

**Food and Drug Administration
House, Senate, Conference Report and Appropriations Bill
Significant Items**

**House Significant Items
Contained in House Report 111-181 (June 23, 2009)**

Item 1 – Neuroblastoma – The Committee continues to note the lack of new therapies associated high-risk neuroblastoma. Unlike other pediatric cancers, five-year survival rates for this devastating disease have remained unchanged at approximately 20 percent for decades. The Committee continues to encourage the FDA to prioritize review of new therapies and treatment protocols for Stage IV neuroblastoma patients. (p. 62)

FDA Action

FDA currently gives priority review to all applications for pediatric cancer treatments that include studies conducted pursuant to a Written Request under the Best Pharmaceuticals for Children Act. Under this standard, applications related to neuroblastoma will likely receive priority review.

Item 2 – Sunscreen rule – In August 2007, FDA published a proposed rule for over the counter sunscreens that would require UVB and UVA testing and labeling. Given the importance of this rule to protecting Americans against skin cancer, the Committee is concerned that FDA has not issued a final rule. The Committee instructs FDA to issue a final rule before December 31, 2009. (p. 63)

FDA Action

FDA has drafted a final rule. Because the final rule must receive agency, department, and OMB clearance, it will not be issued before December 31, 2009.

Item 3 – Dietary guidelines – The Committee notes that during the coming year, the Secretaries of Agriculture and Health and Human Services will receive the report of the 2010 Dietary Guidelines Advisory Committee, and will then have the responsibility to formulate and issue science-based dietary guidance. In view of the need to communicate clear messages and motivate changes in consumer behavior, the Committee recommends that the Secretaries devise targeted communications strategies that will allow consumers to build their diets around their specific nutritional needs and healthful food choices. (p. 63)

FDA Action

The Secretaries of USDA and HHS jointly publish a report every five years entitled the Dietary Guidelines for Americans (DGA). Lead responsibility for this process alternates between the USDA and HHS and rests with USDA for the 2010 DGA report. USDA and HHS will develop communication strategies to provide clear, targeted messages to assist consumers in building healthful diets. For HHS, these activities will be coordinated by the Office of Disease Prevention and Health Promotion (ODPHP) in the Secretary's Office. FDA will assist in outreach activities, and ensure that FDA consumer outreach and education activities are consistent with Departmental messages.

Item 4 – Honey – The Committee recognizes that honey is produced in the United States, traded internationally and consumed as both a packaged food and as a food ingredient. However, there have been instances where manufacturers have been marketing products illegally as “honey” or “pure honey” that contained other ingredients. The Committee believes that guidance about the composition and labeling of honey is needed to protect consumers and the domestic honey industry from misbranded honey and honey-derived products that are currently entering the U.S. market. The Committee directs FDA to remind manufacturers of honey about the misbranding and adulteration provisions of the Federal Food Drug and Cosmetic Act. It is the Committee’s understanding that FDA intends to respond to the pending citizen petition proposing a standard of identity for honey, and the Committee expects the agency to do so. (p. 63)

FDA Action

FDA has received a citizen petition from the American Beekeepers Association and several American honey trade associations requesting that we adopt as a U.S. standard of identity, the Codex Alimentarius standard for honey with some modifications. FDA has reviewed the citizen petition and the agency plans to respond to the petitioner. FDA also intends to issue guidance to remind industry of the adulteration and misbranding provisions of the Act that would be applicable to honey.

**Senate Significant Items
Contained in Senate Report
111 - 39**

Item 5 – Antibiotics in Shrimp – The Committee is concerned about the contamination of farm-raised shrimp imports with banned antibiotics. The Food and Drug Administration currently inspects less than 2 percent of imported shrimp. The Committee strongly encourages FDA to develop, in cooperation with the State testing programs, a program for increasing the inspection of imported shrimp for banned antibiotics. (p.105)

FDA Action

The use of unapproved drugs in farm-raised seafood raises significant public health concerns. FDA is actively working in a variety of ways to assure that farmed raised shrimp and other aquacultured products are free from unapproved chemotherapeutics residues. FDA has a continuous monitoring program to test for animal drugs in imported as well as in domestic seafood products. This program has been expanded with particular attention to products and sources. It is estimated that 90 percent of shrimp, the most consumed seafood in the U.S., is imported. Therefore, shrimp has been identified as a high priority product in our testing program.

