

**Senate Significant Items
Contained in Senate Report
111 – 221
July 15, 2010**

Item 1 – 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.93)

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 aqua cultured products are free from unapproved chemotherapeutics residues. FDA has a monitoring program to test for animal drugs in imported as well as in domestic seafood products. This program targets products and sources based on risk and past compliance. 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 US FDA seafood regulation including controls of aquaculture drug hazard.

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

The FDA district offices work closely with States providing expertise and technical assistance regarding sampling procedure and testing methodology. Analytical methods for a range of unapproved drug residues of concern are available at

<http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/DrugChemicalResiduesMethodology/default.htm>.

Item 2 – Antibiotic Development – The Committee continues to be concerned about unresolved scientific issues regarding clinical development in the antibacterial drug area, which has been identified as a serious impediment to new antibacterial development. Regulatory uncertainty in the antibiotic drug arena has been a serious impediment to new antibiotic development. In its

report last year, the Committee directed FDA to issue clinical trial guidance for several serious indications. The Committee directs FDA to report by December 3, 2010, on its progress, including the status of FDA's work toward a final guidance for multi-drug and pan-resistant organisms.

The Committee last year also encouraged FDA to identify ways to promote the development and/or appropriate use of priority antibacterial drugs for humans for which current market incentives are inadequate, by working with other governmental entities and interested parties to begin the work. The Committee directs FDA to address these issues in its December 2010 report, as well. (p. 93)

FDA Action

FDA will submit the report as directed by the Committee.

Item 3 – Antimicrobial Resistance – Antimicrobial resistance, and the resulting failure of antimicrobial therapies in humans, is a mounting public health concern. To address this problem, the Committee recommends that FDA conduct, and make public, an overall review of the use of antibacterial drugs in food-producing animals and antimicrobial resistance. In addition, the Committee recommends that FDA examine the antibacterial drugs currently approved for use in food-producing animals and identify mechanisms for assuring that such products are aligned with current safety standards. FDA should conduct post market safety reviews to assure that current uses of animal drug products are used in a manner consistent with the standards currently used in premarket safety evaluations. The Committee directs the FDA to report on the progress of this effort within 1 year of the enactment of this act. (p. 94)

FDA Action

As described in the June 2010 draft guidance, FDA has completed a review of the key scientific reports related to the public health concerns associated with the use of antimicrobial drugs in food-producing animals and has outlined several key principles for action to ensure that medically important drugs are used judiciously. These key principles include the recommendation that medically-important antimicrobial drugs be limited to uses in food-producing animals that are considered necessary for assuring animal health, and that this use includes veterinary oversight or consultation.

FDA is reviewing public comments received on the draft guidance and is developing strategies for implementing the recommendations outlined in the draft guidance. This includes seeking input from its stakeholders, including the animal pharmaceutical industry, on approaches for voluntarily modifying medically important antimicrobial drugs currently approved for use in food-producing animals to limit their use to therapeutic purposes under veterinary oversight. FDA is also exploring what statutory or regulatory changes would facilitate the goal of limiting the use of medically important antimicrobial drugs in food-producing animals to therapeutic use under the supervision of a veterinarian.

FDA is collaborating with other relevant government agencies and is seeking input from its stakeholders to develop a sound strategy for addressing this issue.

FDA intends to publish further details regarding implementation in the near future and will submit a progress report as directed by the Committee.

Item 4 – Budget Justification –The Committee directs the agency to submit the fiscal year 2012 budget request in a format that follows the same account structure as the fiscal year 2011 budget request, unless otherwise approved by the Committee. (p. 94)

FDA Action

The FY 2012 Congressional Justification budget submission follows the same account structure as the fiscal year 2011 budget request.

Item 5 – Critical Path and Modernizing Drug Safety – The Committee recommendation includes \$22,450,000 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, and the National Institute for Pharmaceutical Technology and Education. The Committee is also interested in Critical Path activities that advance safety testing, patient reported outcomes and accelerating therapies for serious diseases. Wherever possible, external awards should be competitive. Worldwide, almost 2 million people die from tuberculosis [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 more effective combinations of treatment are needed. Of the \$6,000,000 provided for critical path partnerships, not less than \$2,000,000 shall be used to support a research partnership to advance the prevention, diagnosis and treatment of TB. The Committee directs FDA to report on critical path spending semi-annually. (p. 94)

FDA Action

Congress has not yet enacted a full year appropriation for FY 2011. Therefore, the funding level for this activity has not yet been finalized.

Item 6 – 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. (p. 93)

FDA Action

During FY 2011, FDA will support this activity at the funding level recommended by the Committee.

