21st Century Cures Act Reports on Scientific Conferences

Section 3074 of 21st Century Cures Act requires the FDA to report on scientific conferences hosted, sponsored, co-sponsored, or attendance at non-Federal Scientific Meetings with FDA expenses in excess of $30,000. The following outlines the total expenses for each scientific meeting together with other pertinent information including how the conference advanced the mission of the agency, a description of the conference activities. Section 3074 requires additional information of compelling circumstances for the costs exceeding $150,000.

2020 Annual Report

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1. FDA20 International Council for Harmonisation

Applicable Conference Type:	Non-FDA Conference Attended by FDA
Conference Location:	Singapore, Singapore
Conference Start Date:	11/16/2019
Conference End Date:	11/21/2019

Total FDA cost of the conference: $310,221
Total number of individuals whose travel expenses were paid by the FDA: 56

Explanation of how conference advanced the mission of FDA:

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is unique in bringing together regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration. ICH responds to the increasingly global face of drug development. The ICH is critical to the mission of the FDA because FDA's attendance was required for the working groups to progress in the development of internationally harmonized guidelines aimed to achieve development and registration of medicines in the most efficient and cost effective manner; to prevent duplication of clinical trials; and to provide public assurance that subjects are protected during clinical trials. ICH holds two meetings per year to progress in the development of internationally harmonized guidelines in the areas of Safety, Efficacy, Quality, and Multidisciplinary topics.

General description of the scientific conference activities:

The ICH is the primary venue for the conduct of harmonization of regulatory requirements for the entry of pharmaceutical products to the market. The goal of regulatory harmonization, also referred to as "regulatory coherence," is a central concept being championed by the Administration in its negotiations of the Trans-Pacific Partnership Free Trade Agreement and the Transatlantic Trade and Investment Partnership Free Trade Agreement. The benefits of harmonization had both an economic and a public health dimension. From an economic perspective, the cost of developing drugs can be constrained if disparate regulatory requirements across jurisdictions can be reconciled (based on science). From a public health perspective, the time to market for pharmaceutical products can be reduced allowing patients quicker access to therapies.

Explanation/description of circumstances for conference exceeding $150,000:

FDA participated in the ICH as a primary stakeholder. ICH expert working groups have two experts (a Topic Lead and a Deputy Topic Lead) from each ICH founding member party (the US, EU, and Japan); in some cases, for topics that are cross-cutting, more than two experts might be nominated. The Steering Committee similarly structured with two representatives for each party as well as a Coordinator. In the case of FDA, these seats were filled by one representative from the Center of Drug Evaluation of Research and one from Center for Biologics Evaluation and Research. The rules of ICH state that an official meeting of any given ICH group cannot take place, unless there was representation from each of the founding ICH parties. Therefore, the FDA sent 56 professionals to participate in this international meeting which led the conference cost to be over $150,000.

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2. FDA20 Reducing Risks of Compounded Drugs Engagement with Outsourcing Facilities Conference

Applicable Conference Type:	FDA Hosted/Sponsored/Co-Sponsored
Conference Location:	Virtual
Conference Start Date:	9/21/2020
Conference End Date:	9/22/2020

Total FDA cost of the conference: $298,862
Total number of individuals whose travel expenses were paid by the FDA: N/A

Explanation of how conference advanced the mission of FDA:

The Reducing Risks of Compounded Drugs Engagement with Outsourcing Facilities Conference advanced the mission of the FDA by hosting a meeting to engage the sector on issues related to outsourcing facilities and drug production as well as to educate the sector on relevant policy matters and FDA oversight approaches. Content topics included key and recent policies related to compounding issued by FDA; CGMP for outsourcing facilities; process design and use of automation technology by outsourcing facilities; FDA inspectional process for outsourcing facilities; interactions with FDA during and after inspections, including responses to FDA Form 483s and warning letters, and pre-operational meetings with FDA. Details gathered from training sessions and interviews with outsourcing facilities, state regulators and other stakeholders will be used to solidify the conference agenda and format.

General description of the scientific conference activities:

FDA's Centers worked together to advance FDA's public health mission related to drug compounding. Although compounded drugs can serve an important medical need for certain patients when an approved drug is not medically appropriate, they also present a risk to patients. Compounded drugs are not FDA-approved. Therefore, they do not undergo premarket review by FDA for safety, effectiveness, and quality. The Drug Quality and Security Act of 2013 created "outsourcing facilities" – a new industry sector of drug compounders held to higher quality standards to protect patient health.

Explanation/description of circumstances for conference exceeding $150,000:

Although compounded drugs can fill an important role for patients, and FDA recognizes the need to preserve access to these products, they may also present a greater risk to patients because, among other things, they are not required to undergo the agency's premarket review for safety, effectiveness, and quality. These risks have become evident during inspections of outsourcing facilities when the agency has found concerning

production practices that have resulted in recalls of compounded drug products and enforcement action against some firms. To help mitigate such issues, FDA has been working to develop novel approaches to engage outsourcing facilities and help them produce the highest quality products. Being that the FDA provides oversight for compounded drugs, it was imperative to host this virtual conference which had 414 attendees. The majority of the costs that led this conference to be of $150,000 were due to audio-visual costs and contractor support.