FDA focuses on ensuring the control of food safety hazards associated with unapproved aquaculture drugs in imported seafood through the implementation of the Seafood Hazard Analysis and Critical Control Point (HACCP) program. Under the HACCP system, the importer and the foreign processor share the responsibility for preventative controls and are required to verify that the products they offer for entry are in compliance with the requirements of the FDA seafood regulation including, controls of aquaculture drug hazard.

FDA continues to take regulatory actions against entries where it finds positive samples in order to prevent adulterated fishery products from entering domestic commerce.

The FDA Office of Regulatory Affairs district offices work closely with States to provide expertise and technical assistance regarding sampling procedure and testing methods. Analytical methods for a range of unapproved drug residues of concern are available at <http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/DrugChemicalResidues/Methodology/default.htm>.

Item 6 – Antibiotic Development – Regulatory uncertainty in the antibiotic drug arena has been a serious impediment to new antibiotic development. Although a number of indication-specific draft guidance documents have recently been published, there are several serious infection diseases for which guidance is still needed, including hospital acquired pneumonia, ventilator-associated pneumonia, and complicated skin and skin structure infections. The Committee directs FDA to issue guidance for these diseases. Further, the Committee is aware that as part of the 2001 Interagency Public Health

Action Plan to Combat Antimicrobial Resistance, FDA, along with CDC, agreed to be the designated lead to identify ways to promote the development and/or appropriate use of priority antibacterial drugs for humans, for which current market incentives are inadequate. The FDA is encouraged to work with other governmental entities and interested parties to begin this work, including commissioning a study with an outside entity if necessary, and to report to the Committee on those efforts. (p. 105)

FDA Action

FDA co-sponsored a public workshop on clinical trial designs for community acquired bacterial pneumonia (CABP) in January 2008, which was followed in April 2008 by a public advisory committee meeting on the same topic. Following these meetings, FDA published a draft guidance on CABP in March 2009. In response to comments received on this draft guidance, FDA convened another public advisory committee meeting in December 2009 to discuss clinical trial designs for CABP. FDA will carefully consider the advice received at that meeting in the further development of the CABP guidance. FDA also co-sponsored a public workshop to discuss clinical trial designs for hospital acquired pneumonia (HAP) and ventilator associated pneumonia (VAP) in March 2009. FDA is exploring the feasibility of commissioning a study on incentives for antibacterial drug development.

Item 7 – Antimicrobial Resistance – The Committee directs FDA to continue to implement all directives contained in the Food and Drug Administration Amendments Act and the Animal Drug User Fee Act regarding antimicrobial resistance. The Committee also encourages FDA to conduct a focused reassessment on the human importance ranking of antibiotics, in consultation with infectious disease experts, to determine the appropriateness of the current ranking of these drugs according to their importance in human medicine. (p. 105)

FDA Action

FDA published the final guidance, *Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices* in March 2009. FDA also convened a public advisory committee meeting in October 2009 to discuss implementing the guidance. The Animal Drug User Fee Act of 2008 requires annual reporting of sales and distribution data beginning in March 2010. FDA is preparing to receive this new data, and we intend to issue regulations to incorporate new requirements into existing regulations. FDA agrees that a reassessment of the human importance ranking in Guidance for Industry (GFI) 152 is appropriate and we are exploring mechanisms for seeking input on the issue from infectious disease experts, other stakeholders, and the public.

Item 8 – Budget Justification –The Committee directs the agency to submit the fiscal year 2011 budget request in a format that follows the same account structure as the fiscal year 2010 budget request, unless otherwise approved by the Committee. Further, the Committee directs that in future budget requests, all performance measures and outputs ,

such as number of staff hired and number of inspections performed, be measured according to budget authority requests. The Committee directs FDA to provide any performance measures and outputs related to proposed or current law user fees separately and independent of one another. (p. 106)

FDA Action

The FY 2011 Congressional Justification budget submission follows the same account structure as the fiscal year 2010 budget request. The Congressional Justification separately identifies includes performance measures and outputs for budget authority increases and increases associated with unauthorized user fees.

Item 9 – Cosmetics – The Committee recommendation includes an increase of \$2,000,000 for the cosmetics program. With this increase, total funding for cosmetics activities at FDA will be \$10,200,000 in fiscal year 2010, which includes the Office of Cosmetics and Colors in the Center for Food Safety and Applied Nutrition and inspection activities in the Office of Regulatory Affairs.

