

**Food and Drug Administration
Significant Items
Table of Contents**

	<u>Page</u>
<u>Significant Items:</u>	
Item 1 – Spending Plans	440
Item 2 – Bacterial Contamination of Blood	440
Item 3 – Seafood Advisory	440
Item 4 – Global Health	441
Item 5 – Pediatric Cancer	441
Item 6 – Tanning Devices	441/442
Item 7 – Centers of Excellence	442
Item 8 – Gluten-free Rulemaking	442
Item 9 – Antibacterial Resistance	442/443
Item 10 – Mammography Quality Assurance	443
Item 11 – Food Safety Rulemaking	443/444
Item 12 – Pathway to Global Product Safety	444
Item 13 – Dietary Supplements	444
Item 14 – Food Contact Notification	444
Item 15 – Nutritional Rating Systems	444/445
Item 16 – Projects, Activities, Laboratories, Programs	445
Item 17 – Antimicrobial Drugs	445/446
Item 18 – Camelina	446
Item 19 – Artificial Pancreas	446/447
Item 20 – Budget Justification	447
Item 21 – Critical Path Initiative	447
Item 22 – Dietary Supplements	447
Item 23 – Drug Shortages	447/448
Item 24 – Ethanol	448/449
Item 25 – Honey	449
Item 26 – Nanotechnology	449/450
Item 27 – Information Technology	450
Item 28 – Pediatric Devices	450/451
Item 29 – Seafood Advisory	451
Item 30 – Tobacco	451
Item 31 – Tanning Bed Labeling	452
Item 32 – Tissue Reference Group	452
Item 33 – Drug Shortages	453

**Food and Drug Administration
House and Senate FY 2014
Significant Items**

**House Significant Items
Contained in House Report 112-542
June 19, 2012**

Item 1 – Spending Plans – Within 30 days from the enactment of this Act, the Commissioner shall notify the Committees on Appropriations of both Houses of Congress, on the allocation of the funds provided herein by account, and within each account by program, project and activity.

FDA Action

FDA will provide the report that the Committee requested.

Item 2 – Bacterial Contamination of Blood –The Committee is aware that bacterial contamination of blood platelets is a risk for blood transfusion recipients. The Committee also is aware of a recent study that showed the vast majority of bacterially contaminated platelets are being missed by culture testing and that bacterial testing of platelets on the day of transfusion using an existing FDA approved technology may be beneficial to some transfusion recipients. The Committee directs FDA to provide a report to the Committees on Appropriations of both Houses of Congress, within 90 days of enactment of this Act, on the need to make the medical community aware of the safety risks to transfusion patients from bacterially contaminated platelets and to determine what further actions FDA should take to reduce the risk of this type of infection.

FDA Action

FDA will provide the report that the Committee requested.

Item 3 – Seafood Advisory – The Committee is concerned that FDA has not published a final seafood advisory as directed in House Report 112-101 and Senate Report 112-73. The Committee directs FDA to issue a final seafood advisory consistent with USDA's dietary guidelines by July 31, 2012. The Committee directs the FDA Commissioner to notify the Committee in writing prior to this date if this directive will not be met and include the reasons for not meeting it.

FDA Action

FDA began reconsideration of its 2004 seafood advisory regarding the nutritional value of seafood consumption during pregnancy, in consultation with the Environmental Protection Agency (EPA), in 2011. FDA and EPA are working to issue updated seafood consumption advice.

Item 4 – Global Health –The Committee recognizes the critical contribution that FDA's global health research, development funding, and leadership in licensing health technologies make to improve global health. The Committee also recognizes the need to sustain and support U.S. investment in this area by providing funding to FDA to carry out this work. The Committee directs FDA to submit a report to the Committees on Appropriations of the House of Representatives and the Senate, within 60 days of enactment of this Act, outlining the implementation of the findings and recommendations in the Report to Congress referred to in paragraphs (2) and (3) of section 740(c) of Public Law 111-80. The Committee also urges FDA to make the necessary modifications to include Chagas disease in its list of neglected diseases in line with the World Health Organization list of neglected and tropical diseases.

FDA Action

FDA will provide the report that the Committee requested.

Item 5 – Pediatric Cancer –The Committee notes that cancer remains the leading cause of disease-related death in children, that the incidence of childhood cancer is increasing, and that more effective and less toxic treatments are needed. The Committee encourages FDA to collaborate with industry and the pediatric cancer community to promote the development of new therapies.