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3. FDA20 American Association of Blood Bank Conference

Applicable Conference Type:	Non-FDA Conference Attended by FDA
Conference Location:	San Antonio, Texas
Conference Start Date:	10/19/2019
Conference End Date:	10/22/2019

Total FDA cost of the conference: $157,596
Total number of individuals whose travel expenses were paid by the FDA: 61

Explanation of how conference advanced the mission of FDA:

The FDA sends Consumer Safety Officers to the American Association of Blood Bank Conference (AABB) for education on best practices, new practices, and case studies. The AABB conference advanced the mission of the FDA because it is mission critical that the agency continues to participate in the workshops to further the education of the industry and other regulatory counter-parts for a uniform understanding of the laws and regulations, enhance compliance, and strengthen donor eligibility knowledge. The Biologics Program intends the use of certification funds for maintenance of biologics certifications.

General description of the scientific conference activities:
The AABB meeting brought together the latest research and practice-changing resources for the fields of blood and biotherapies. Colleagues from throughout the world connected to network, learn, and advance the field. A state-of-the art virtual meeting platform combined an innovative learning environment with reliable functionality and intuitive navigation. The schedule included live and on-demand sessions, along with an interactive exhibit hall, networking spaces and poster hall.

Explanation/description of circumstances for conference exceeding $150,000:

The AABB Annual Meeting was the premiere event for healthcare professionals in the fields of transfusion medicine and cellular therapies. With over 5,000 domestic and international attendees, the AABB Annual Meeting attracted Chief Executive Officers, medical directors, laboratory supervisors and administrators, transfusion specialists, cellular therapy, blood banking professionals, medical technologists, donor recruiters, physicians, and nurses. The FDA sent 61 participants domestically and the majority of the conference cost were travel related, which caused the conference to exceed $150,000.

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4. FDA20 American Society of Hematology 2019

Applicable Conference Type:	Non-FDA Conference Attended by FDA

Conference Location: Orlando, Florida
Conference Start Date: 12/07/2019
Conference End Date: 12/10/2019

Total FDA cost of the conference: $116,952
Total number of individuals whose travel expenses were paid by the FDA: 48

Explanation of how conference advanced the mission of FDA:

FDA works in cooperation with other government agencies, foreign counterparts, industry and academia at the American Society of Hematology. This conference provided invaluable education and the opportunity to review thousands of scientific abstracts highlighting updates in the hottest topics in hematology. This conference advanced the mission of the FDA because it was critical that the Agency participate in the conference to further the education and understanding the hematology field with the global community.

General description of the scientific conference activities:

The range of topics were geared to specific audiences such as: medical, pharmacy, clinical, consultant, geriatric professionals and include MedWatch/AERS reporting, new drug safety messages, Treatment INDs, new programs or issues (Breakthrough Therapy, Biosimilars, GDUFA, opioids, etc.).

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5. FDA20 Regulatory Affairs Professionals Society 2020 Convergence

Applicable Conference Type: Non-FDA Conference Attended by FDA
Conference Location: Virtual
Conference Start Date: 9/13/2020
Conference End Date: 9/16/2020

Total FDA cost of the conference: $106,620
Total number of individuals whose travel expenses were paid by the FDA: N/A

Explanation of how conference advanced the mission of FDA:

Attendance to the Regulatory Affairs Professionals Society Convergence advanced the mission of the FDA because it enhanced the regulatory aspect of Investigator's by learning the latest innovation practices in the regulatory field. The conference allowed the FDA to interact with regulatory experts and health professionals, exchange experiences, and enabled the attendees to not only maintain and improve their ability to understand issues in regulatory affairs, but also celebrate their regulatory success and innovations in the field. Overall, the knowledge learned will be used to apply towards evaluation of policy development processes within the agency.

General description of the scientific conference activities:

The Regulatory Affairs Professionals Society (RAPS) is the largest global organization for those involved with the regulation of healthcare and related products, including medical devices, pharmaceuticals, biologics

and nutritional products. Founded in 1976, RAPS helped establish the regulatory profession and continues to actively support the professional and lead the profession as a neutral, nonlobbying nonprofit organization. RAPS offers education and training, professional standards, publications, research, knowledge sharing, networking, career development opportunities and other valuable resources, including Regulatory Affairs Certification (the only post academic professional credential to recognize regulatory excellence).

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6. FDA20 Drug Information Association 2020 Global Annual Meeting

Applicable Conference Type:	Non-FDA Conference Attended by FDA
Conference Location:	Virtual
Conference Start Date:	6/14/2020
Conference End Date:	6/18/2020

Total FDA cost of the conference: $103,661
Total number of individuals whose travel expenses were paid by the FDA: N/A

Explanation of how conference advanced the mission of FDA:

FDA's mission is to protect and promote the public health. The Agency assures that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. The FDA provides consumers, patients, their caregivers, and providers with understandable and accessible science-based information about the products the Agency oversees. Attendance at this year's DIA Annual meeting advanced the mission of the FDA because the information learned at this conference could be applied to FDA's ongoing work for the Partner with Patients strategic priority and supported the development of the Patient Program currently under development. This year's conference included sessions on patient engagement, focused on how patient engagement effects the medical product lifecycle and clinical trials, measuring the effectiveness of patient-centric activities and the science of patient input.

General description of the scientific conference activities:

The DIA 2020 Global Annual Meeting brought together patients, industry, regulators, and academia from all angles of the product lifecycle, from more than 50 countries. It was the intersection of science, healthcare, and regulation, with no barriers, just a catalyst for thoughtful dialogue and debate. The pharmaceutical, biotechnology, and medical device communities explored solutions and the processes that allow these healthcare solutions to expeditiously improve the well-being of the world and drive specific patient-positive outcomes.