FDA Action

During FY 2010, FDA will support this activity at the funding level recommended by the Committee.

Item 10 – Critical Path and Modernizing Drug Safety – The Committee recommendation includes \$18,000,000 for the critical path initiative, including no less than \$6,000,000 for critical path partnerships as authorized by section 566 of the Federal Food, Drug and Cosmetic Act (FD&C Act). The Committee expects that this funding will be used to further FDA's work on critical path opportunities and to promote collaborations with other government agencies, academia, patient groups and other interested parties including, but not limited to, the Critical Path Institute, the National Institute for Pharmaceutical Technology and Education, the Coalition Against Major Diseases, and the Coalition Against Tuberculosis. Of the \$6,000,000 provided for critical path partnerships, not less than \$2,000,000 shall be used to support research partnerships for the treatment and/or rapid diagnosis of tropical diseases as defined by section 524 of the Federal Food, Drug, and Cosmetic Act. The Committee is particularly concerned with treatments for tuberculosis [TB] and drug-resistant TB. Worldwide almost 2 million people die from TB and more than 9 million people develop active disease every year. The rise of drug-resistant TB can result in a global, untreatable epidemic. The Committee believes that the use of single drugs too often results in drug resistance, and that more effective combinations of treatment are needed. Therefore, the Committee directs the Center for Drug Evaluation and Research to enter into a competitive agreement with an entity eligible for funding under section 566 of the FD&C Act to assist with the development of new combinations of drugs for the rapid and effective therapy of tuberculosis. The Committee directs FDA to report on critical path spending quarterly. Reports should include activities undertaken with the \$18,000,000 provided for the overall initiatives, and more specifically projects awarded with the \$6,000,000 in partnership funding. The report shall include the amount of each project or activity, the center responsible for the funding, a description of the specific project or activity being funded, and in the case of partnership funding, the recipient of the funds. (p. 106)

FDA Action

During FY 2010, FDA will support use the Critical Path activities at the funding level recommended by the Committee, and in a manner consistent with the report language. FDA will report quarterly to the Committee as requested.

Item 11 – Definition of Food – The Food and Drug Administration Amendment Act of 2007 included section 912, which prohibits interstate commerce of food to which certain article have been added. On July 29, 2008, FDA published a Federal Register notice seeking comments on the section. One of the questions for which FDA requested comments was the applicability of section 912 to dietary supplements, given that dietary supplements already clearly exclude certain articles as defined in section 201 of the Federal Food, Drug and Cosmetic Act. The Committee notes that comments were due on October 27, 2008, and more than 8 months later, FDA still has not resolved this issue. The Committee directs FDA to dispose of this issue. (p. 107)

FDA Action

FDA has reviewed all of the comments received in response to the July 2008 Federal Register notice and is in the process of developing implementation options. One issue presented by section 912 is whether the section applies to dietary supplements. FDA's draft options will address this question. FDA's implementation decisions will depend in substantial part on the available options based on legal analysis.

Item 12 – Demonstration Grants for Improving Pediatric Device Availability – The Committee recommendation includes \$3,000,000 for Demonstration Grants for Improving Pediatric Device Availability, as authorized by the Food and Drug Amendments Act of 2007.

FDA Action

During FY 2010, FDA will support this activity at the funding level recommended by the Committee.

Item 13 – Epilepsy Drug Safety Research – The Committee is concerned about recent reports of unexpected side effects, including seizures, when epileptic individuals switch among different manufacturers' versions of the same therapeutic agent. The Committee directs the FDA to submit a report not later than September 30, 2010 detailing FDA proposed guidance or actions to minimize the health impact or side effects as a result of the agency's research on switching bioequivalent anti-epileptic drugs. (p. 107)

FDA Action

FDA will submit the report as requested by the Committee.

Item 14 – Generic Drugs – The Committee recommendation includes no less than \$92,966,000 for the generic drugs program at FDA, of which \$51,545,000 is for the Office of Generic Drugs. Total funding for the office of Generic Drugs is an increase of 10,000,000 above the fiscal year 2009 level.

FDA Action

During FY 2010, FDA will support this activity at the funding level recommended by the Committee.

