SMG 2350.5

FDA Staff Manual Guides, Volume III – General Administration

Financial Management - Financial Integrity

Conference Approval and Reporting

Effective Date: 08/07/2020

1. Purpose.

The Division of Travel Services (DTS) is a Division within the Office of Financial Management (OFM), Office of Finance, Budget, and Acquisitions (OFBA).

Within DTS, the Conference Approval and Reporting (CAR) Team is responsible to provide CAR guidance to Food and Drug Administration (FDA) staff.

The purpose of this Staff Manual Guide (SMG) is to ensure:

- Conference obligations and costs are in compliance with applicable

Federal laws, regulations, and Department of Health & Human Services (DHHS) and FDA policies

- Taxpayer funds are safeguarded against fraud, waste, abuse, unauthorized use, or misappropriation

- Conference expenditures are properly recorded and reported to maintain accountability over funds

- Effective and efficient internal controls are implemented to mitigate risks

This policy sets forth the requirements for the review and approval of requests to host, sponsor, or co-sponsor FDA held conferences; and requests to attend Non-FDA conferences. This policy also sets forth the requirements for reporting conference expenditures to internal and external stakeholders. Additionally, this policy provides for the review of all FDA hosted meetings to ensure such meetings are properly reported if required.

2. Background.

In accordance with Federal regulations, OMB guidance, and HHS policy; FDA is charged with ensuring that FDA funds are used only for necessary and appropriate purposes to support the FDA mission. In addition, FDA must ensure that all conference expenses and activities comply with both the Federal Travel Regulation (FTR) and the Federal Acquisition Regulation (FAR) requirements on lodging, food and beverages, per diem reimbursement, and contracting of goods and services.

DHHS has identified two conference categories that align with the Department's overall mission:

- Scientific Conferences
- Non-Scientific Conferences

Each conference category can be further divided into the following two sub-categories:

- FDA Hosted/Sponsored/Co-Sponsored Conference (includes FDA employees attending these conferences)

- Non-FDA Conference Attended by FDA

Procedures for FDA’s CAR process are divided into two (2) distinct phases:

- The conference approval phase occurs prior to the obligation of funds and incurring of expenses for conferences. This phase consists of conference approval requests that are reviewed by the FDA CAR Team and approved by

the Chief Operating Officer (COO), Deputy COO, and/or Executive Officer (EO) or delegated authority depending on the conference approval thresholds.

- The conference reporting phase consists of the required reporting of conference activities. When conference activities are reported by the Center/Office point of contact (POC), the FDA reports the activities to the HHS Office of Inspector General (OIG) and publishes additional required reports to the FDA Annual Report on Conference website (https://www.fda.gov/newsevents/meetingsconferencesworkshops/ucm590499.htm). The reports listed below make up the reporting requirements component of the CAR process.

#	Report Name	Conference Type	Expenditure Threshold	Frequency/ Submission Date	Distribution
1	**FDA Conference Expense Report**	• Scientific • Non-Scientific • FDA Hosted, Sponsored/Co-Sponsored • Non-FDA Conference Attended by FDA	All conferences	Monthly / 15 calendar days after end of each month	Submitted via email to Deputy Chief Financial Officer
2	**HHS OIG Reporting of Conferences in Excess of $20,000**	• Scientific • Non-Scientific • FDA Hosted, Sponsored/Co-Sponsored	Conferences with expenditures greater than $20,000	Quarterly / 15 calendar days after end of each fiscal year quarter	Submitted to OIG via email
3	**OMB M-17-08 Annual Report**	• Scientific • Non-Scientific • FDA Hosted, Sponsored/Co-Sponsored	Conferences with expenditures greater than $100,000	Annually / January 31st of the next calendar year	Published to FDA Annual Report on Conference website and submitted to Assistant Secretary of Financial Resources (ASFR) for inclusion on HHS website

#	Report Name	Conference Type	Expenditure Threshold	Frequency/ Submission Date	Distribution
4	**HHS OIG Annual Report**	• Scientific • Non-Scientific • FDA Hosted, Sponsored/Co-Sponsored	Conferences with expenditures greater than $100,000	Annually / January 31st of the next calendar year	Submitted to OIG via email
5	**Reporting of Scientific Conferences**	• Scientific • FDA Hosted, Sponsored/Co-Sponsored • Non-FDA Conference Attended by FDA	Conferences with expenditures greater than $30,000	Annually / 90 calendar days after the end of each fiscal year	Published to FDA Annual Report on Conference website

3. Reference/Authority.

FDA policy is consistent with guidance set forth by the following policies regarding the requirements of CAR. These include:

A. 21st Century Cures Act, Public Law 114-255, December 2016 (https://www.congress.gov/bill/114th-congress/house-bill/34/text)

B. OMB Memorandum M-17-08, Promoting Efficient Spending to Support Agency Operations, Section 2, November 2016 (https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2017/m-17-08.pdf)

C. Federal Travel Regulation (FTR), Chapters 300-304, Issued January 2004, Updated February 2016 (https://www.gsa.gov/policy-regulations/regulations/Federal-travel-regulation-ftr)

D. Joint Travel Regulation (JTR), Published January 2018 (http://www.defensetravel.dod.mil/Docs/perdiem/JTR.pdf)
Note: The JTR applies to FDA employees who are Uniformed Service Members

E. HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meeting Space, Food, Promotional Items, and Printing and Publications (https://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/index.html)
Note: This link leads to the published version of the policy that is currently listed on the HHS.gov website.

