDA budget justification and expressly provided by Congress, or approved by Congress in the official reprogramming process as required in the General Provisions of this bill. FDA has included a table and exhibit in this document, the Congressional Justification, entitled “DHHS Charges and Assessments.” This table and exhibit list the actual and estimated fees or charges from DHHS. We have also included an exhibit on “Funding from Outside Sources.” Any significant changes to these estimates will be handled through an official reprogramming.

Item

Shellfish safety -- The Committee expects that FDA will continue its work with the Interstate Shellfish Sanitation Commission (ISSC) to promote educational and research activities related to shellfish safety in general, and Vibrio vulnificus in particular. The Committee directs the use of not less than $250,000 for this effort. In addition, the Committee expects that FDA will continue its work with ISSC through a memorandum of understanding, and that FDA will devote not less than $200,000 to that work. The Committee expects the FDA to require all states to work cooperatively in conformity with the National Shellfish Sanitation Program implemented by the ISSC. (Page 117)

Action Taken or to be Taken

Expenditures for ISSC are pending resources available in a final enacted FY 2007 Agriculture appropriations bill. However, FDA plans to continue support education and outreach on *Vibrio vulnificus.*

FDA also plans on continuing to work cooperatively with all relevant states in accord with the ISSC's National Shellfish Sanitation Program. These joint efforts include actions to encourage the use of post-harvest treatment by the shellfish industry (e.g., improvements in validation of treatment methods, marketability studies), education of at-risk consumers on the risks posed by the organism, and monitoring of the frequency of occurrence of *Vibrio vulnificus* illnesses.

Item

WERC -- The Committee expects the FDA to continue its support for the Waste Management Education and Research Consortium (WERC) and its work in food safety technology verification and education at the fiscal year 2006 level. (Page 117)

Action Taken or to be Taken

In FY 2006, FDA funded $98,200 to a grant awarded in 1995 to continue support for the Waste Management Education and Research Consortium and its work in food safety technology verification and education. The Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $99,200 specified in the Congressional report. Expenditures for WERC are subject to the requirements in the final appropriations act for FDA.

Item

Sec. 742. None of the funds made available in this Act may be used— (1) to grant a waiver of a financial conflict of interest requirement pursuant to section 505(n)(4) of the Federal Food, Drug, and Cosmetic Act for any voting member of an advisory committee or panel of the Food and Drug Administration; or 2) to make a certification under section 208(b)(3) of title 18, United States Code, for any such voting member. (H.R. 5384 as passed by the House, Page 79-80)

Action Taken or to be Taken
The House and the Senate have not reached an agreement on bill language related to this item. FDA is waiting on final action on the FY 2007 appropriations bill and will implement the legislative provision enacted into law based on the terms of the statute.

Item
None of the funds appropriated or otherwise made available by this Act for the Food and Drug Administration may be used under section 801 of the Federal Food, Drug, and Cosmetic Act to prevent an individual not in the business of importing a prescription drug within the meaning of section 801(g) of such Act, wholesalers, or pharmacists from importing a prescription drug which complies with sections 501, 502, and 505. (H.R. 5384 as passed by the House, Page 81-82)

Action Taken or to be Taken
The House and the Senate have not reached an agreement on bill language related to this item. FDA is waiting on final action on the appropriations bill and will implement the legislative provision enacted into law based on the terms of the statute.

Item
Of the total amount made available in title VI in the first undesignated paragraph under the heading 'FOOD AND DRUG ADMINISTRATION—SALARIES AND EXPENSES'', $1,000,000 is available to the Center for Veterinary Medicine for application review activities to assure the safety of animal drugs with respect to antimicrobial resistance, pursuant to section 512 of the Federal Food, Drug and Cosmetic Act, in addition to all other allocations for such purpose made from such total amount. (Page 82-83).

Action Taken or to be Taken
Expenditures for antimicrobial resistance are subject to resources available in a final enacted FY 2007 Agriculture appropriations bill. Antibiotic resistance is a significant concern that affects both human and animal health. The Center of Veterinary Medicine plans on using $1,000,000 in resources appropriated to the Animal Drugs and Feeds Program to conduct application review activities designed to assure the safety of animal drugs with respect to antimicrobial resistance, as authorized by the Federal Food, Drug, and Cosmetic Act. FDA has a strategic framework in place to vigorously address antimicrobial resistance. This framework has allowed FDA to wage an effective fight against antimicrobial resistance.

Item
None of the funds made available in this Act may be used to send or otherwise pay for the attendance of more than 50 employees from a Federal department or agency at any single conference occurring outside the United States. (H.R. 5384 as passed by the House, Page 83)

Action Taken or to be Taken

For each delegation FDA sends outside the United States, for at least the past decade, FDA has had a process in place to ensure that we only send the minimum number of officials needed to carry out the public health mission. FDA will conform to the report provision should it be included in a final enacted FY 2007 Agriculture appropriations bill.

Senate Significant Items

H.R. 5384 as reported by the Senate
NOTE: Unless otherwise indicated, page numbers refer to Senate Report 109-266.

FDA's execution of all the significant items identified below is subject to the requirements in the final FY 2007 appropriations act for FDA.