Item 15 – Human Resources – The Committee is concerned that FDA is not being appropriately serviced by the Rockville Human Resources [HR] Center. In 2004, HHS consolidated all human resource functions into five human resource centers. FDA, along with several other agencies, is serviced by the Rockville HR Center. An audit conducted by the Office of Personnel Management [OPM] and HHS in 2008, found that the Rockville HR Center was failing in many areas, and the center's authority to hire individuals from outside the Government was suspended. As a result, FDA made the decision to independently contract with OPM to facilitate FDA's continued need to hire

individuals from outside of Government. It may be more than a year before Rockville HR Center gets all of its hiring authority back. Currently, FDA is paying HHS for service that is not being provided as contractually agreed, and is outsourcing additional human resource activities to OPM in order to fill the gap left by the Rockville HR Center. The Committee has invested significant resources at FDA so the agency can backfill positions and hire new staff too meet increasing agency demands. The Committee believes FDA will be better serviced by a fully functioning human resource operation. Therefore, the Committee directs HHS and FDA to come to a resolution that ensures FDA is being serviced by a fully functioning HR center and report to the Committee on the measures that are being taken to meet FDA's hiring needs. (p. 107)

FDA Action

FDA will provide the report as requested.

Item 16 – Infant Formula – The Committee is aware that, in recent years, infant formula manufacturers have increasingly added new ingredients to infant formulas, such as long chain polyunsaturated fatty acids, prebiotics, and probiotics. The stated goal of such food ingredients additions is to obtain certain beneficial outcomes with respect to infant health and nutrition. These products are heavily marketed as offering specific health and developmental advantages through nutrition but at the same time cost more than traditional infant formulas. Without a doubt, all infants should have access to infant formulas that promote healthy growth and development. However, the Committee is concerned that product development in the infant formula industry is outpacing FDA's regulatory action with respect to new infant formulas and the claims associated with them. The Committee directs the FDA to submit to Congress, within 120 days of enactment, a report containing a list of new infant formulas introduced into interstate commerce in the last decade; information on the agency's efforts to issue structure/function claim guidance for infant formulas; the health claim petitions (either statutory or qualified) pertaining to infant growth, development or nutrition received by FDA; and actions taken by FDA in response to the petitions for these claims for infants formula, including the number of rejections and the reasons for each rejection. (p. 108)

FDA Action

FDA will provide the report as requested.

Item 17 – Mammography – The Committee is aware that the Mammography Quality Standards Act [MQSA] has resulted in improved quality of mammography to make mammograms a more reliable tool to detect breast cancers. Appropriated funds pay for inspection in Government entities and in facilities where at least 50 percent of mammograms performed are funded by the Centers for Disease Control and Prevention's National Breast and Cervical Cancer Early detection Program, as well as other important activities. The Committee recommends no less that \$5,296,000 in appropriated funds, as well as \$ 19,318,000 in user fee collections, for activities related to MQSA.

FDA Action

During FY 2010, FDA will support this activity at the funding level recommended by the Committee.

Item 18 – Neglected Diseases – The Committee is concerned about the challenge of increasing the number of approved treatments for diseases that, although not necessarily rare, may have few if any therapeutic options. The Committee recognizes that the definition of a rare disease or condition under the Orphan Drug Act includes many tropical diseases or conditions that affect more than 200,000 persons in the United States.

Because the Orphan Drug Act already embraces therapies to treat many tropical diseases, the Committee urges FDA to take active steps to stimulate orphan status and support their development. Where appropriate, FDA should engage in partnerships and collaborations to identify compounds that may be suitable to treat this subset of orphan diseases and work in a proactive way to identify compounds to treat such diseases. (p. 108)

FDA Action

The Office of Critical Path Programs has initiated the process for selecting appropriate representatives from CDER, CBER and CDRH for a working group on neglected diseases. The group will address the development of a guidance on drugs for neglected diseases and will explore other collaborative opportunities to facilitate the development of drugs for tropical diseases. We anticipate constituting this working group during the second quarter of FY 2010.

Item 19 – 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 recommendation includes \$6,000,000 for the Office of Women's Health. 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.

FDA Action

During FY 2010, FDA will support this activity at the funding level recommended by the Committee.