FDA Action

FDA is committed to the development and approval of safe and effective new therapies for childhood cancer. To facilitate more active communication and collaboration between investigators, sponsors and regulators, FDA increased the frequency of annual meetings of the Pediatric Subcommittee of the Oncologic Drugs Advisory Committee to semi-annual. In addition, the meetings now focus on new cancer therapies to be used in earlier stages of pediatric development.

Sponsors of products which are potentially relevant to childhood cancers are invited to present data followed by in depth discussion with pediatric oncology experts resulting in advice to the Agency on the contents and submission of Written Requests to sponsors for pediatric studies. In addition, FDA pediatric oncology staff meet by monthly teleconference with NIH's Pediatric Oncology Working Group to solicit products of potential interest to the pediatric oncology investigator community. This information exchange is critical to the expeditious evaluation of potentially important new pediatric cancer drugs,

Item 6 – Tanning Devices – The March 2010 meeting of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee recommended more accurate classification of tanning devices to save lives. FDA is encouraged to quickly promulgate an interim final rule to reclassify tanning devices.

FDA Action

The General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee convened in March, 2010, to receive testimony from more than 50 professional societies, industry representatives, melanoma survivors or family members of melanoma victims, and other interested parties on the public health issues surrounding tanning lamps. The expert panel reached a consensus that tanning beds and lamps should be up-classified from their current Class I medical device status to provide greater scrutiny of their safety and effectiveness. A majority of the panel also favored restricting tanning lamps to adult use and disclosing more information on the risks of tanning to consumers. FDA has reviewed the Advisory.

FDA has reviewed the Advisory Committee's recommendations to reclassify tanning lamps. FDASIA requires FDA to reclassify medical devices through a proposed and final administrative order process. FDA is in the process of developing the appropriate regulatory documents to address the risks associated with these medical devices.

Item 7 – Centers of Excellence – The Committee is aware of the important support provided to FDA's food and veterinary medicine programs and through its research and program relations with their centers of excellence. The Committee encourages FDA to maintain an appropriate funding level for both Food Safety Modernization Act related activities and the base work performed by these centers.

FDA Action

FDA will maintain an appropriate funding level for both Food Safety Modernization Act related activities and the base work performed by these centers.

Item 8 – Gluten-free Rulemaking – The Committee is aware of FDA's intention to issue a final rule by the end of 2012 to define gluten-free labeling of foods. The Committee encourages FDA to work with USDA to assist its agencies in adopting the definition of gluten-free set by the FDA final rule to provide uniform labeling requirements and best protect consumers with celiac disease and other conditions.

FDA Action

Issuance of the final gluten-free labeling rule continues to be a priority for FDA, and we anticipate its publication in the near future. FDA will continue to work with USDA on gluten-free labeling.

Item 9 – Antibacterial Resistance –To assist efforts intended to curb antibacterial resistance, the Committee directs the Secretaries of Agriculture and Health and Human Services to require agencies to: (1) seek public comment on collecting more detailed sales and distribution data for antibacterial drugs approved for use in food-producing animals, including estimates of the amount sold or distributed in specific animal species; (2) seek public comment on alternative methods for obtaining additional data and information about the extent of antibacterial drug use in food-producing animals; and (3) based on input received, work collaboratively to develop a strategy for implementing the

best approach. The Committee further directs FDA to ensure that the Agricultural Research Service continues to analyze, characterize, and report on data collected through NARMS.

FDA Action

FDA published an advance notice of proposed rulemaking (ANPRM) in the July 27, 2012 Federal Register, soliciting comments from the public on possible enhancements to the existing requirements related to the collection of antimicrobial drug sales and distribution data and on alternative methods for monitoring antimicrobial use in food-producing animals.

In response to several requests to allow interested persons additional time to submit comments, FDA extended the comment period from 60 to 120 days. The comment period closed on November 26, 2012, and FDA is currently performing an in-depth analysis of the submissions from a wide range of stakeholders as part of our ongoing efforts to enhance collaborative efforts to curb antimicrobial resistance. Further, FDA continues to collaborate with its NARMS partners at CDC and USDA – including the Agricultural Research Service – to analyze, characterize, and report on data collected through NARMS.

Item 10 – Mammography Quality Assurance –The Committee urges FDA to quickly follow up on the November 2011 meeting of the National Mammography Quality Assurance Advisory Committee by promptly reviewing the evidence supporting the inclusion of information related to an individual's breast density in the mammogram lay report and physician report.