Item
Advisory Committees -- The Committee believes that FDA should try to find sufficiently qualified candidates for its advisory committees with minimal or no potential conflicts of interest and requests a semi-annual report on FDA's efforts to find such candidates. In cases where individuals are appointed that have medium or high involvement as specified in the FDA Waiver Criteria 2000 document, the Committee requests that FDA provide a rationale for the appointment, including: the lack of other available experts; the individual offers considerably more expertise than other willing candidates; or there are no willing candidates who have no or low involvement as specified in the FDA Waiver Criteria 2000 document. (Page 139)

Sec. 742. Advisory Committees - (a) Subject to subsection (b), none of the funds made available in this Act may be used to— (1) grant a waiver of a financial conflict of interest requirement pursuant to section 505(n)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.355(n)(4)) for any voting member of an advisory committee or panel of the Food and Drug Administration; or (2) make a certification under section 208(b)(3)of title 18, United States Code, for any such voting member. (b) Subsection (a) shall not apply to a waiver or certification if—(1)(A) not later than 15 days prior to a meeting of an advisory committee or panel to which such waiver or certification applies, the Secretary of Health and Human Services discloses on the Internet website of the Food and Drug Administration— (i) the nature of the conflict of interest at issue; and (ii) the nature and basis of such waiver or certification (other than information exempted from disclosure under section 552 of title 5, United States Code); or (B) in the case of a conflict of interest that becomes known to the Secretary less than 15 days prior to a meeting to which such waiver or certification applies, the Secretary shall make such public disclosure as soon as possible thereafter, but in no event later than the date of such meeting; and (2)(A) not later than 15 days prior to a meeting of an advisory committee or panel, the Secretary of Health and Human Services discloses on the Internet website of the Food and Drug Administration— (i) any recusal due to the potential for conflict of interest, and (ii) the nature of the conflict of interest at issue (other than information exempted from disclosure under section 552 of title 5, United States Code); or (B) in the case of a recusal that becomes known to the Secretary less than 15 days prior to a meeting to which such recusal applies, the Secretary shall make such public disclosure as soon as possible there after, but in no event later than the date of such meeting. (c) None of the funds made available in this Act may be used to make a new appointment to an advisory committee or panel of the Food and Drug Administration unless the Commissioner of Food and Drugs submits a semi annual report to the Inspector General of the Department of Health and Human Services and the Committees on Appropriations

of the House and Senate, the Energy and Commerce Committee of the House, and the Health, Education, Labor, and Pensions Committee of the Senate on the efforts made to identify qualified persons for such appointments with minimal or no potential conflicts of interest. Such report must include a description (that identifies no individual by name or affiliation), by advisory committee or panel, of the types of experts sought, the number of candidates considered, the number of those candidates willing to serve, the number of those willing to serve who have no or low involvement as specified in the FDA Waiver Criteria 2000 document, the number of new appointees that have no or low involvement as specified in the FDA Waiver Criteria 2000 document, the number of vacancies remaining, the number of meetings and waivers granted by type of meeting, and, when an individual who has a medium or high involvement as specified in the FDA Waiver Criteria 2000 document is appointed, the rationale for such appointment. (H.R. 5384 as reported by the Senate, Page 163 - 166)

Action Taken or to be Taken

The House and the Senate have not reached an agreement on bill language related to this item. FDA is waiting on final action on the appropriations bill and will implement the legislative provision enacted into law based on the terms of the statute.

Item

Agricultural Products Food Safety Laboratory -- The Committee recommends no less than the fiscal year 2006 amount for the FDA's contract with New Mexico State University's Physical Sciences Laboratory to operate the Food Technology Evaluation Laboratory, which conducts evaluation and development of rapid screening methodologies, technologies, and instrumentation; and provides technology deployment, modeling, and data analysis for food safety and product safety, including advanced risk-based systems for screening and inspection, to facilitate FDA's regulations and responsibilities in food safety, product safety, homeland security, bioterrorism, and other initiatives. (Page 139)

Action Taken or to be Taken

The Committee recommends no less than the fiscal year 2006 amount for the FDA's contract with New Mexico State University's (NMSU) Physical Sciences Laboratory to operate the Food Technology Evaluation Laboratory. NMSU conducts evaluation and development of rapid screening methodologies, technologies, and instrumentation and provides technology deployment, modeling, and data analysis for food safety and product safety. This includes advanced risk-based systems for screening and inspection, to facilitate FDA's regulations and responsibilities in food safety, product safety, homeland security, bioterrorism, and other initiatives.

Under contract to FDA, NMSU Physical Science Laboratory has provided method assessment, development and validation data for targeted commodities identified as high profile/high risk for implementation into national food safety and food defense programs. Expenditures for NMSU are subject to the requirements in the final appropriations act for FDA.

Item

Authorized Generics -- The Committee is aware that amendments to the Hatch-Waxman Act (Public Law 98-417) provided 180 day marketing exclusivity to a generic drug that successfully challenges the patent of a name brand pharmaceutical company, and that the purpose of this exclusivity was to provide incentives to bring lower cost generic drugs to the market as quickly as possible. The Committee has been informed that "authorized" generics are entering the market at the same time as generic drugs, and is concerned that this practice may have the ultimate effect of decreasing the number of generic drugs that enter the market, keeping prices ultimately higher for the consumer. Therefore, the Committee strongly encourages FDA to work to ensure that incentives for generic drugs, which are currently written into law, are protected, and that consumers continue to have access to safe, effective generic drugs at the earliest possible time. (Page 139)

Action Taken or to be Taken

In July 2004, in response to two Citizen Petitions submitted by Teva Pharmaceuticals and Mylan Pharmaceuticals, FDA explained that it does not have legal authority to prohibit or delay marketing of authorized generics to protect 180-day exclusivity. In June 2005, in a suit by Teva, the Court of Appeals for the District of Columbia Circuit upheld FDA's reading of the statute. Subsequently, the Court of Appeals for the Fourth Circuit upheld the agency's interpretation as well.

FDA is aware of the industry and congressional concern about the effect authorized generics may have on pharmaceutical competition. The Federal Trade Commission has announced that it intends to conduct a study to analyze the use and likely short- and long-term competitive effects of authorized generic drugs in the prescription drug marketplace. FDA will assist this effort as necessary.

FDA continues to work to ensure that current incentives for generic drugs, including 180-day exclusivity, are protected. FDA also continues to take other actions to ensure that consumers have access to safe, effective generic drugs at the earliest possible time. For example, FDA has introduced a number of process changes and other quality systems approaches to enable improvements in the time it takes generic medicines to reach the market.