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7. FDA20 Rapid Response Team Meeting

Applicable Conference Type:	FDA Hosted/Sponsored/Co-Sponsored
Conference Location:	Louisville, Kentucky
Conference Start Date:	12/09/2019
Conference End Date:	12/12/2019

Total FDA cost of the conference: $90,393
Total number of individuals whose travel expenses were paid by the FDA: 73

Explanation of how conference advanced the mission of FDA:

The Rapid Response Team (RRT) cooperative agreement, funded through FDA ORA Office of Partnerships (OP), addresses the need for improved, integrated rapid response to food and feed emergencies. Multiple national initiatives, such as the Food and Drug Administration Amendment Act (2007), formation of the President's Food Safety Working Group (2009), and the passage of Food Safety Modernization Act (2011), all point to the priority of this issue for the nation. Awards are made under the authorization of Section 317R of the Public Health Service Act (42 USC 247b-20), and Section 1004 of the Food and Drug Administration Amendments Act (21 USC 2104). This conference advanced the mission of the FDA because the RRT Program supports the FDA strategic plan by strengthening existing partnerships with international, federal, state, local, tribal, and territorial agencies to improve the effectiveness and efficiency of the FDA's food safety program for government and industry.

General description of the scientific conference activities:

FDA provided information on the Rapid Response Team (RRT) investigation of human illnesses associated with exposure to pig ears adulterated with Salmonella. This information stressed the FDA's public health mission as well as its partnership with States and Federal agencies, and it provided a pathway for future investigations, advancing the mission of the agency. In addition to presenting the information, the attendees were on a panel addressing the investigation. The FDA attendees work with the RRT's as part of their emergency coordinator activities, and this venue provided an opportunity to strengthen the partnerships.

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8. FDA20 American Society of Hospital Pharmacists Midyear Clinical Meeting and Exhibition

Applicable Conference Type:	Non-FDA Conference Attended by FDA
Conference Location:	Las Vegas, Nevada
Conference Start Date:	12/08/2019
Conference End Date:	12/12/2019

Total FDA cost of the conference: $87,485
Total number of individuals whose travel expenses were paid by the FDA: 32

Explanation of how conference advanced the mission of FDA:

The range of topics were geared to specific audiences such as: medical, pharmacy, clinical, consultant, and geriatric professionals. The professional meeting exhibits also supported FDA's hiring efforts as they were used to actively recruit scientists and health care professionals for job openings in the Offices, such as Generic Drugs, Compliance, Surveillance and Epidemiology, and various other offices. Travel and attendance at this meeting supported the mission of the FDA because it furthered the goal of protecting and promoting public health, strengthening science, improving product quality, working with industry, and improving overall interaction and communication.

General description of the scientific conference activities:

The mission of pharmacists is to help people achieve optimal health outcomes. The American Society of Hospital Pharmacists (ASHP) helps its members achieve this mission by advocating and supporting the professional practice of pharmacists in hospitals, health systems, ambulatory care clinics, and other settings spanning the full spectrum of medication use. ASHP serves its members as their collective voice on issues related to medication use and public health.

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9. FDA20 Manufactured Food Regulatory Program Alliance 9th Annual Meeting

Applicable Conference Type:	Non-FDA Conference Attended by FDA
Conference Location:	Spokane, Washington
Conference Start Date:	2/10/2020
Conference End Date:	2/13/2020

Total FDA cost of the conference: $87,460
Total number of individuals whose travel expenses were paid by the FDA: 63

Explanation of how conference advanced the mission of FDA:

The Manufactured Food Regulatory Program Alliance (MFRPA) provided topic specific training and resource materials on the Manufactured Food Regulatory Program Standards (MFRPS) to State Food Program Managers, State food safety program coordinators, and FDA personnel. Achieving and maintaining conformance with the MFRPS was critical for improving public health outcomes, reducing the incidence of food-borne illness, and advancing an integrated national food safety system, as mandated by the Food Safety Modernization Act (FSMA). This meeting advanced the mission of the FDA because participation in the meeting assisted State manufactured food programs in achieving conformance with the MFRPS and promoted the continuous quality improvement of state food safety programs.

General description of the scientific conference activities:

The Manufactured Food Regulatory Program Alliance (MFRPA) meeting provided topic specific training and resource materials on the Manufactured Food Regulatory Program Standards (MFRPS) to State Food Program Managers, State food safety program coordinators, and FDA personnel. The meeting included presentations, round-table discussions, and interactive exercises. The elements of the MFRPS described the best practices of a high-quality food regulatory program and encouraged continuous program improvement and innovation.

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10. FDA20 American College of Toxicology 40th Annual Meeting

Applicable Conference Type:	Non-FDA Conference Attended by FDA
Conference Location:	Phoenix, Arizona
Conference Start Date:	11/17/2019
Conference End Date:	11/20/2019

Total FDA cost of the conference: $73,901

Total number of individuals whose travel expenses were paid by the FDA: 31

Explanation of how conference advanced the mission of FDA:

The Annual Meeting is the heart of American College of Toxicology (ACT). This year's meeting brought together a community of toxicologists at small venues conducive to idea exchange, professional networking, and continuing education. ACT's first-rate scientific sessions were member driven, pharma focused (but not pharma exclusive), and organized to maximize learning opportunities. The ACT 40th Annual Meeting advanced the mission of the FDA because the knowledge gained was crucial to the exposure and non-clinical endpoint analysis of ingredients, extractables, and leachable of plastics surgery implant and infection control devices, which is vital to the evaluation of 510K, Investigational Device Evaluation, Premarket Approval, and Q-Sub submissions.