Item 20 – Packaged Ice Manufacturing – The Committee recognizes that ice is a food product produced in the United States for both interstate and intrastate commerce, and has been made aware of concerns regarding individual retail outlets that manufacture and bag ice. The Committee directs FDA to work to educate manufacturers regarding safe production of ice, including the issuance of a Food Facts sheet informing the public about existing FDA regulations that apply to ice manufacturers. Further, the Committee directs FDA to consider whether or not formal regulations regarding the safe handling,

processing and packaging of packaged ice sold for human consumption would be an appropriate measure. (p. 109)

FDA Action

FDA protects the safety of packaged ice in interstate commerce by enforcing the Current Good Manufacturing Practice and Food Labeling regulations applicable to all foods. FDA also works through the FDA Food Code to affect state and local regulation of retail ice producers. FDA is currently developing a Food Facts information sheet on packaged ice. The sheet will include information on such topics as regulation of packaged ice in interstate commerce by FDA, regulation of packaged ice in intrastate commerce by state and local authorities, and ice handling safety. By publicizing FDA regulations applicable to ice, the Food Facts information sheet should address concerns raised by the packaged ice industry about lack of awareness of ice safety and of FDA's role in regulating packaged ice. FDA expects to issue the Food Facts information sheet in early 2010.

Item 21 – Pediatric Cancer – The Committee continues to note the lack of new therapies associated with high-risk neuroblastoma. Unlike other pediatric cancer, 5-year survival rates for this devastating disease have remained unchanged at approximately 20 percent for decades. The Committee encourages FDA to continue to give priority attention to new therapies and treatment protocols for Stage IV neuroblastoma patients. (p. 109)

FDA Action

FDA currently gives priority review to all applications for pediatric cancer treatments that include studies conducted pursuant to a Written Request under the Best Pharmaceuticals for Children Act. Under this standard, applications related to neuroblastoma will likely receive priority review.

Item 22 – Seafood Economic Integrity – The Committee recognizes the importance of seafood to a healthy diet, but is concerned that FDA does not focus sufficient attention on economic integrity issues, particularly with respect to mislabeling of species, weights, country of origin, and treatment. The Committee encourages FDA to work with States to more aggressively combat fraud in parts of the seafood industry. (p. 109)

FDA Action

For more than 30 years, the Food and Drug Administration has been implementing systems and protocols with our State, territorial, tribal, and local regulatory partners to rapidly identify contaminated food via inspectional and sample analysis collaboration, determine the cause, and remove contaminated products from the marketplace. Within the Food Inspection State Contract Program, FDA currently collaborates with 23 states that perform 1,143 Seafood HACCP inspections. FDA shares the results of these inspections with the FDA district offices. During the past 2 years, FDA has delivered seven joint (FDA & State) Seafood Training courses and is scheduling 6 more for FY

2010. Along with HACCP food safety principles and label reviews, the joint training sessions include a dedicated section to economic fraud. The FDA also works closely with the National Fisheries Institute and NOAA's National Marine Fisheries Service to address economic fraud issues.

Item 23 –Standards of Identity – The Committee recognizes that honey is produced in the United States, traded internationally and consumed as both a packaged food and as a food ingredient, and believes FDA needs to work to prevent misbranded honey and honey-derived products from entering the U.S. market. The Committee is aware that the FDA has been in receipt of a proposed standard of identity for honey 3 years, and directs FDA to respond to this proposal and, if deemed appropriate, begin working toward a U.S. standard of identity for honey. (p. 109)

FDA Action

FDA has received a citizen petition from the American Beekeepers Association and several American honey trade associations requesting that we adopt as a US standard of identity, the Codex Alimentarius standard for honey with some modifications. FDA has reviewed the citizen petition and plans to respond to the petitioner. FDA also intends to issue guidance to remind industry of the adulteration and misbranding provisions of the Act that would be applicable to honey.

Item 24 – Tobacco Regulation – On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act was signed into law giving FDA authority to regulate tobacco products. The tobacco program will be fully supported by user fees. However, in the interim period before FDA starts collecting fees, the law permits the agency to use appropriated funds for start up costs. The Committee expects start up costs funded with appropriations will be minimal and that the agency will work diligently to initiate collection of the fee so appropriated funds will no longer be necessary for the operation of the tobacco program. The Committee instructs FDA to report quarterly on tobacco program implementation. These reports should include significant milestones in implementing the tobacco program, the amount of appropriated funds used for tobacco regulation by the program, the specific activities from which appropriated funds are taken, and the impact this reduction in funds will have on the activity, if any. The Committee notes that at the time of the writing of this bill the specific U.S.C. citation for the collection of the tobacco fee was not available. The Committee will authorize collection of this fee in fiscal year 2010. (p. 109)

FDA Action

FDA will report to the Committee quarterly on the implementation of the Tobacco Program.