Item

Base Reductions -- The Committee believes that FDA should not abandon core food safety and research activities to fund other activities and is deeply concerned that the Agency took this approach in its fiscal year 2007 budget request. (Page 139 – 140)

Action Taken or to be Taken

FDA is waiting on final action on the appropriations bill and will implement the legislation based on the terms of the statute.

Item

Base Reductions -- The funding level in the Committee recommendation will permit the foods program to continue fiscal year 2006 activities including, but not limited to, facility inspection (including reinspection), the food contact notification program, review of food and color additive petitions, active participation in Codex Alimentarius, the cosmetics program, export certification, and monitoring for chemical contaminants. Further, the Committee recommendation will permit the National Center for Toxicological Research to maintain scientific expertise and continue important research to support the Critical Path initiative, biohazard identification, and the safety of FDA-regulated compounds. (Page 140)

Action Taken or to be Taken

FDA is waiting on final action on the appropriations bill and will implement the legislation based on the terms of the statute.

Item

Budget Justification -- The Committee directs the Agency to submit the fiscal year 2008 budget request in a format that follows the same account structure as the fiscal year 2007 budget request unless otherwise approved by the Committee. (Page 140)

Action Taken or to be Taken

FDA will notify the Committee of any proposed changes in account structure.

Item

Carcinogens -- The Committee believes that the FDA should conduct consumer testing on the wording and location of the current warning label on indoor tanning equipment and any proposed changes to the warning label to ensure that the appropriate risk information is being conveyed to consumers using sunbeds and sunlamps. This testing should take into account that exposure to sunbeds and sunlamps have been acknowledged as a known human carcinogen. In addition, the Committee believes it is important to receive public input on the labeling and any proposed changes and would encourage the FDA to hold public hearings on the issue. The Committee directs the FDA to conduct the above actions and to report back to Congress their findings within 120 days of enactment of this Act. (Page 140)

Action Taken or to be Taken

CDRH estimates that it needs 11 months to conduct consumer focus testing and hold public hearings on the proposed wording and location of warning labels on indoor tanning equipment. CDRH will compare the existing warning label with proposed changes to the warning label to ensure that the appropriate risk information is being conveyed to consumers using sunbeds and sunlamps. Currently, CDRH is drafting the moderator's guide for the focus testing. Subject to the results of the FY 2007 Agriculture appropriations bill, CDRH will prepare the contractual, OMB, and the Research Involving Human Subjects Committee (RIHSC) paperwork for review and clearance. Once the paperwork is complete, CDRH will recruit individuals for focus testing, conduct group sessions, prepare transcripts from the focus testing, analyze the findings, and

prepare the report. Following the consumer focus testing, CDRH will hold a public hearing to present the findings of the focus testing and obtain public input. CDRH will also address these activities in our report to Congress.

Item
Chloramphenicol -- The Committee continues to have serious concerns regarding seafood safety issues posed by banned antibiotic contamination in farm-raised shrimp imports. In addition, the Committee is concerned that the FDA inspects less than 2 percent of shrimp being imported into the United States. Therefore, the Committee strongly encourages the FDA to develop, in cooperation with State testing programs, a program for increasing the inspection of imported shrimp, possibly including cold-storage inventories, for banned antibiotics, including chloramphenicol. (Page 140)

Action Taken or to be Taken
In the United States, there is no established acceptable residue level of the antibiotic drug Chloramphenicol (CAP) in foods and its use is specifically prohibited in food producing animals in the United States due to its risk to human health. Since a safe level has not been established for this drug, the presence of any CAP residues in seafood renders products adulterated under the Federal Food, Drug, and Cosmetic Act. FDA's general policy is to place firms found exporting seafood testing positive for CAP to the United States on an Import Alert, which generally results in the detention of subsequent shipments from these firms called DWPE (Detention without Physical Examination).

In collaboration with U.S. Customs and Border Protection, FDA expanded its import seafood monitoring program for CAP residues to include crabmeat and crayfish in addition to shrimp. FDA also provides states with advice on analytical methodologies and our import controls.

The most recent sample analysis data show that FDA tested a total of 216 samples of imported and domestic seafood products (shrimp, crab and crayfish) for CAP residues between October 1, 2005, and September 30, 2006, with the following results:

- 1.5% of samples of shrimp tested positive for CAP in Vietnam and Malaysia.
- 11% of samples of crabmeat tested positive for CAP in Vietnam, Indonesia, and Brazil.
- No domestic samples tested positive for CAP residues.

At present, there are eleven shrimp exporters in China, Malaysia, Vietnam, Peru and Venezuela and eighteen crabmeat exporters in Vietnam, Indonesia, China and Brazil that are subject to FDA's DWPE (Detention without Physical Examination) for presence of CAP residues.

Due to a high rate of positive findings of unapproved drug residues (Malachite green, Fluoroquinolones, Nitrofurans, CAP) in aquaculture seafood products coming from Asia, FDA carried out two inspection missions to Vietnam and China in 2006. The selected

countries are the major producers of aquaculture products and exporters of seafood to the United States. The objective of these missions was to evaluate the countries' veterinary drug residues control system for farmed fish and attempt to determine existing problems with implementation of their measures and adequate control of drug use at the farm. FDA is working with these countries to ensure that control programs are put in place to address the issue of drug residues in aquaculture seafood products destined for the United States.

In FY 2007 and FY 2008, FDA intends to continue sampling and testing for seafood for CAP residues, as resources permit. Subject to available resources, FDA plans to visit countries from which manufactures/shippers are the most frequent violators to evaluate their aquaculture drug control systems, determine what additional regulatory steps are needed, and to provide any necessary assistance.