General description of the scientific conference activities:

The American College of Toxicology meeting provided an opportunity for continuing education and exchange of ideas with other FDA and potential Sponsor scientists. Keeping current with the latest information on toxicology and safety assessments, this meeting helped maintain the ability of FDA scientists to work effectively with sponsors to carry out the mission of the FDA, which is to assure that safe and effective drugs are available to the American people.

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11. FDA20 Association of American Feed Control Officials (AAFCO) Mid-Year Meeting

Applicable Conference Type:	Non-FDA Conference Attended by FDA
Conference Location:	Albuquerque, New Mexico
Conference Start Date:	1/21/2020
Conference End Date:	1/23/2020

Total FDA cost of the conference: $67,247
Total number of individuals whose travel expenses were paid by the FDA: 39

Explanation of how conference advanced the mission of FDA:

The Association of American Feed Control Officials (AAFCO) mid-year meeting advanced the mission of the FDA because the participants met with the AAFCO Board, attended plenary sessions and committee meetings, and discussed updates on policy and regulatory issues at FDA, affecting animal feed and pet food. This meeting included the final rules for the Food Safety Modernization Act, Veterinary Feed Directive implementation, Generally Recognized as Safe (GRAS), and the AAFCO definition process, pet food labeling, and FDA's interest in listeria and salmonella in raw pet food diets.

General description of the scientific conference activities:

The AAFCO allowed direct face-to-face communication with State partners, who were currently implementing the Animal Feed Regulatory Program Standards (AFRPS) and performing work under contracts or cooperative agreements for Animal Feed and Tissue Residue Programs, aiding the migration toward a nationally integrated feed safety system. The focused topics were: Adopting the Food Safety

Modernization Act (FSMA) within State Feed laws, Feed Ingredients, Feed Terms, Feed Inspection and Sampling, Feed Contaminant Levels, Labeling Requirements for Potentially Toxic Nutrients, and Pet Food.

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12. FDA20 2019 American Public Health Association 147th Annual Meeting

Applicable Conference Type:	Non-FDA Conference Attended by FDA
Conference Location:	Philadelphia, Pennsylvania
Conference Start Date:	11/02/2019
Conference End Date:	11/06/2019

Total FDA cost of the conference: $59,967
Total number of individuals whose travel expenses were paid by the FDA: 29

Explanation of how conference advanced the mission of FDA:

The 2019 American Public Health Association 147th Annual meeting advanced the mission of the FDA because it allowed the FDA to coordinate with its members of state and regional affiliates on protecting and promoting public health. The public health concerns included ensuring access to care, protecting funding for core public health programs and services, and eliminating health disparities. APHA is also working on other critical public health issues, including public health and emergency preparedness, food safety, hunger and nutrition, climate change, and other environmental health issues, such as public health infrastructure, disease control, international health, and tobacco control.

General description of the scientific conference activities:

The range of topics was geared to specific audiences (medical, pharmacy, clinical, consultant, geriatric, etc.) and included MedWatch/AERS reporting, new drug safety messages, Treatment INDs, and new programs or issues (Breakthrough Therapy, Biosimilars, GDUFA, opioids, etc.). Professional meeting exhibits also supported FDA's hiring efforts as they are used to actively recruit scientists and health care professionals for job openings in various FDA's Centers/Offices.

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13. FDA20 Interstate Shellfish Sanitation Conference

Applicable Conference Type:	Non-FDA Conference Attended by FDA
Conference Location:	San Diego, California
Conference Start Date:	10/05/19
Conference End Date:	10/10/19

Total FDA cost of the conference: $51,692
Total number of individuals whose travel expenses were paid by the FDA: 18

Explanation of how conference advanced the mission of FDA:

Attendance and participation at this national conference fostered and promoted molluscan shellfish sanitation through the FDA Cooperative Program of the National Shellfish Sanitation Program (NSSP).

FDA personnel fulfilled the following roles and responsibilities at the Conference: first, served as Agency spokespersons on issues/proposals submitted to the Conference; second, served as consultants to the committees and task forces that deliberated the issues/proposals; third, served as technical resources for state regulatory and industry officials who deliberated the issues/proposals; fourth, participated in the committees that have been charged by the task forces to deliberate issues/proposals; fifth, served as recorders and assistants to ensure the successful execution of the Conference; and sixth, attended Regional Regulatory caucus meetings, if invited by state agencies when the issues/proposals are discussed.