FDA Action FDA has drafted regulation amendments currently under internal review that we believe will address the breast density reporting issue.

Item 11 – Food Safety Rulemaking – The Committee is aware the Administration missed the January 4, 2012, statutory deadline for publishing a notice of proposed rulemaking for fresh produce safety standards and final regulations on the content of the Foreign Supplier Verification Program for imported food. The Committee encourages the Administration to meet the statutory timelines for implementing P.L. 111-353 and expects FDA to follow a timeline for issuing rulemakings consistent with the sequence and logistics of establishing requirements for a preventive controls framework for domestic and imported foods. The Committee directs FDA to submit a report within 180 days of enactment of this Act that describes the justification for any proposed rule or final regulation being 60 days or more beyond the timeline. The Committee further directs FDA to continue to provide such report at the same time that the agency submits its annual budget justification to the Committee.

FDA Action

FDA will provide the report as requested by the Committee. On January 16, 2013, FDA published two proposed rulemakings, Preventive Controls for Human Food and Produce Safety Standards, mandated by FSMA. These foundational rulemakings, when implemented, will improve food safety and help modernize our food safety system.

Item 12 – Pathway to Global Product Safety – The Committee directs FDA to provide a report by June 1, 2013, on the implementation of the Pathway to Global Product Safety and Quality initiative.

FDA Action

FDA will provide the report as requested by the Committee.

Item 13 – Dietary Supplements – The Committee notes that FDA released draft guidance in July 2011 on New Dietary Ingredients (NDI) for Dietary Supplements. Though the Committee wants to ensure that dietary supplements are safe, it is concerned that the draft guidance is being utilized by FDA for enforcement activities against manufacturers despite the guidance only being in draft form, containing nonbinding recommendations, and for comment purposes only. The Committee urges FDA to withdraw the July 2011 NDI draft guidance and re-engage the dietary supplement community to develop a new guidance on what constitutes NDI.

FDA Action

FDA announced in July 2012 that we will be reissuing a revised NDI draft guidance for comment in order to add clarity where there was confusion regarding FDA's interpretation of the statutory authority in the NDI provision.

Item 14 – Food Contact Notification – The Committee directs FDA to maintain the fiscal year 2012 funding level for the Food Contact Notification program.

FDA Action

Subject to any changes to the FDA appropriation, after enactment, FDA will maintain the fiscal year 2012 funding level for the Food Contact Notification program.

Item 15 – Nutritional Ratings Systems – The Committee is concerned about the use of nutritional rating and front of package claims in the marketplace. To promote public health and facilitate consumer understanding, such information should be consistent with the Institute of Medicine's recommendations for front of package nutrition rating systems and symbols and the Dietary Guidelines for Americans and based on criteria that are public and readily available to consumers. Further, such systems and symbols should be evaluated by FDA to ensure their usefulness for American consumers, consistency with FDA nutrition programs, and compliance with relevant FDA food labeling requirements. The Committee directs FDA to provide a report regarding its plans to establish guidance for developing such systems and to provide the Committee a timetable for issuing such guidance.

FDA Action

FDA will provide the report as requested by the Committee.

Extensive analysis is required to assess the appropriateness and type of possible guidance to address front-of-package labeling concerns and ensure consistency with current regulations. To inform these decisions, FDA is working with the HHS Assistant Secretary for Planning and Evaluation on evaluating front-of-package labeling systems.

FDA is also monitoring the use of various front-of-package (FOP) labeling systems – including the system developed by the Grocery Manufacturers Association. FDA also issued a letter of enforcement discretion for the FOP labeling system developed by the Grocery Manufacturers Association and, as stated in the letter, intends to assess whether this system promotes public health and is useful to consumers. This letter may be found at: <http://www.fda.gov/Food/LabelingNutrition/ucm302720.htm>.

Senate Significant Items Contained in Senate Report Number 112-163 Date April 26, 2012

Item 16 – The Committee expects FDA to continue all projects, activities, laboratories, and programs as included in the fiscal year 2013 budget request, unless otherwise specified.

FDA Action

Subject to any changes to the FDA appropriation, after enactment, FDA will continue all projects, activities, laboratories, and programs as included in the fiscal year 2013 budget request, unless otherwise specified.