Item 7 – E-Pedigree – The Committee believes that a full electronic track and trace system for prescription drugs is critical to improve the security of the drug supply chain from counterfeit or other substandard products, and to protect consumers. A full electronic track and trace system would include the serialization, authentication, and recording the distribution history (also known as the pedigree) documenting all parties involved in the prior sale, purchase or trade of the prescription drug beginning with the manufacturer. The Committee directs FDA to provide a report to the Committee by March 1, 2011, that describes the status of developing standards for track and trace and authentication; the status of FDA’s consideration of technologies for track and trace and authentication; efforts to harmonize, to the extent practical, with international standards and efforts; updates of international efforts for serialization, track and trace, and authentication; and all other activities planned or undertaken with the funding provided in fiscal year 2010 and 2011 for policy development related to the importation of prescription drugs. (p. 95)

FDA Action

FDA will submit the report as directed by the Committee.

Item 8 – Food Labeling – The Committee is pleased that FDA recognizes that importance of accurate food labeling in helping consumers follow a healthy diet, and is working to ensure that nutritional claims by food manufacturers are accurate. The Committee recommendation includes an increase of \$1,400,000, as requested, for FDA to use data from well-designed studies to support a modernized food label to encourage Americans to eat healthier diets and potentially reduce the prevalence of obesity and its associated health care costs in the United States. In undertaking this effort, the Committee encourages FDA to consider concerns addressed to the Committee regarding false or misleading structure/function claims, ingredient lists that are difficult to read or may not contain a declaration of the percentage of key ingredients, exaggerated representations regarding whole grain content, and a lack of information regarding caffeine and sugar. (p. 95)

FDA Action

Congress has not yet enacted a full year appropriation for FY 2011. Therefore, the funding level for this activity has not yet been finalized.

Item 9 – Generic Drugs – The Committee recommendation includes no less than \$96,966,000 for the generic drugs program at FDA, of which \$55,545,000 is for the Office of Generic Drugs. Total funding for the Office of Generic Drugs is an increase of \$4,000,000 above the fiscal year 2010 level, and \$2,000,000

above the budget request. The President's budget proposal acknowledges that generic drugs now account for 70 percent of all prescriptions dispensed in the United States, an increase of 20 percent in 4 years. Further, annual generic drug application submissions have nearly tripled since 2001. Although the Committee has provided substantial funding increases for generic drug review, and remains firmly committed to supporting these activities, the demand continues to outpace staffing. The administration's proposals for user fees for generic drug applications have not yet been authorized by the Congress, but could provide a significant increase in funding levels for this important program. The Committee encourages FDA to continue to work with the generic drug industry and the Congress on this issue. (p. 95)

FDA Action

Congress has not yet enacted a full year appropriation for FY 2011. Therefore, the funding level for this activity has not yet been finalized.

Item 10 – H1N1 Emergency Use Authorizations – In response to the 2009 H1N1 influenza pandemic, the FDA issued several Emergency Use Authorizations (EUAs). The Committee directs FDA to submit a report to Congress by March 1, 2011, regarding the use of EUA authorities over the past 24 months, the number of EUA declarations issued and whether they remain in effect, and FDA's assessment of whether the EUA authority is sufficient, including an assessment of the strengths and weaknesses of using EUAs. (p. 95)

FDA Action

FDA will submit the report as directed by the Committee.

Item 11 – 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 inspections 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 than \$6,918,000 in appropriated funds, as well as \$19,318,000 in user fee collections, for activities related to MQSA. (p. 96)

FDA Action

Congress has not yet enacted a full year appropriation for FY 2011. Therefore, the funding level for this activity has not yet been finalized.

Item 12 – Nanotechnology – The Committee supports the budget increase of \$7,300,000 to expand upon current research in nanotechnology. The Committee is pleased that FDA has established a Nanotechnology Core Facility at the National Center for Toxicological Research, and encourages FDA to design this center to support nanotechnology toxicity studies, develop analytical tools to quantify nanomaterials in complex matrices, and develop procedures for characterizing nanomaterials in FDA regulated products. (p. 96)

FDA Action

Congress has not yet enacted a full year appropriation for FY 2011. Therefore, the funding level for this activity has not yet been finalized.

Item 13 – Orphan Product Development – The Committee is interested in making every tool available to FDA to get new products to those who suffer from rare diseases, and the Committee has been encouraged by the success of the orphan product grant program.