Item

Collaborative Drug Safety Research -- The Committee commends FDA for its work in developing the Critical Path Initiative to foster collaboration with outside researchers and develop new tools to both promote drug safety and accelerate the development of innovative new therapies. The Committee further commends the C-Path Institute, founded by the University of Arizona, for its innovative research efforts to develop more efficient tools for medical product development and drug safety. For this important effort, the Committee recommends no less than the fiscal year 2006 amount to support collaborative research with the C-Path Institute and the University of Utah on cardiovascular biomarkers predictive of safety and clinical outcomes. The Committee understands the research would involve identifying candidate genes and proteins in University of Utah databases, designing and conducting genomic and proteomic biomarker validation experiments by the C-Path Institute, the University of Utah, FDA and manufacturers, determining which biomarkers identify heart failure patients who are most likely to respond favorably to drug therapy and those at highest risk of adverse events. The Committee expects that this research will enhance patient safety, reduce the number of patients necessary for clinical testing, and enable manufacturers to accelerate drug development and bring safer, innovative life-saving drugs to market more quickly. (Page 141)

Action Taken or to be Taken

The Committee recommends no less than the fiscal year 2006 amount to support collaborative research with the C-Path Institute and the University of Utah on cardiovascular biomarkers predictive of safety and clinical outcomes. FDA plans on spending $742,500 to support collaborative research with the C-Path Institute and the University of Utah on cardiovascular biomarkers predictive of safety and clinical outcomes, subject to the requirements in our FY 2007 appropriations act. The Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $750,000 specified in the Congressional report.

In FY 2006, FDA received $750,000 from Congress for collaboration with the Critical Path Institute in Tucson, Arizona and the University of Utah specifically to "promote

drug safety and accelerate the development of innovative new therapies." In response, FDA executed a co-operative agreement with the Critical Path Institute, which put in place a Letter of Agreement with the University of Utah for the conduct of scientific and clinical studies in support of these goals. The results of these studies, along with independent FDA assessment and evaluation, will be placed in the public domain to ensure maximum utility by clinicians and to inform drug labeling and regulatory guidance development.

Item
Congressional Reports -- The Committee is concerned that, to date, FDA has transmitted only 5 of the approximately 13 reports requested in the Senate and conference reports accompanying the fiscal year 2006 appropriations bill. All of these reports should have been received by May 10, 2006. The Committee reminds FDA that reports to Congress play an important role in the Committee's decision making process. The Committee understands that FDA is aware of these concerns and has begun implementing a new process for preparing reports. The Committee directs FDA to take all necessary action to provide reports in a timely fashion. (Page 141 and 142)

Action Taken or to be Taken
FDA and the Department of Health and Human Services have implemented a process for submitting required reports to the Congress in a timely fashion. FDA will submit reports to the Congress consistent with the FY 2007 appropriations act.

Item
Dietary supplement Current Good Manufacturing Practice regulations -- The Committee is encouraged by FDA's activities to enforce provisions contained within the Dietary Supplement Health and Education Act of 1994 [DSHEA] (Public Law 103-417). The Committee has recommended funding to continue enforcement of the provisions contained in DSHEA. It is the Committee's intent that these funds be prioritized by the agency to step up activities against products that are clearly in violation of DSHEA. In addition, the Committee is concerned that Current Good Manufacturing Practice [CGMP] regulations, which have been under development for some time, have not been issued. Accordingly, the Committee directs FDA to issue the dietary supplement CGMP regulations. (Page 142)

Action Taken or to be Taken
Final regulations are under review and clearance by the Administration.

Item
FDA has indicated that the ability to identify and analyze specific components in ingredients, including botanical ingredients, is an essential component of research and regulatory programs directed at ensuring the safety and effectiveness of dietary supplements. The Committee recommends no less than the fiscal year 2006 amount for review of botanicals in dietary supplements. This work is being carried out by FDA in collaboration with the National Center for Natural Products Research, Oxford, Mississippi. (Page 142)

Action Taken or to be Taken

FDA will continue to identify and obtain botanical dietary ingredients of concern to FDA from a safety perspective, and determine research needs to support comprehensive safety evaluations. FDA will continue to acquire and characterize authenticated botanical materials, including raw plant materials, processed plant materials, and purified natural products. FDA scientists will continue to exchange technical and scientific information, methods, and botanical materials with NCNPR scientists and continue to build international network of botanical experts to meet needs for sourcing and identification. Expenditures on the National Center for Natural Products Research are subject to the requirements in the final appropriations act for FDA.

Item

Expedited filing -- The Committee directs FDA to expedite and support the filing, review, and final action on new drug applications or a supplement to a new drug application seeking approval of a reformulated active ingredient, or combination of active ingredients, previously approved as safe and effective that would replace or provide a therapeutic alternative to a currently marketed drug product that contains an active ingredient that is the subject of diversion and/or abuse outside regulated channels of commerce. (Page 142)

Action Taken or to be Taken

There are several provisions in the Act and regulations that already authorize FDA to expedite the review of certain drug applications (e.g., fast track products in section 506 of the Act and accelerated approval under21 CFR 314.500). FDA may exercise flexibility in applying these statutory standards of safety and effectiveness to expedite the development, evaluation, and marketing of new drugs intended for life-threatening or severely-debilitating diseases. FDA will take that flexibility into consideration when faced with a therapeutic alternative to a currently-marketed drug product that contains an active ingredient that currently is the subject of diversion and/or abuse outside of regulated channels of commerce.

Item

Food Labeling -- The Committee notes that FDA when approving qualified health claims is required to take into consideration the effect upon consumers' ability to understand labeling, and encourages the Agency to continue to do so. (Page 142)

Action Taken or to be Taken

FDA intends to conduct consumer research on disclaimers to help consumer understanding of qualified health claims and FDA intends to work to develop a research strategy regarding the role of symbols on food labeling in helping consumers construct healthful total daily diets. In addition, FDA intends to work toward rulemaking on Daily Values and prominence of calories on the Nutrition Facts label.

FDA completed a major study on consumer understanding of qualified health claims and shared its findings with the public in a public meeting held on November 17, 2005. FDA

also completed another major study on consumer understanding of authorized health claims and other health messages on food labels. FDA plans to post results of the study on its Web site in 2007.