General description of the scientific conference activities:

The Interstate Shellfish Sanitation Conference (ISSC) was formed in 1982 to foster and promote shellfish sanitation through the cooperation of state and federal control agencies, the shellfish industry, and the academic community. To achieve this purpose the ISSC: First, adopts uniform procedures, incorporated into an Interstate Shellfish Sanitation Program, and implemented by all shellfish control agencies; second, gives state shellfish programs current and comprehensive sanitation guidelines to regulate the harvesting, processing, and shipping of shellfish; third, provides a forum for shellfish control agencies, the shellfish industry, and academic community to resolve major issues concerning shellfish sanitation; and fourth, informs all interested parties of recent developments in shellfish sanitation and other major issues of concern through the use of news media, publications, regional and national meetings, internet, and by working closely with academic institutions and trade associations. The ISSC promotes cooperation and trust among shellfish control agencies, the shellfish industry, and consumers of shellfish; and insures the safety of shellfish products consumed in the United States. This meeting focused on issues of importance to shellfish sanitation. Issues for Conference consideration were submitted to the Program Chairman 90 days prior to the annual meeting. All new issues are mailed to Conference membership for review prior to the annual meeting.

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14. FDA20 Medicines and Healthcare Regulatory Agency Good Pharmacovigilance Practice

Applicable Conference Type:	FDA Hosted/Sponsored/Co-Sponsored
Conference Location:	London, United Kingdom
Conference Start Date:	2/11/2020
Conference End Date:	2/14/2020

Total FDA cost of the conference: $49,561
Total number of individuals whose travel expenses were paid by the FDA: 13

Explanation of how conference advanced the mission of FDA:

This series of good practice symposium and workshop covered good pharmacovigilance and laboratory practices as well as data integrity in global clinical trials and good clinical practice case studies. This conference met the FDA strategic goals of operational excellence and ensuring compliance through collaboration with all stakeholders including commercial sponsors and foreign regulatory counterparts.

General description of the scientific conference activities:

The 2020 Good Pharmacovigilance Practice Symposium provided an insight into the key topics and compliance trends in pharmacovigilance observed by the MHRA GPvP inspectors since the 2018 Symposium. The event was relevant to anyone working in pharmacovigilance, medical information and regulatory affairs, including EU QPPVs and service providers. This year's Laboratories event highlighted the importance of 'fit for intended use' in the context of regulated work across GLP, GCP and GMPQC Laboratories. The content of the event was intended to illustrate that this topic is not just limited to facilities and equipment but can be applied across an organization, from people and training to quality management systems and report production. The day included presentations from Laboratory inspectors, example findings and expectations relating to laboratory practice, an opportunity to meet with Inspectors to ask questions and interactive sessions to get the audience involved. After the event, delegates had a better understanding of the Laboratory inspectors' position on the topic of 'fit for intended use' and how this can be applied in day to day regulated work. This Symposium was in partnership with the US Food and Drug Administration (FDA).

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15. FDA20 American Association for The Study of Liver Diseases Liver Meeting 2019

Applicable Conference Type:	Non-FDA Conference Attended by FDA
Conference Location:	Boston, Massachusetts
Conference Start Date:	11/08/2019
Conference End Date:	11/12/2019

Total FDA cost of the conference: $45,680
Total number of individuals whose travel expenses were paid by the FDA: 18

Explanation of how conference advanced the mission of FDA:

This conference advanced the mission of the FDA because it provided protection of public health by supplying prescription drug promotion comprehensive surveillance enforcement and education by fostering better communication of labeling and promotional information to both professionals and consumers. The Annual Liver Meeting allowed FDA to meet and interact with scientists and clinicians, who study and treat liver diseases. It also allowed an important opportunity for FDA to learn about the most recent technological advances and devices regarding the treatment and diagnosis of liver diseases (such as HCV, NASH and iDILI). Furthermore, attending this event allowed FDA to understand the newest types of technologies the community is interested in and critical needs that are unmet by the available diagnostic tools in this field.

General description of the scientific conference activities:

The American Association for the Study of Liver Diseases (AASLD) is the leading organization of scientists and health care professionals committed to preventing and curing liver disease. AASLD was founded by a small group of leading liver specialists to bring together those who had contributed to the field of hepatology. AASLD's Mission is to advance and disseminate the science and practice of hepatology, and to promote liver health and quality patient care. Hepatology has been recognized as a discipline only in the last few decades, and AASLD played a seminal and unifying role in focusing interest on hepatological problems, as well as the founding of other hepatological societies. AASLD is the leading organization of scientists and health care professionals committed to preventing and curing liver disease. They foster research that leads to improved treatment options for millions of liver disease patients. They advance the

science and practice of hepatology through educational conferences, training programs, professional publications, and partnerships with government agencies and sister societies.

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16. FDA20 Pharmaceutical Inspectorate Cooperation Scheme, PIC/S, GMP Symposium

Applicable Conference Type:	Non-FDA Conference Attended by FDA
Conference Location:	Toyama, Japan
Conference Start Date:	11/13/2019
Conference End Date:	11/15/2019

Total FDA cost of the conference: $44,184
Total number of individuals whose travel expenses were paid by the FDA: 10

Explanation of how conference advanced the mission of FDA:

This seminar provided FDA a further understanding of the PIC/S Good Manufacturing Practice (GMP) Guide Annex1 based on issues discussed during its ongoing revision and through a case study of sterility assurance. Furthermore PIC/S GMP Symposium furthered the mission of the FDA because it allowed participants to acquire skills on how to make science and risk-based decisions related to product quality during GMP inspections. PIC/S GMP guidelines are standards which were used in the Mutual Recognition Assessment (MRA) activities to determine European Union (EU) members capability. Additionally, FDA participated in discussions with regulatory agencies from other countries to provide FDA's views on sterile process manufacturing to provide improved alignment globally.