Item 17 – Antimicrobial Drugs – The Committee is encouraged by the finalization of FDA Guidance for Industry 209, which calls for the voluntary elimination of growth promoting uses of medically important antibiotics and increased veterinary oversight of these drugs. However, the Committee believes that FDA should continue to make progress to implement the recommendations outlined in the finalized Guidance for Industry 209. The Committee understands that the FDA has issued a companion draft guidance, Guidance for Industry 213, that provides further details on the strategy for implementing the changes recommended in guidance 209. Because of the importance of this issue to human and animal health, the Committee will continue to monitor FDA's efforts to finalize and implement the plan outlined in draft Guidance for Industry 213. The Commissioner is directed to provide a report regarding compliance with the final guidance and further details about how the FDA intends to meet its public health responsibilities. This report shall be due within 120 days of the completion issuance of the agency's final guidance for industry.

FDA Action

FDA will provide the report as requested by the Committee.

Item 18 – Camelina – The Committee recognizes the importance of developing markets for biofuel feedstock byproducts in building advanced biofuel supply chains. In particular, the Committee notes that multiple departments of government are currently engaged in advancing biofuel produced from Camelina. The FDA is directed to report to the Committee within 90 days after enactment of this Act on all previous petitions that have been approved at lower ratios than requested, what regulatory barriers, if any, remain preventing a finding of 'Generally Recognized as Safe' status for camelina, and how those barriers can best be overcome under current law and with the resources available to FDA.

FDA Action

FDA will provide the report as requested by the Committee.

Item 19 – Artificial Pancreas – The Committee is encouraged by the Food and Drug Administration's draft guidance for accelerating the development and availability of artificial pancreas technologies which have the potential to be an important tool for patients with type 1 diabetes to achieve better glycemic control, increasing their quality of life and overall health. The FDA's actions will allow these systems to be further developed, tested in outpatient pivotal trials, and eventually approved for people with type 1 diabetes. The Committee encourages the FDA to finalize the draft guidance and continue its interactions with researchers, clinicians, policymakers, and patient advocates to advance the development of artificial pancreas systems for people with type 1 diabetes.

FDA Action

On November 9, 2012, FDA finalized the draft guidance, "The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Artificial Pancreas Device Systems," to help investigators and manufacturers develop and seek approval for artificial pancreas device systems to treat Type 1 diabetes.

FDA worked with many stakeholders to develop this final guidance and received approximately one hundred comments during the public comment period from physicians, professional societies, industry and patients. FDA took all public comments into account in the final version of the guidance.

The final guidance explains how regulatory burdens can be reduced, for example, by leveraging existing preclinical data from devices already on the market and by using existing safety and effectiveness information for individual device components that have already been approved or cleared by FDA.

FDA has continued its outreach efforts with researchers, clinicians, policymakers, and patient advocates to advance the development of artificial pancreas systems for people

with Type 1 diabetes by participating in conferences and meeting with interested parties throughout 2012. FDA is committed to ensuring that the devices that become available that utilize this technology provide a favorable benefit to risk profile for the patients that use them.

Item 20 – Budget Justification – The Committee directs FDA to submit the fiscal year 2013 budget request in a format that follows the same account structure as the fiscal year 2013 budget request unless otherwise approved by the Committee.

FDA Action

FDA will submit the fiscal year 2014 budget request in a format that follows the same account structure as the fiscal year 2013 budget request unless otherwise approved by the Committee.

Item 21 – Critical Path Initiative – The Committee expects FDA to continue its work on critical path, regulatory science and innovate opportunities, and to promote collaborations with other government agencies, academia, patient groups and other interested parties, including existing partnerships with academic institutions.

FDA Action

Subject to available funding, FDA will continue its support of public-private partnerships with academic institutions and other interested parties to advance critical path and regulatory science initiatives.

Item 22 – Dietary Supplements – The Committee is aware that U.S. consumers widely use plant-derived dietary supplements, and that FDA inspects manufacturers and distributors that are responsible for ensuring that such products are not adulterated or contaminated, and do not cause harm to the consumer. The Committee believes that methods and standards are needed to verify source plants and ingredients and to detect toxic contaminants. The Committee encourages FDA to develop guidance for industry on such methods and standards, which would enhance FDA's ability to inspect and assess industry practices for manufacturing botanical dietary supplements.

FDA Action

FDA's Center of Excellence at the University of Mississippi is currently conducting extensive work on methodologies for identification of botanicals. The Center's work in this area will inform FDA's next steps.