Conference Report
H. Rept. 111 - 279

Item 25 – Generic Drugs – The conference agreement includes no less than \$92,966,000 for the generic drugs program, of which \$ 51,554,500 is for the Office of Generic Drugs, which is an increase of \$10,000,000 above the fiscal year 2009 level.

FDA Action

During FY 2010, FDA will support this activity at the funding level recommended by the Committee.

Item 26 – Cosmetics Programs –The conference agreements includes an increase of 2,000,000 for the cosmetics program, bringing total funding for cosmetics activities at FDA to \$10, 200,000. (p. 85)

FDA Action

During FY 2010, FDA will support this activity at the funding level recommended by the Committee.

Item 27 – Pediatric Devices – The conference agreement includes \$3,000,000 for Demonstration Grants for Improving Pediatric Device Availability, as authorized by the Food and Drug Administration Amendments Act of 2007.

FDA Action

During FY 2010, FDA will support this activity at the funding level recommended by the Committee.

Item 28 – Critical Path Initiative – The conference agreement includes \$18,000,000 for the critical path initiative, including not less than \$6,000,000 provided for critical path partnerships, \$2,000,000 shall be used to support research partnerships for the treatment or rapid diagnosis of tropical diseases. The conferees are particularly concerned with improving treatments for tuberculosis (TB) and drug-resistant TB.

FDA Action

During FY 2010, FDA will support this activity at the funding level recommended by the Committee and in a manner consistent with the report language.

Item 29 – Interstate Shellfish Sanitation Commission – The conference agreement includes funding for the following item, as included in the budget: \$174,000 for the Interstate Shellfish Sanitation Commission.

FDA Action

During FY 2010, FDA will support this activity at the funding level recommended by the Committee.

Item 30 – National Center for Food Safety and Technology -- The conference agreement includes funding for the following item, as included in the budget: \$2,077,000 for the National Center for Food Safety and Technology.

FDA Action

During FY 2010, FDA will support this activity at the funding level recommended by the Committee.

Item 31 – National Center for Natural Products Research – The conference agreement includes funding for the following item, as included in the budget: \$1,608,000 for the National Center for Natural Products Research.

FDA Action

During FY 2010, FDA will support this activity at the funding level recommended by the Committee.

Item 32 – New Mexico State University Agricultural Products Food Safety Laboratory – The conference agreement includes funding for the following item, as included in the budget: \$1,650,000 for the New Mexico State University Agricultural Products Food Safety Laboratory.

FDA Action

During FY 2010, FDA will support this activity at the funding level recommended by the Committee.

Item 33 – FY 2010 Budget Request – The conferees further expect FDA to continue all projects, activities and programs as included in the fiscal year 2010 budget request, unless otherwise specified.

FDA Action

During FY 2010, FDA will support activities at the funding level recommended in the budget request, consistent with the FY 2010 appropriation.

Item 34 – Future Budget Requests – The conferees direct that in future budget requests, all performance measures and outputs, such as number of staff hired and number of inspections performed, be measured according to budget authority requests. The conferees further direct FDA to provide any performance measures and outputs related to proposed and/or current law user fees separately and independent of one another, as well as independent from budget authority requests.

FDA Action

The FY 2011 Congressional Justification budget submission follows the same account structure as the fiscal year 2010 budget request. The FY 2011 Congressional Justification

separately identifies performance measures and outputs for budget authority increases and increases associated with unauthorized user fees.

Item 35 – Anti-Epilepsy Drugs – The conferees request the FDA report on adverse events and seizures associated with brand and generic anti-epileptic drugs. Specifically, the agency should examine the pharmacokinetic profiles of “A” rated anti-epileptic drugs from different manufacturers of the same therapeutic agent. The Committee directs the FDA to submit a report not later than September 2010, detailing equivalence testing should be recommended. (p. 86)

FDA Action

FDA will provide the report as requested.

Item 36 – Imported Seafood – The conferees direct FDA, working with appropriate Federal agencies, to conduct a study and report on the challenges associated with imported seafood. The report shall include, by product and country of origin, the number of physical inspections of seafood products offered for import in the previous fiscal year, and the percentage of inspected seafood products that do not meet applicable food safety laws and the reason the products do not meet such standards. The report shall also include an analysis of the imported seafood products that are most susceptible to violations of applicable food safety standards, the aquaculture and mariculture practices that are of greatest concern to FDA, and propose methods for improving policies and procedures to ensure the safety of imported seafood. (p. 86)

FDA Action

FDA will provide the report as requested.