Item
Food label enforcement efforts -- The Committee also notes that as part of FDA's labeling compliance program, FDA investigators review selected food labels during regularly scheduled food manufacturer inspections performed under the agency's food safety compliance programs. Approximately 28,000 field examinations of domestic and imported food labels were conducted between October 1, 2005 and December 6, 2005. The Committee believes that State food and drug officials can help supplement FDA

enforcement efforts, and encourages FDA to consult with the States to leverage the training and enforcement activities conducted by each entity. (Page 142-143)

Action Taken or to be Taken
The Committee believes that State food and drug officials can help supplement FDA enforcement efforts, and encourages FDA to consult with the States to leverage the training and enforcement activities conducted by each entity. FDA's nutrition labeling regulations, as required under the Nutrition Labeling and Education Act of 1990 (NLEA), include specific requirements for the nutrition labeling of foods

FDA leverages with states by way of a contractual agreements. FDA's current contract with states asks states to assist FDA investigators in the review of selected food labels to determine whether the labels are comply with nutrition labeling requirements as part of routine food manufacturer inspections under State contracts.

Item
Foodborne Illness -- The Committee is aware of the effective work of the Partnership for Food Safety Education to provide information to the general public about simple, common sense suggestions regarding safe food preparation and handling. Currently, the Partnership for Food Safety Education is working to develop a public education campaign aimed at populations vulnerable to listeria, including pregnant women and adults with weakened immune systems. The Committee believes this is a worthwhile effort, and encourages FDA to continue working with the Partnership for Food Safety Education in executing this education campaign. In addition, the Committee encourages the FDA to provide funding, as appropriate, to support this collaborative effort. (Page 143)

Action Taken or to be Taken
As specified by the Memorandum of Understanding (MOU) between FDA and the Partnership for Food Safety Education (the "Partnership"), FDA continues to fulfill its coordination and programmatic participation and supply in-kind services and materials to promote food safety measures. The Partnership has established three work groups to carry out its initiatives: public education and web activities, program evaluation and outreach. During FY 2007, FDA celebrates 10 years of participating in the Partnership,

which provides information to the general public about simple, common sense suggestions regarding safe food preparation and handling.

Recent focus areas include Spanish language materials, food safety education program recognition, and the BAC Down! Campaign. FDA and the Partnership are completing work on food safety education materials in the Spanish language aimed at under-served Spanish speaking populations and the updating of the Partnership's comprehensive web site aimed at the media, consumers, and food safety educators. FDA also joined with the Partnership as co-sponsors with USDA and CDC of an international food safety conference for health care workers and educators of individuals at-risk for foodborne illness. In conjunction with this conference and in celebration of the 10th Anniversary of Fight BAC!®, the Partnership announced the first national BAC Fighters! Program Awards to recognize outstanding local food safety education programming based on the Fight BAC!® campaign's four core safe food handling practices: Clean, Separate, Cook and Chill. In addition, FDA continues to promote the BAC Down! campaign, which aims to make consumers aware that the bacterium *Listeria monocyotogenes* can grow at refrigerator temperatures.

FDA participates in the development of E-cards to the Partnership's BAC fighters list serve, a database of state, local and Federal health educators, food industry staff, teachers and consumer activists. Topics include the importance of drinking pasteurized milk, safe produce handling, keeping refrigerators at the proper temperature, and the necessity of proper hand washing to prevent illness. All eighteen of the education projects conducted by FDA Public Affairs Specialists around the country emphasize the Partnership's four basic food safety messages and utilize FIGHT BAC! materials extensively.

FDA and the Partnership also collaborated to develop and promote BE FOOD SAFE, a media campaign on food safety, that details food safety precautions consumer can take through public service announcements for electronic and print media outlets.

Item

Generic Drugs -- On April 26, 2006, FDA published a paper noting that while the first generic drug to enter the market is normally priced approximately six percent below its comparative brand name drug, the second generic drug reduces prices more significantly, nearly in half. The Committee is supportive of FDA's efforts to improve its generic drug approval process, and strongly encourages the agency to take into account this information when making those decisions. (Page 143)

Action Taken or to be Taken

CDER has changed the order of review of certain applications for generic drug products. The Office of Generic Drugs (OGD) now identifies applications for first generic products for which there are no blocking patents or exclusivities on the listed drug at the time of submission. The review of these applications is then expedited to get some lower cost products on the market sooner. Second or subsequent applications for the products may be approved earlier because of the more timely review of the first. In addition, OGD has instituted a number of review efficiencies, including the question-based review. This

effort has been found to decrease review time by 20 percent, thus allowing earlier availability of second and subsequent applications.

Item

Human Drug Compounding -- The Committee acknowledges the important and increasing role that compounding pharmacists play in providing health care to consumers. The Committee also acknowledges the important role the United States Pharmacopeia [USP] and Pharmacy Compounding Accreditation Board [PCAB] play in promoting consumer health through activities directed at promoting quality pharmacy compounding practices and products. The Committee encourages FDA to work with, including providing funding if available, USP and PCAB to develop monographs for commonly prescribed or critically needed compounded preparations. The Committee encourages USP and PCAB to consult with compounding pharmacists to identify commonly prescribed or critically needed compounded preparations for monograph development and to encourage participation in the PCAB accreditation program. The Committee makes clear that the development of monographs will not limit or infringe upon the current practice of compounding pharmacists in preparing and dispensing prescriptions, or alter the existing State and Federal regulatory roles regarding compounding. (Page 143)

Action Taken or to be Taken

FDA believes that having monograph standards might improve the quality of compounded products with regard to identity, strength, purity, and potency. A properly formulated and administered pharmacy compounding accreditation program might afford similar benefits. However, without an extensive testing, surveillance, and enforcement program to determine compliance, and to take action in cases of non-compliance, the existence of monographs standards or an accreditation program will have limited effect on the quality of compounded drugs. The development of an appropriate testing and enforcement program would require substantial FDA and/or State resources.