General description of the scientific conference activities:

The PIC/S' mission is to lead the international development, implementation and maintenance of harmonized Good Manufacturing Practice (GMP) standards and quality systems of inspectorates in the field of medicinal products. It developed and promoted harmonized GMP standards and guidance documents; Trained Competent Authorities, GMP Inspectors; Assessed (and re-assessed) GMP Inspectorates; and Facilitated co-operation and networking for Competent Authorities and International Organizations. This seminar was an ideal opportunity for both novice and experienced inspectors to enhance their inspection skills through knowledge sharing and discussion.

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17. FDA20 Cooperation Centre for Scientific Research Relative to Tobacco - Smoke Techno Conference

Applicable Conference Type:	Non-FDA Conference Attended by FDA
Conference Location:	Hamburg, Germany
Conference Start Date:	10/06/2019
Conference End Date:	10/10/2019

Total FDA cost of the conference: $40,025
Total number of individuals whose travel expenses were paid by the FDA: 7

Explanation of how conference advanced the mission of FDA:

The Cooperation Centre for Scientific Research Relative to Tobacco - Smoke Techno Conference provided insight into currently accepted methodologies and practices in key areas of regulatory science, such as tobacco-specific nitrosamines and cigarette design features, as well as developing areas such as e-cigarette science. Additionally, Cooperation Centre for Scientific Research Relative to Tobacco is leading the efforts in establishing tobacco related ISO methods and standards that will significantly impact future FDA tobacco rulemaking. The Congress is held every 2 years, and there is no U.S based conference that covers this topic. During the Smoke Science and Product Technology Conference, emerging methods for the detection and quantification of aromatic amines, volatile organic compounds, B[a]P and carbonyls, which occur in smoke, filler, and aerosol, all were discussed and evaluated. It was essential that FDA attended this conference to advance the mission of the FDA because it provided input into the standard methods for the detection of these toxicants as FDA may publish standard methods for tobacco regulatory submissions.

General description of the scientific conference activities:

The conference promoted international cooperation and research regarding non-competitive scientific issues as well as developed methods for physical or chemical measurement. In order to produce and maintain these methods, and for laboratory accreditation, proficiency tests, collaborative studies and reviews were conducted, leading to the publication of study and technical reports. FDA was able to offer CORESTA members guidance on FDA's requirements for method validation to determine proper system suitability, performance criteria, and limitations, with the overall goal of ensuring compliance with all Federal rules and regulations. Tobacco is a complicated matrix, and the presentations in this tobacco specific meeting provided useful information to develop new regulatory methods.

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18. FDA20 The Pittsburgh Conference on Analytical Chemistry and Applied Spectroscopy Conference

Applicable Conference Type:	Non-FDA Conference Attended by FDA
Conference Location:	Chicago, Illinois
Conference Start Date:	3/01/2020
Conference End Date:	3/05/2020

Total FDA cost of the conference: $38,099
Total number of individuals whose travel expenses were paid by the FDA: 18

Explanation of how conference advanced the mission of FDA:

With FDA's attendance at the four-day conference was critical to advancing the mission of the FDA because this provided the opportunity for interaction and the gaining of current knowledge from other researchers in the field. This was also an excellent opportunity to access leading-edge technical developments of exhibitors showcasing state-of-the-art technologies. Some of our scientists also assisted in screening potential Oak Ridge Institute for Science and Education candidates for their Branch. It allowed for practical hands-on information that helped in running labs and provided information on new food regulations. If the attendance at this conference was not approved, the FDA labs would have been denied the opportunity to network with other scientists, putting them behind in receiving information and presentations on new technology.

General description of the scientific conference activities:

Pittcon, a vital resource for knowledge, happens yearly to help keep others informed as well as connected to updated, significant, ongoing findings and new instrumentation. Anyone who develops, buys, or sells laboratory equipment, performs physical or chemical analyses, develops analysis methods, or manages scientists should attend Pittcon. Pittcon was a dynamic, transnational exposition and comprehensive technical conference, a venue for presenting the latest advances in research and scientific instrumentation, and a platform for continuing education and career-enhancing opportunity. Pittcon advanced scientific endeavor through collaboration, brought together a world of knowledge to impact, enriched, and inspired the future of science. Pittcon was a catalyst for the exchange of information, a showcase of the latest advances in laboratory science, and a venue for international connectivity.

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19. FDA20 2019 Advancing Ethical Research and Social, Behavioral, and Educational Research Conferences

Applicable Conference Type:	Non-FDA Conference Attended by FDA
Conference Location:	Boston, Massachusetts
Conference Start Date:	11/17/2020
Conference End Date:	11/20/2020

Total FDA cost of the conference: $35,513
Total number of individuals whose travel expenses were paid by the FDA: 15

Explanation of how conference advanced the mission of FDA:

Attendance to the 2019 Advancing Ethical Research and Social, Behavior, and Educational Research (SBER) Conference was mission critical because it forded the opportunity for FDA attendees to learn about ethical issues and the federal regulations governing human subjects research, best practices for the review and monitoring of research, implementing the revised Common Rule, and other late-breaking topics through a series keynotes, panels, and 100+ breakout sessions in this conference. The conference informed and educated stakeholders (researchers and IRB members) about FDA's efforts to incorporate real-world evidence (RWE) into the Agency's regulatory considerations regarding the safety and efficacy of drugs and biological products.