Item 37 – Labeling Standards – The conferees direct that the FDA provide to the Committees on Appropriations in the House and Senate; the Committees on Agriculture, Nutrition, and Forestry; and Health, Education, Labor, and Pensions in the Senate; and the Committees on Agriculture, and Energy and Commerce in the House of Representatives any recommendations on the need to establish labeling standards for personal care products for which organic content claims are made, including whether FDA should have pre-market approval authority for personal care product labeling. (p. 86)

FDA Action

FDA will provide any recommendations on organic content claims that may be necessary.

Bill Language

Item 38 – Section 715 – None of the funds made available to the Food and Drug Administration by this Act shall be used to close or relocate, or to plan to close or relocate, the Food and Drug Administration Division of Pharmaceutical Analysis in St. Louis, Missouri, outside the city or county limits of St. Louis, Missouri.

FDA Action

FDA does not plan to close or relocate the Division of Pharmaceutical Analysis.

Item 39 – Section 728 – Section 728 of the FY 2010 Appropriations Act provides the following: “\$1,000,000 for the International Food Protection Training Institute.”

FDA Action

During FY 2010, FDA will support this activity at the funding level recommended by the Committee.

Item 40 – Section 728 – Section 728 of the FY 2010 Appropriations Act provides the following: “\$200,000 for the Center for Foodborne Illness Research and Prevention.”

FDA Action

During FY 2010, FDA will support this activity at the funding level recommended by the Committee.

Item 41 – Section 740 of FY2010 Appropriations Bill – (a) The Commissioner of Food and Drugs shall establish within the Food and Drug Administration a review group which shall recommend to the Commissioner of Food and Drugs appropriate preclinical, trial design, and regulatory paradigms and optimal solutions for the prevention, diagnosis, and treatment of rare diseases: *Provided*, That the Commissioner of Food and Drugs shall appoint individuals employed by the Food and Drug Administration to serve on the review group: *Provided further*, That members of the review group shall have specific expertise relating to the development of articles for use in the prevention, diagnosis, or treatment of rare diseases, including specific expertise in developing or carrying out clinical trials.

(b) The Commissioner of Food and Drugs shall establish within the Food and Drug Administration a review group which shall recommend to the Commissioner of Food and Drugs appropriate preclinical, trial design, and regulatory paradigms and optimal solutions for the prevention, diagnosis, and treatment of neglected diseases of the developing world: *Provided*, That the Commissioner of Food and Drugs shall appoint individuals employed by the Food and Drug Administration to serve on the review group: *Provided further*, That members of the review group shall have specific expertise relating to the development of articles for use in the prevention, diagnosis, or treatment of neglected diseases of the developing world, including specific expertise in developing or

carrying out clinical trials: *Provided further*, That for the purposes of this section the term “neglected disease of the developing world” means a tropical disease, as defined in section 524(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360n(a)(3)).

(c) The Commissioner of Food and Drugs shall—

(1) submit, not later than 1 year after the date of the establishment of review groups under subsections (a) and (b), a report to Congress that describes both the findings and recommendations made by the review groups under subsections (a) and (b);

(2) issue, not later than 180 days after submission of the report to Congress under paragraph (1), guidance based on such recommendations for articles for use in the prevention, diagnosis, and treatment of rare diseases and for such uses in neglected diseases of the developing world; and

(3) develop, not later than 180 days after submission of the report to Congress under paragraph (1), internal review standards based on such recommendations for articles for use in the prevention, diagnosis, and treatment of rare diseases and for such uses in neglected diseases of the developing world.

FDA Action

FDA leadership and the FDA Chief Scientist share a strong commitment to global public health and rare and neglected diseases. To implement Section 740, FDA will establish two internal review groups to address rare and neglected diseases. The Office of the Chief Scientist will oversee this effort.

The Office of the Chief Scientist has coordinated initial planning meetings and activities to implement section 740. FDA has identified a chair for both working groups. The chairs are in the process of identifying and selecting members for their respective groups, developing the scope of work, identifying strategies for robust stakeholder engagement, and developing a work plan to complete the deliverables in section 740, which include reports to Congress and developing guidance.