FDA resource levels do not permit the agency to establish a testing, surveillance, and enforcement program in support of the monograph development and pharmacy accreditation processes. Establishing a testing and enforcement program at current resource levels will take away from other critical FDA programs, such as initiatives that target pharmacies engaged in inappropriate compounding (*e.g.*, drug manufacturing under the guise of compounding, compounding copies of FDA-approved, commercially available drugs, and compounding drugs that place consumers at significant risk of injury).

FDA does not believe that PCAB participates in developing monographs for commonly prescribed or critically needed compounded preparations. Rather, PCAB is an industry-sponsored organization that accredits compounding pharmacies based on their compliance with principles and standards that PCAB has developed. FDA has met with PCAB on at least two occasions and has commented on PCAB's principles and standards. These comments included identifying gaps and opportunities for improvement in those principles and standards.

Item

Medical Device Application Review -- The Committee recommendation includes an appropriated amount of $230,549,000 for the Devices and Radiological Health Program. This amount is sufficient to meet the triggers as defined in the Medical Device User Fee and Modernization Act (Public Law 107-250) and the Medical Device User Fee Stabilization Act (Public Law 109-43). The Committee notes with concern that this is the second year in a row that the inflation rate assumed in the budget request is not sufficient to meet the mandated trigger amount. (Page 144)

Action Taken or to be Taken

The Administration submits the President's budget request in February of each fiscal year using the most recent and available economic assumptions. The FY 2007 President's budget submission met the MDUFMA statutory trigger for the Devices and Radiological Health Program when the budget was submitted. However, the Department of Labor released the April Consumer Price Index in May, 2006, after the President's budget was submitted. The May announcement included a higher Consumer Price Index than the President's economic assumptions.

Item

National Antimicrobial Resistance Monitoring System -- The Committee supports the work of the National Antimicrobial Resistance Monitoring System [NARMS] and its collaborative relationship between FDA, USDA, and the Centers for Disease Control and Prevention. The Committee expects the coordination of activities among these three areas of government to result in the most unbiased presentation of timely, accurate data in the best interest of public health, and encourages FDA to equally divide research funding among the three branches of the program. (Page 144)

Action Taken or to be Taken

FDA strongly supports NARMS and all its components. FDA believes that all three arms are integral to the success of the NARMS program and to achieve the benefits envisioned at its inception and agreed upon by all three agencies. FDA continues efforts to maximize cooperation and communication among FDA, USDA, and CDC to increase efficient use of resources. In addition, FDA continues to enhance the transparency of the program for stakeholders. FDA has funded NARMS since it was conceived in 1996 and is committed to the continued funding of this program to the extent possible without compromising other core programs.

Item

National Center for Food Safety and Technology -- With the growing threat of foodborne illness to the public health, the Committee believes that collaborative research in food safety should continue among Government, academia, and private industry. The national model for that collaboration has been the National Center for Food Safety and Technology [NCFST] in Summit-Argo, Illinois. The Committee recommends $3,000,000 for NCFST to continue the important work done there. This funding should be exclusive of any initiative funds which the FDA may provide in addition to NCFST. (Page 145)

ActionTaken or to be Taken
A five-year renewal of the cooperative agreement with NCFST was completed in FY 2004. Subject to the requirements in FDA's FY 2007 appropriations act, FDA plans to continue to provide funding support to NCFST. The Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $3,000,000 specified in the FY 2006 Congressional report.

Item
Office of Women's Health -- The Committee believes that it is imperative for FDA to pay sufficient attention to gender-based research, ensuring that products approved by the FDA are safe and effective for women as well as men. The Committee notes that in the budget request, the Office of Women's Health at FDA is funded at not less than $4,000,000 for program operation and oversight. The Committee encourages FDA to ensure that the Office of Women's Health is sufficiently funded to carry out its activities, and to enhance its funding if necessary. (Page 145)

Action Taken or to be Taken
Expenditures for the Office of Women's Health are pending resources available in a final enacted FY 2007 Agriculture appropriations bill. However, FDA plans on spending not less than $4,000,000 or not less than in FY 2006 for program operation and oversight of the Office of Women's Health.

Item
Operations Maintenance -- The Committee notes that FDA's overall budget is approximately 60 percent salaries and benefits. Further, in FDA's field organization, front-line inspection staff for imports and manufacturing facilities, salaries and benefits is approximately 80 percent of the budget. The fiscal year 2007 budget request includes an increase of $20,267,000 to cover an anticipated pay increase of 2.2 percent, which the Committee recommends. However, the Committee also notes that FDA routinely absorbs additional pay and benefit costs that are not requested in the budget. Therefore, the Committee directs the FDA to use the recommended programmatic funding increases to support current activities and staff levels before entering into new agreements or engaging in new activities. (Page 145)

Action Taken or to be Taken
FDA will ensure that current activities and staff levels critical to ensuring the safety of FDA-regulated products are supported before entering into new agreements or engaging in new activities.

Item
Perchlorate -- The Committee believes it is important to continue to include perchlorate as part of the Total Diet Study of both infant and adult food in order to determine the need for risk management strategies. (Page 145)

Action Taken or to be Taken

In February 2005, FDA issued an expanded survey assignment to determine perchlorate levels in 450 samples of various domestic and imported foods. The first phase of the assignment called for collection and analysis of 240 food samples that include fresh fruits and vegetables, fruit juices, and grain products. The second phase of the assignment called for collection and analysis of additional samples of fresh fruits and vegetables, fruit juices, grain products, and seafood. FDA also expanded application of the method for perchlorate analysis to baby food samples collected for four market baskets of FDA's FY 2005 Total Diet Study (TDS). In addition, FDA performed a preliminary exposure assessment for perchlorate using the data from its surveys in FY 2004 and FY 2005.

In FY 2006, the FDA analyzed for perchlorate levels in samples of foods typically consumed by adults collected for four market baskets of FDA's FY 2006 TDS. For FY 2007, the FDA plans to analyze additional relevant foods requested for collection in the FDA 2007 field assignment.