Item 23 – Drug Shortages – The Committee is concerned with the significant number of drug shortages occurring in the United States and the impact it is having on patient access to needed life-saving treatments. By Executive order, the President has instructed FDA to broaden its reporting of potential shortages and speed reviews of applications to begin or alter production of drugs in short supply. As part of this enhanced activity, the

Committee encourages FDA to increase its communication with medical practitioners through specialty-specific list serves and other means of targeted communications to provide information on potential shortages, the anticipated length of time of the shortage and options for obtaining therapies while they are in short supply.

FDA Action

FDA shares the Committee's concerns regarding drug shortages and the impact that these shortages have on patients. Preventing drug shortages is a top priority for FDA. The number of drug shortages has risen steadily since 2005 to a high of 251 shortages in 2011, and this is a very troubling situation that FDA takes very seriously. Once FDA becomes aware of a potential drug shortage, FDA works with pharmaceutical manufacturers to manage the shortage.

For products that are in shortage or may progress to a shortage, FDA expedites review of manufacturers' submissions. These submissions may support a marketing application for a new product under a New Drug Application (NDA) or an Abbreviated New Drug Application (ANDA), or may support manufacturing changes for existing products – for example, a supplemental application for a new manufacturing site.

In addition, FDA may:

- Help firms qualify additional manufacturing sites or raw material supplies, if those firms are interested in having additional manufacturing capacity
- Identify alternate manufacturers who can initiate or increase production
- Help manufacturers find and qualify new or additional sources of raw materials
- Advise and consult with sponsors on resolution of manufacturing issues
- Use enforcement discretion for the temporary importation of a non-U.S. product, after ensuring the drug does not pose undue risks for U.S. patients, and ensuring it is manufactured in a facility that meets FDA quality standards.

In order to provide healthcare providers with timely product information, including availability status and timeframes, alternate manufacturers, reasons for shortage, and firm contact information, FDA updates the FDA Drug Shortage website with product information on a daily basis.

Additional enhancements have been made to the Drug Shortage website as well, to improve navigation and to aid in easily finding information. The FDA Drug Shortage RSS Feed also provides drug shortage information and updates. In addition, FDA is considering additional mechanisms to further enhance communication of potential and actual shortages to medical practitioners.

Item 24 – Ethanol – The Committee directs the Food and Drug Administration to conduct periodic surveillance sampling of antibiotic use in ethanol production. The Food and Drug Administration should make public information about the results of its surveillance sampling.

FDA Action

The expansion of the fuel ethanol industry markedly increased the volume of distillers' products being produced and marketed as animal feed ingredients. In order for FDA to evaluate the impact of antibiotic use in ethanol production on animal feed it was necessary to analyze the distillers' products, which are the residual feed components of ethanol production, for antibiotic residues.

In 2007, FDA developed a method and published "Multiclass, multi-residue method for the detection of antibiotic residues in distillers grains by liquid chromatography and ion trap tandem mass spectrometry," in the Journal of Chromatography^[1] and disseminated in Laboratory Information Bulletin 4438, "Analysis of Antibiotics in Distillers Grains Using Liquid Chromatography and Ion Trap Tandem Mass Spectrometry."^[1]

In 2008 and in 2010, FDA conducted a survey of distiller's products for residues of antibiotics. The results of these surveys are available on the FDA website^[2]. The 2010 results showed a significant decrease in the number of samples in which antibiotics were found. FDA will continue to monitor the presence of antibiotics in distillers' products through routine surveillance sampling or directed sampling and, when the results of sampling activities are complete, will continue to make such results available.

^[1]<http://www.fda.gov/downloads/AnimalVeterinary/Products/AnimalFoodFeeds/Contaminants/UCM151206.pdf>

^[2]<http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/Contaminants/ucm300126.htm>

Item 25 – 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 impermissibly marketing products 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 from misbranded and adulterated honey and honey-derived products that are currently entering the U.S. market. The Committee directs FDA to issue guidance to remind manufacturers of honey about the misbranding and adulteration provisions in law, about the proper labeling of honey, and other guidance that reinforces the FDA's existing labeling regulations.

FDA Action

FDA understands the concerns presented by the Committee and is currently working on drafting the guidance on honey. FDA will provide an update to the Committee when the draft guidance is ready to be published.