FDA has approved 44 products that received development support from orphan products grants. However, because the cost of clinical trials continues to increase far faster than the rate of inflation, FDA's funds are covering less and less of the true cost of conducting clinical trials. Therefore, the Committee recommendation includes \$16,035,000 for orphan product development grants within the budget for the Center for Drug Evaluation and Research. This represents an increase of \$2,000,000 above the budget request and is the first substantial increase in funding for these grants since fiscal year 2005. (p. 96)

FDA Action

Congress has not yet enacted a full year appropriation for FY 2011. Therefore, the funding level for this activity has not yet been finalized.

Item 14 – 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 \$6,040,000 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. (p. 96)

FDA Action

Congress has not yet enacted a full year appropriation for FY 2011. Therefore, the funding level for this activity has not yet been finalized.

Item 15 – Rare Diseases – The Committee recommendation includes an increase of \$1,000,000 for the office of the Associate Director for Rare Diseases in the Center for Drug Evaluation and Research [CDER]. The Associate Director coordinates the development of policies and procedures for the review and approval of treatments for rare diseases throughout CDER, ensures appropriate training of staff, establishes consistent processes for providing advice to sponsors, and oversees the development of products for rare diseases across multiple scientific disciplines. In conjunction with the Office of Orphan Products Development, the Associate Director supports collaboration among scientists and clinicians throughout FDA, promoting scientific and regulatory innovations to help facilitate timely development and approval of new treatments for patients with rare diseases. The Committee expects the Associate Director to use these funds to hire additional staff with specific expertise in facilitating the development of drugs to treat rare diseases. (p. 96)

FDA Action

Congress has not yet enacted a full year appropriation for FY 2011. Therefore, the funding level for this activity has not yet been finalized.

Item 16 – 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. 97)

FDA Action

For over 30 years, FDA 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 24 states to perform 1131 Seafood HACCP inspections in which results and outcomes are shared with the respective FDA district offices. In the last two years, FDA has delivered 14 joint (FDA & State) Seafood Training courses and is scheduling four more for FY 2011. Along with HACCP food safety principles and label reviews, the joint training sessions include a dedicated section to economic fraud. FDA also works closely with the National Fisheries Institute and NOAA's National Marine Fisheries Service to address economic fraud issues.

Item 17 – 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. However, there have been instances where manufacturers have been marketing products illegally as “honey” or “pure

honey” that contain other ingredients. FDA has been in receipt of a citizen petition regarding a proposed standard of identity for honey for a significant and unacceptable length of time, and is directed to respond to this citizen petition within 6 months, and provide monthly status reports to the Committee on this effort until a response has been provided. Further, FDA is directed to work to find ways to protect consumers from misbranded honey and honey-derived products that are currently entering the U.S. market. (p.97)

FDA Action

FDA will submit the reports as directed by the Committee.

Item 18 – Traceability – The Committee directs FDA to initiate one or more traceability projects on food products and/or ingredients known to be linked to foodborne disease outbreaks, or that have significant potential to cause serious adverse health consequences. When designing traceability projects, FDA should consider the challenges identified during previous outbreaks or build on previous efforts to improve product tracing along the supply chain. To prevent duplication of efforts and to more rapidly implement these pilot projects, the Committee encourages FDA to consider pilot projects already under way, either within the United States or the European Union, when implementing this directive. The Committee directs FDA to begin implementation of this project within 1 year, and to report back to the Committee upon the conclusion of the projects. (p.97)

FDA Action

FDA will submit the report as directed by the Committee.

Item 19 – Seafood Safety – The Committee is supportive of the current MOU between NOAA and FDA and encourages both agencies, the Secretary of Commerce, and the Secretary of HHS to continue to work together to strengthen cooperation on seafood safety, seafood labeling, and seafood fraud. The agreements should focus on coordination of testing seafood imports, inspection of imported seafood at both domestic and international facilities, data standardization and collection, joint training and outreach for testing facilities, and information sharing. The Committee encourages an increase in the use of NOAA laboratory testing and the commissioning of NOAA officers by the Secretary of HHS as needed in order to increase capacity for seafood inspection and testing. In addition, the Secretaries are encouraged to share information with the Federal Trade Commission as appropriate on consumer protection issues with respect to fraud in seafood marketing and labeling. (p. 97) (CFSAN)

FDA Action

FDA and NOAA recognize the need and value to work together and strengthen the interagency cooperation in the areas of seafood safety. As a result of this

combined effort and interest, the original 1974 Memorandum of Understanding (MOU) between FDA and NOAA was updated and reissued in 2009. The MOU describes how FDA and NOAA will work toward common goals to promote efficient use of existing resources in both agencies. Other areas specifically addressed in the MOU are formal cross training of the other agency's inspectional staff, shared development of regulations and guidance related to fish or fishery products, and utilizing the inspectional capabilities of the other agency's staff when appropriate and as resources permit.