General description of the scientific conference activities:

This conference included high level talks and in-depth breakout sessions designed to help build and strengthen effective Human Research Protections Program (HRPP)/Institutional Review Boards (IRB) that oversee SBER. Attendees learned about ethical issues and best practices for reviewing and monitoring social science research, and speakers explored strategies for implementing the revised Common Rule. The 2019 Advancing Ethical Research Conference (AER19) included three keynote addresses, nine panels, and over 100 breakout sessions where attendees increased their knowledge and understanding of ethical requirements, learned the best practices and strategies for their implementation, and sharpened their skills

for dealing with myriad of late-breaking and longstanding challenges, especially those related to implementation of the revised Common Rule. This meeting also featured a poster gallery composed of work on novel approaches to the management, function, and operations of HRPPs/IRBs and empirical studies or conceptual analysis of challenging issues related to the conduct or oversight of research involving human subjects.

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20. FDA20 Consumer Electronic Show 2020

Applicable Conference Type:	Non-FDA Conference Attended by FDA
Conference Location:	Las Vegas, Nevada
Conference Start Date:	1/07/2020
Conference End Date:	1/10/2020

Total FDA cost of the conference: 35,359
Total number of individuals whose travel expenses were paid by the FDA: 14

Explanation of how conference advanced the mission of FDA:

Attending the Consumer Electronic Show was imperative to advance the mission of the FDA because it gave the FDA attendees the opportunity to learn about current and upcoming novel technologies in the areas of rehabilitation, neurodiagnostic, psychiatry, and mental health, which are specific review areas in OHT5. FDA attendance of supervisory and review staff responsible for reviewing products benefited the agency and center to anticipate and prepare for upcoming device-related submissions, prepare for regulatory strategies for novel technologies and difficult to treat/diagnose medical conditions, listen to industries scientific and regulatory challenges, all in an effort to expedite patient access to safe and effective devices and reduce pain points for sponsors navigating different regulatory pathways. It attracted global business leaders, pioneering thinkers, and provided a proving ground for emerging trends. Digital Health, Internet of Things (IOT), fitness and wearables, artificial intelligence, remote patient monitoring, and augmented and virtual reality were all topics of major focus for CES 2020 that significantly pertain to the rapidly involving work of the Office of Medical Policy (OMP) within the FDA.

General description of the scientific conference activities:

The conference offered presentations on these subjects, and there are panel discussions that included industry leaders and other stakeholders, who are developing and supporting products in these areas. The conference also provided hands-on and face-to-face interaction with devices and sponsors in the exhibit halls. The conference included sessions, exhibits, and presentations by start-up and mature firms, who are involved in bringing innovative health products to market. The interaction with these sponsors and their products gave us a better understanding of their goals and challenges so that they could be addressed in order to bring more of these products to market more quickly, as part of FDA's mission to protect and promote public health by applying the regulatory standard to these novel technologies in demand by the public.

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21. FDA20 Society of Photo-Optical Instrumentation Engineers Photonics West

Applicable Conference Type: Non-FDA Conference Attended by FDA
Conference Location: San Francisco, California
Conference Start Date: 2/01/2020
Conference End Date: 2/06/2020

Total FDA cost of the conference: $33,192
Total number of individuals whose travel expenses were paid by the FDA: 13

Explanation of how conference advanced the mission of FDA:

Attendance at the Society of Photo-Optical Instrumentation Engineers Photonics West Conference was critical to fulfill the FDA mission of promoting public health through communication of our regulatory science research program. This conference provided access to the latest research in biphotonic, laser technologies, and optoelectronics materials and devices. It was a full week with over 5,200 technical papers, 65 course and workshop options, notable plenary speakers, a powerful industry program, and plenty of networking opportunities. The International Society for Optics and Photonics Conference was an established industry meeting, and the most important meeting of scientists involved in spectroscopic/imaging technologies that have the potential to be developed as cutaneous pharmacokinetics-based bioequivalence methodologies. World experts in the field attended in order to advance the goals of developing technologies that can be applied to the bioequivalence assessment of different types of complex generic products. The science and research were highly aligned with the FDA's mission to make high quality generic drugs increasingly accessible to patients. Participation in this meeting facilitated the comprehensive scientific consultation necessary to develop appropriate bioequivalence approaches and standards to facilitate the development and regulatory review of high-quality generic drugs that can be made available to the American public.

General description of the scientific conference activities:

This conference was one of the largest international conferences focused on novel laser technologies, including materials processing, micro-nano packaging, fiber, diode, solid state lasers, resonators, ultrafast, semiconductor, 3D fabrication, and LEDs. Both nascent research and commercially available products were presented here, and these products are regulated by FDA. Non-attendance to this meeting would have severely inhibited the FDA from accurately regulating commercially available laser-based products. To accurately review and inspect these laser products, emerging technologies in developing and manufacturing must be understood. Additionally, because the conference was internationally attended, technologies that are used overseas were presented, and the products purchased in the US are often manufactured in these overseas countries, increasing the importance to attend this internationally attended conference. Some of the FDA attendees are member of the international society of optics and photonics, and they presented FDA findings and research.