Item 26 – Nanotechnology – The Committee recognizes that FDA is developing the facilities and expertise to study nanotechnology at both its headquarters in Silver Spring, MD and within FDA's Jefferson Laboratory Campus, including the National Center for Toxicological Research. The Committee supports FDA in its mission to expand upon

current research in nanotechnology and supports the development of Nanotechnology Core Centers. The Nanotechnology Core Centers support the conduct of research to establish methods for use by agency scientists through providing access to equipment, expertise, and infrastructure. These activities include supporting nanotechnology toxicity studies, developing analytical tools to quantify nanomaterials in complex matrices, and developing procedures for characterizing nanomaterials in FDA-regulated products.

FDA Action

FDA investments will continue to enable us to address questions related to the safety, effectiveness, product quality, and regulatory status of products that contain nanomaterials or otherwise involve the use of nanotechnology; develop models for safety and efficacy assessment; and study the behavior of nanomaterials in biological systems and their effects on human health.

FDA will continue activities that meet the following FDA-wide priorities that are the basis of FDA's Nanotechnology Regulatory Science Research Program: (1) scientific staff development and professional training, (2) laboratory and product testing capacity, and (3) collaborative and interdisciplinary research to address product characterization and safety.

Item 27 – Information Technology – The Committee notes with concern that the Government Accountability Office [GAO] recently found that FDA does not have a comprehensive list of its information technology [IT] systems, and as a result, the agency cannot ensure that it is investing in the mix of projects that will best support its mission or that it is managing them appropriately. Given that FDA currently spends approximately ten percent of its overall funding on IT systems, the Committee insists that FDA address GAO's findings and determine the most efficient use of its IT resources. In addition, the Committee directs FDA to develop a comprehensive IT investment plan. Within 60 days of the enactment of this Act, the Committee directs FDA to provide a report on the agency's IT systems. The report shall include a complete inventory of systems, a description of each system's purpose, annual cost for each system and the source of funding, and status of each system including whether it is in the process of being upgraded.

FDA Action

FDA will provide the report as requested by the Committee.

Item 28 – Pediatric Devices – The Committee is pleased that the five FDA-funded Pediatric Device Consortia have assisted in advancing the development of 135 proposed pediatric medical devices, as well as promoted job growth in the healthcare sector, and as such, continues to support this critical effort. However, the Committee remains concerned that children's medical devices can lag 5 to 10 years behind those manufactured for adults and directs FDA to maintain funding at the current level.

FDA Action

Subject to any changes to the FDA appropriation, after enactment, FDA will maintain the fiscal year 2013 funding level for Pediatric Devices.

Item 29 – Seafood Advisory – The Committee is highly concerned that over a year has passed since USDA published its dietary guidelines and more than 6 months have passed since the publication of this Committee's fiscal year 2012 report directing FDA to commence reconsideration of its 2004 seafood advisory, and yet FDA has not published its draft revision of the advisory. Given data demonstrating that women of childbearing years, pregnant women, and mothers with young children are eating too little seafood for their health and the health of their babies, and the role the language of FDA's 2004 advisory may play in discouraging healthy consumption of seafood, the Committee expected a more urgent response by FDA. Therefore, the Committee directs FDA to issue final seafood advisory consistent with USDA's dietary guidelines by December 31, 2012.

FDA Action

FDA began reconsideration of its 2004 seafood advisory regarding the nutritional value of seafood consumption during pregnancy, in consultation with the Environmental Protection Agency (EPA), in 2011. FDA and EPA are working to issue updated seafood consumption advice. FDA will notify and provide this advice the committee in advance of its public release, as requested.

Item 30 – Tobacco – The Committee recognizes FDA has declared its intent to issue a proposed rule clarifying the agency's jurisdiction over tobacco products. The Committee strongly encourages the agency to issue this proposed rule and promulgate regulations as necessary. The Committee instructs the agency to consider, among other things, the issue of cigars with characterizing flavors, particularly as it applies to the marketing and sale of these products to children.

FDA Action

The Family Smoking Prevention and Tobacco Control Act provides FDA with the authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. The law also permits FDA to issue regulations deeming other “tobacco products,” such as e-cigarettes, certain dissolvable tobacco products, cigars, pipe tobacco, hookah, etc., to be subject to Chapter IX of the Food Drug & Cosmetic Act (FD&C Act). In the February 2012 edition of the Unified Agenda, FDA included an entry for a proposed rule that would deem products meeting the statutory definition of “tobacco product” to be subject to Chapter 9 of the FD&C Act and would clarify additional restrictions under the FD&C Act.