Item

Personalized Medicine -- The Committee is aware that, with the completion of the Human Genome Project, pharmaceutical and biologics research is moving rapidly into an era of personalized medicine. Developing products that are tailored to the specific genetic make-up of the individual patient promises to improve effectiveness, reduce adverse events, and save money currently wasted on treatment modalities that are less safe and less effective than desired. Specific targeting of drugs based on an individual's genotype will create new review issues for FDA and for industry. In March 2005, the FDA issued guidance for industry on the agency's current thinking with regard to pharmacogenomics and on data submission. As the science matures, FDA will need to regularly review and update its position. The Committee encourages FDA to work closely with government, academic, and industry researchers to assure that its actions serve to bring balance to a field of research that will ultimately enhance the public's health. (Page 145)

Action Taken or to be Taken

FDA works closely with Federal and State government, academia, and industry researchers in all areas that affect FDA-regulated products to assure that its actions serve to bring balance to a field of research that will ultimately enhance the public's health. Pharmacogenomics is having an ever increasing impact on drug discovery and development. FDA is encouraging this effort and is putting significant emphasis and support into personalized medicine, promoting the translation of research findings into medical practice. Several examples of targeted therapies exist already, including Herceptin for the treatment of breast cancer and Tarceva for the treatment of lung cancer.

The FDA has organized various workshops with PhRMA, BIO, NIH, academia, and other organizations designed to educate and provide feedback on pharmacogenomics. FDA's new lecture series entitled "Pharmacogenomics from the Ground Up" designed for scientists with diverse academic and professional backgrounds is being held regularly and

has been integrated into the ongoing education for reviewers within CDER. So far, the course is set up in three sessions

- Concepts and Tools in Pharmacogenomics
- Submissions and Labels in Regulatory Pharmacogenomics
- Final training on ArrayTrack, an integrated genomics analysis tool developed by the National Center for Toxicology Research (NCTR).

Additional continuing education lecture series are planned to include speakers from the diagnostic and pharmaceutical industries responsible for the development of molecular diagnostics and of drugs for which pharmacogenomic data made a difference in therapeutic efficacy or safety.

Item
Prescription Drug Monographs -- The Committee is interested in ensuring that FDA adopts a uniform and transparent system for regulating pharmaceuticals that have been marketed for a material extent and for a material amount of time without documented safety problems and outside of the current new drug approval process. Last year, the Committee requested a report on an alternative approach that provides for the uniform and transparent regulation of these products. To date, the Committee has not received this report. Therefore, the Committee directs the FDA to devise an approach that provides for the uniform and transparent regulation of these drugs. The Committee encourages the agency to ensure that enforcement resources are prioritized to address safety and effectiveness concerns. (Page 146)

Action Taken or to be Taken
FDA acknowledges that the Committee requested a report on an alternative approach that provides for the uniform and transparent regulation of "marketed unapproved" products. FDA will expedite getting this report to the Committee, which explains our approach for providing a uniform and transparent regulation of these drugs.

Item
Seafood Safety -- The Committee supports the ongoing work of the Interstate Shellfish Sanitation Conference [ISSC] and its joint efforts with the FDA and the shellfish industry to formulate shellfish safety regulations through the National Shellfish Sanitation Program. The Committee recommends no less than $200,000 be directed through the Office of Seafood Inspection to continue these activities and $250,000 be directed to the ISSC for the Vibrio Vulnificus Education Program. The Committee is concerned that FDA has not taken effective action to address foodborne illness risks from the consumption of raw shellfish. In particular, the Committee is concerned that ISSC's proposed steps to reduce the rates of death and illness due to consumption of Vibrio Vulnificus-contaminated raw shellfish may not effectively address public health concerns. (Page 146)

Action Taken or to be Taken

Expenditures for ISSC are pending resources available in a final enacted FY 2007 Agriculture appropriations bill. However, FDA plans to continue to work with the Interstate Shellfish Sanitation Conference (ISSC) to address Vibrio vulnificus and work cooperatively with all relevant states in conformity with the ISSC's National Shellfish Sanitation Program. These joint efforts include actions to encourage the use of post-harvest treatment by the shellfish industry (e.g., improvements of invalidation of treatment methods, marketability studies), education of at-risk consumers on the risks posed by the organism, and monitoring of the frequency of occurrence of Vibrio vulnificus illnesses. FDA also plans to continue supporting education and outreach on Vibrio vulnificus.

Item

HAACP (Seafood Safety) -- The Committee also continues its concern with the agency's failure to bring FDA-regulated seafood into compliance with Hazard Analysis Critical Control Point [HACCP] standards. However, the Committee is aware that special or unique circumstances may exist for particular seafood processors. While ultimate HAACP compliance is not in question, the Committee is specifically aware of Hawaii's lengthy and culturally important history of hook-and-line fisheries, auction markets, and the high consumption of raw tuna and other pelagic fish in Hawaii, and strongly encourages the Agency to take into account both the history and the industry's practical experience in approving a plan that is consistent with healthy seafood products and national standards for seafood safety. (Page 146)

Action Taken or to be Taken

FDA's seafood HACCP program is designed to allow processors to design preventive controls that best accommodate their own circumstances so long as they provide an appropriate assurance of product safety. The level of safety assurance cannot be compromised based on cultural or traditional processing practices at the point of origin.

The special or unique circumstances for particular seafood processors involve proper handling practices on board fishing vessels to insure that tuna do not form scombrotoxin as a result of time/temperature abuse. Scombrotoxin is one of the three most frequently reported causes of illnesses from seafood in the United States and is completely avoidable with proper care of the catch. Once a tuna dies, it can begin to decompose and form scombrotoxin if not properly chilled.

FDA's Office of Seafood has engaged in a continuing dialogue with the auction house in Hawaii on how the auction house can most effectively and practically ensure the control of scombrotoxin as a result of the death of tuna and other species while still in the line. During 2005, the Hawaiian seafood industry, the National Marine Fisheries Service (NMFS) and FDA collaborated in an important study on the conditions under which large, longline-caught tuna will form histamine. The samples collected during this study are being analyzed and FDA is developing guidance to refine its recommendations to the Hawaiian industry and other scombroid fishing industries on appropriate controls for this hazard.