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22. FDA20 American Statistical Association Biopharm Section Regulatory Industry Statistics Workshop

Applicable Conference Type: FDA Hosted/Sponsored/Co-Sponsored
Conference Location: Alexandria, Virginia (Virtual)
Conference Start Date: 9/22/2020

Conference End Date: 9/25/2020

Total FDA cost of the conference: $32,250
Total number of individuals whose travel expenses were paid by the FDA: 226

Explanation of how conference advanced the mission of FDA:

Concerning the conference, the short course and sessions organized by FDA covered adaptive designs, Bayesian approaches, big data, and innovative designs and analysis in bioequivalence studies. Attendance advanced the mission of the agency as these topics are in line with FDA's current mandate to provide guidance on the use of innovative investigational designs for animal drug evaluation. This is a scientific meeting covered a range of topics for biostatisticians in the medical product area. Each session of the conference included presentations by attendees from FDA, academics, and industry. It was an opportunity for statisticians from diverse backgrounds to reach common understanding on the appropriate methods and statistical analyses to use for many regulatory decisions. The meeting provided training and professional development to statisticians, and thus it enhanced their ability to carry out statistical reviews. This was directly applicable to their day-to-day duties, specifically the reviewing of pre-market medical device submissions. This conference directly benefited the FDA and supported the mission critical activity of pre-market review.

General description of the scientific conference activities:

The workshop was originally a meeting for FDA statisticians that later expanded to include all statisticians interested in statistical practices for all areas regulated by the FDA. Although the workshop achieved a high level of attendance, it also maintained the same grass-roots approach for its planning. By bringing both FDA and industry speakers into each session, the highly valued original intent of the conference is maintained. The value is enhanced further when academic speakers can be engaged, as well as speakers from other regulatory agencies. The result was the most relevant conference for statistical practitioners in the biopharmaceutical arena as well as enhanced and obtained up-to-date scientific knowledge to facilitate review of applications at work. ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop relied heavily on careful planning and hard-working volunteers. Several subcommittees were formed to handle different tasks and support the two co-chairs. This involved additional meetings within each subcommittee. In addition, the steering committee members were expected to review session proposals. Selection of steering committee members were based on a series of factors, including balance between affiliations (FDA and industry), balance of levels of experience in similar volunteering and organizational work at this or other conferences/workshops/short courses, broad representation across companies (for industry representatives), variety of areas of interest and technical expertise (CMC, clinical, preclinical, early and late development of drugs, devices, etc.), and strong commitment—including active participation and attendance at steering committee meetings—to do the best for the workshop. All were welcomed to submit a session proposal and participate in the grass-roots organizing meeting held online.

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23. FDA20 Society of Environmental Toxicology and Chemistry North America 10th Annual Meeting

Applicable Conference Type: Non-FDA Conference Attended by FDA
Conference Location: Toronto, Canada

Conference Start Date: 11/03/2019
Conference End Date: 11/07/2019

Total FDA cost of the conference: $30,845
Total number of individuals whose travel expenses were paid by the FDA: 11

Explanation of how conference advanced the mission of FDA:

The environmental assessment (EA) of FDA implemented the environmental review of drugs under 21 CFR Part 25. Attending this conference allowed the EA team to help communicate to the scientific and regulatory community the FDA's current approach to EA's and new issues regarding drug disposal (in particular opioids and related drugs) as well as presented/learned about the recent research regarding pharmaceuticals in the environment, particularly regarding chemical testing and risk assessment approaches used in the US and internationally for the drugs regulated by FDA. These areas were especially important because the EA team is updating the EA guidance for industry. Information presented by others at this meeting were state-of-the art for risk assessments of drugs in the environment and were crucial to the development of a scientifically supportable EA guidance update. The guidance in turn helped the FDA develop a more targeted and efficient environmental review processes for drug applications and related FDA oversight requirements, which ultimately will help FDA meet its goals of protecting the public health by assuring the safety, efficacy and security of human drugs and advancing the public health by helping to speed innovations that make medicines more effective, safer, and more affordable. FDA attendance advanced the mission of the agency by providing the attendees with knowledge and new research in the areas of environmental toxicology and chemistry, and statistics related to environmental toxicity studies. The information gained will aid FDA's environmental safety evaluations required under FDA's regulations and National Environmental Policy Act (NEPA) for new animal drugs and food additive petitions. Research from FDA was also presented on analytical method developments. The meeting emphasized the need for environmental scientists and managers from all sectors to work together at a global scale to address shared environmental challenges.

General description of the scientific conference activities:

The Society of Environmental Toxicology and Chemistry North America 10th Annual conference meeting supported and facilitated the development of principles and practices for the protection, enhancement and management of sustainable environmental quality and ecosystem integrity. It also promoted the advancement of environmental sciences, education in the field, and the use of science in environmental policy and decision-making. It provided a forum where environmental professionals exchange information and ideas for the development and use of multidisciplinary scientific principles and practices leading to sustainable environmental quality. The conference promoted multidisciplinary approaches to solving environmental problems, the balance in participation from all involved stakeholders from all sectors, and science-based objectivity. All members and guests were expected to adhere to the SETAC Code of Ethics and Code of Conduct. Furthermore, the conference embraced a set of values to which all members and organizational entities of SETAC adhere, such as being committed to having an open and transparent society, having personal and scientific integrity, and striving for both scientific and individual diversity and inclusivity in all aspects of governance and programming. Diversity in sciences were inclusive of collaborative sciences and sometimes referred to as multidisciplinary, interdisciplinary and transdisciplinary environmental science fields. The meeting also promoted impartiality and fair-mindedness within procedures and processes, embraced sustainability in all its activities, and allowed

transparency to extend into open science with a goal of stimulating knowledge sharing through cooperation and dialogue.