While the Agency cannot comment on the details related to a pending rulemaking, the Committee can be assured that FDA will continue to carefully consider the public health impact of the proposed rule, especially as it pertains to youth.

Item 31 – Tanning Bed Labeling –The Committee is aware of the FDA report to Congress as required by section 230 of Public Law 110-85, which determined that certain modifications to the labeling requirements for sunlamp products may communicate the risks of indoor tanning more effectively and stated that the agency was considering changes to the performance requirements of the sunlamp performance standard. The Committee encourages the agency to update the labeling and performance requirements for sunlamp products within 180 days of enactment of this act.

FDA Action

FDA has developed proposed amendments to the Performance Standard for Sunlamp Products in 21 CFR 1040.20. These amendments will improve safety, bring the requirements in line with current science and more closely harmonize them with the International Electrotechnical Commission Standard. The amendments include an improved warning label which strengthens the warnings to consumers about the risks of indoor tanning and makes them easier to read. This improved warning label was developed after the consumer focus group testing described in the required (by section 230 of Public Law 110-85) report to Congress.

These amendments are expected to publish during the first half of 2013 after review is completed.

Item 32 – Tissue Reference Group – To improve transparency, the committee urges the FDA to update FDA's procedures for the work of the Tissue Reference Group [TRG] to include specifying the format and content of submissions, projected timelines for review of inquiries, and procedures for sponsors to meet with FDA, and the process by which FDA communicates regularly with the sponsor regarding the submission. The committee further recommends that FDA conduct stakeholder meetings and use other means to make publicly available the scientific rationale for its recommendations regarding human cell, tissue, and cellular and tissue-based product jurisdiction and classification while protecting proprietary information. The committee directs the FDA to update on a biannual basis the TRG report summary the agency posts on its Web site, with the first update due within 90 days of enactment of the fiscal year 2013 appropriation.

FDA Action

FDA assembled a working group to update Standard Operating Procedure and Policy (SOPP) 8004 for the TRG. The working group meets to discuss how SOPP 8004 could be updated, including specifying the format and content requirements for submissions, timelines for issuing a response, and best practices for communicating with those submitting inquiries to the TRG. The TRG's SOPP Working Group is also currently considering what would constitute the most effective and efficient outreach activities. It is taking into consideration the method and manner of communication as well as how to provide specific, useful information without revealing trade secrets or other confidential information. The TRG plans to post updates on their website on a biannual basis, within 90 days of enactment of the fiscal year 2013 appropriation.

**Significant Items
Contained in Senate/Labor/HHS Bill
Number 112-176
Date June 14, 2012**

Item 33 – Drug Shortages –The Committee urges the Secretary, in consultation with FDA, to establish an interagency and intra-agency task force to address drug shortages. The task force should have stakeholder input, including an expert in how shortages affect pediatric patients. The study should examine whether other countries have experienced drug shortages, the extent and effect of the shortages, as well as any steps these countries are taking to mitigate or prevent such shortages.

FDA Action

FDA has expanded the drug shortage program to 11 full time staff who are dedicated to coordination efforts for prevention and mitigation of shortages. We have been able to prevent shortages and over 150 in 2012. We've prevented these shortages through working with firms on specific quality problems as well as through expedited reviews, asking other manufacturers to increase production, and also through temporary importation from overseas firms.

We have further expanded our program to include additional experts from throughout the Agency and we have a highly skilled team we can call upon for specific shortage issues including manufacturing experts, chemists, microbiologists, pharmacologists and clinicians including pediatric experts and other disciplines needed to help resolve and prevent specific issues. Furthermore, we have enhanced intra-Agency communications with the field staff (investigators) as well as our Office of Compliance regarding any issues that are potentially impacting supply at the manufacturers. In addition, we are in regular, if not daily, contact with various stakeholder groups, regarding products in shortage and drug shortage issues.

Drug shortages are not unique to the FDA or the US, but a global problem. FDA works closely with other regulatory authority (EMA, TGA, MHRA, HC) on existing drug shortage problems. During our discussions, under shared confidentiality agreements, crucial information regarding the availability of important drug products and potential alternate facilities is shared. Additionally, when a shortage is triggered by quality problems or manufacturing constraints to limited production capacity, FDA and other regulatory authorities exchange information regarding the quality issues identified or leading to the drug shortage, and communicate when necessary, with the company to explore options that will ensure the availability of drug products, while also ensuring that the drug is safe and effective.