Item

Additives and dyes in seafood -- The Committee has been advised that farmed salmon imported from overseas is fed feed with chemical additives to change the color of its flesh or the flesh is artificially dyed. A lawsuit was filed against national grocery chains alleging they do not adequately label the fish which are dyed. The Committee directs the Food and Drug Administration to continue to monitor information concerning the safety of the use of such additives and dyes in seafood and to more aggressively enforce the clear and conspicuous disclosure of such additives and dyes to consumers on consumer packaging. (Pages 146-147)

Action Taken or to be Taken

Under the Federal Food, Drug and Cosmetic Act, retailers are required to label salmon that has been colored by the use of astaxanthin or canthaxanthin to clearly denote that the food has had color added. The FDA will continue to monitor information concerning the safety of the use of such additives in seafood.

Item

Alaska Inspections -- In addition, the funding recommended for food safety will ensure the continuation of food contract inspections in the State of Alaska. Specifically, it will allow the FDA to renew its contract with the State of Alaska for inspections of food and seafood processors operating in Alaska. The contract funds at least 292 inspections, approximately 272 seafood/HACCP inspections and 20 other food inspections. The establishments to be inspected will be mutually agreed upon by FDA and the State of Alaska. (Page 147)

Action Taken or to be Taken

The Committee directs that the funding provided for food safety in the bill ensures the continuation of food contract inspections in the State of Alaska. Subject to the requirements in the final appropriations act for FDA, funding provided for food safety in a final FY 2007 enacted appropriations bill will ensure the continuation of food contract inspections in the State of Alaska. Specifically, it will allow the FDA to renew its contract with the State of Alaska for inspections of food and seafood processors operating in Alaska. A new contract was negotiated in July 2006. Subject to the requirements in FDA's FY 2007 appropriations act, FDA plans to fund at least 292 inspections, approximately 272 seafood/HACCP inspections and 20 other food inspections. The establishments to be inspected will be mutually agreed upon by FDA and the State of Alaska.

Item

Standards of Identity -- The Committee is aware of the ongoing debate surrounding increased importation and use of milk protein concentrate. The Committee remains concerned with FDA's current lack of enforcement of standards of identity as it relates to the potential use of milk protein concentrate in standardized cheese and the labeling thereof. (Page 147)

Action Taken or to be Taken
In response to complaints, FDA conducted inspections at specific cheese manufacturing sites to determine compliance with the cheese standards and to document the use of milk protein concentrate (MPC) in standardized cheeses and cheese products. As a result of these inspections, FDA sent warning letters to two cheese manufacturers, Kraft Foods North America, Inc. and Lactoprot USA, advising them that standardized cheese and cheese products containing MPCs is in violation of the misbranding provisions o the FD&C Act.

Both firms responded to the warning letters outlining the actions they were taking. Kraft Foods indicated that it would no longer label products containing MPC as a standardized cheese. Lactoprot USA announced that it would remove MPC as an ingredient in its standardized cheese products. FDA will continue to monitor to ensure that MPCs are not being used in standardized cheeses and cheese products.

Item
Unified Financial Management System -- The Committee recommendation includes no more than $13,026,000 for the Unified Financial Management System. Of this amount, $9,720,000 is for development and implementation, and $3,306,000 is for operations and maintenance. The Committee reminds FDA that these amounts are subject to the reprogramming requirements outlined in the general provisions of this Act. (Page 147)

Action Taken or to be Taken
The FDA plans to limit fiscal year 2007 spending for UFMS to the fiscal year 2006 level of $12,896,000. This number reflects a 1 percent rescission under Public Law 109-148 applied to $13,026,000, the amount specified in the FY 2006 Appropriations Public Law 109-148. Of the $12,896,000, $9,452,000 is for development and implementation, and $3,444,000 is for operations and maintenance. Any significant changes to these estimates will be addressed through an official reprogramming request. The above statements in response to this significant item are subject to the requirements in the final appropriations act for FDA.

Item
Waste Management Education and Research Consortium -- The Committee recommends no less than the fiscal year 2006 amount for the FDA to continue its support for the Waste Management Education and Research Consortium and its work in food safety technology verification and education. (Page 147)

Action Taken or to be Taken
In FY 2006, FDA funded $98,200 to a grant awarded in 1995 to continue support for the Waste Management Education and Research Consortium and its work in food safety technology verification and education. The Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $99,200 specified in the Congressional report. Expenditures for WERC are subject to the requirements in the final appropriations act for FDA.

Labor-HHS-Education Appropriations

Item

Vulvodynia -- In recent years, NIH has supported two important research conferences on vulvodynia, as well as the first prevalence study and clinical trial on the disorder. These efforts have both clearly demonstrated the need for substantial additional research and served to heighten the research community's level of interest in studying vulvodynia. The Committee calls upon the Director to build upon these initial successes by coordinating through the ORWH an expanded, collaborative extramural and intramural research effort into the causes of, and treatments for, vulvodynia. This expanded effort should involve ORWH, NICHD, NINDS and other relevant ICs, as well as the NIH Pain Consortium. The Committee commends ORWH for initiating a dialogue with the National Vulvodynia Association to determine the best approach for launching an educational outreach campaign on vulvodynia, as the Committee requested last year. ORWH is encouraged to implement this effort with the help of other relevant ICs and women's health offices in governmental agencies including HHS, FDA, HRSA and CDC. Finally, the Committee encourages the Director to work with the Center for Scientific Review and ICs to ensure that experts in vulvodynia, and related chronic pain and female reproductive system conditions, are adequately represented on peer review panels. (From Senate Report 109-287, Labor-HHS-Education Appropriations, Page 124)

Action Taken or to be Taken

FDA's Office of Women's Health is ready and available to work and collaborate with NIH ORWH on this effort, as appropriate.