F. Code of Federal Regulations (CFR) - Determining If a Conference is a Training Activity, Title 5 Part 410.404. January 2002 (https://www.gpo.gov/fdsys/granule/CFR-2002-title5-vol1/CFR-2002-title5-vol1-sec410-404/content-detail.html)

4. Definitions.

A. **Conference** – A meeting, retreat, seminar, symposium or event that involves attendee travel. The term "conference" also applies to training activities that are considered to be conferences under 5 CFR 410.404. Meeting and events that are not considered conferences are listed in Appendix A. They are exempt from the request, approval, and reporting requirements of this SMG.

B. **Conference Activities** – Consist of conference expenditures, location, dates, justifications for expenditures, etc. A full listing of conference activities for each report can be found in Appendix E.

C. **Conference Expenses** – All costs paid by the Government related to the conference, whether paid directly by agencies or reimbursed by agencies to travelers or others associated with the conference, but do not include funds that are payment in kind. Conference expenses include any associated authorized travel and per diem expenses, hire of rooms for official business, audiovisual use, registration fees, ground transportation, and other expenses as defined by the FTR Part.301. All disbursements for conference preparation and planning should be included, but the Federal employee time for conference preparation should not be included. Conference expenses should be net of any fees or revenue received by the agency through the conference and should not include costs to ensure the safety of attending governmental officials.

D. **Payment** - A monetary payment from a Non-Federal source to a Federal agency for travel, subsistence, related expenses by check or other monetary instrument payable to the Federal agency (i.e., electronic fund transfer (EFT), money order, charge card, etc.) or payment in kind.

E. **Payment in Kind (Sponsored Travel)** – Includes transportation, food, lodging, or other travel-related services provided by a Non-Federal source instead of monetary payments to the Federal agency for these services. Payment in kind also includes waiver of any fees that a Non-Federal source normally collects from meeting attendees (e.g., registration fees).

F. **Scientific Conference** – A meeting that is attended by scientific or medical personnel, or other professionals, of the HHS, to advance the knowledge of science through the presentation and discussions of the results of scientific

research and potential directions for further scientific research.

G. **Non-Scientific Conference** – A meeting that falls within the definition of conference but does not meet the definition of "scientific conference".

H. **FDA Hosted/Sponsored/Co-Sponsored Conference** – Conferences hosted, sponsored, or co-sponsored by the FDA and funded via any formalized agreement such as contract, order/call, purchase card, Tribal contract, compact, or funded via grants or cooperative agreements, inter/intra-agency agreements, or co-sponsorship agreement with the other organization.

I. **Non-FDA Conference Attended by FDA** – Conference held by another Federal agency or external organization that is attended by FDA employees.

J. **Funds -** The term "funds", as used herein, refers to all HHS appropriations, regardless of whether such appropriations are annual, multi-year, or no year, and regardless of whether they are provided in an annual appropriations act or a permanent law.; The term "HHS appropriations" includes all amounts appropriated by law, regardless of whether the funds are derived from the General Fund of the US Treasury, authorized user fees, gift funds, amounts transferred from another appropriation; or reimbursements that HHS has statutory authority to retain to the credit of an HHS appropriation.

5. Policy.

A. General Requirements

Conference Approval Requests. All conferences, for which approval is sought in accordance with the Policies and Procedures herein outlined, must meet the definition of a conference as contained in Section 4, Definitions.

International Conference Approval Requests. All conference approval requests must comply with the policy and procedures defined in SMG 2342.2 'Request for Approval of International Travel'.

Training Activities That May Be Considered Conferences. FDA may sponsor an employee's attendance at a conference as a developmental assignment under section 4110 of title 5, United States Code when:

- The announced purpose of the conference is educational or instructional; and

- More than half of the time is scheduled for a planned, organized exchange of information between presenters and audience which meets the definition of training in section 4101 of title 5, United States Code; and

- The content of the conference is germane to improving individual and/or organizational performance; and

- Development benefits will be derived through the employee's attendance.

Payment in Kind Requirements (Sponsored Travel). Under limited circumstances FDA employees may accept payments from a Non-Federal source receiving Federal grants or contracts for a conference traveler. The following are the requirements when financing conference travel with payment from a Non-Federal source:

- The employee must be performing authorized official duties for FDA that is consistent with FDA's mission.

- The Non-Federal source must indicate in the request for attendance "Letter of Invitation" that it is using either Federal grant or contract monies obtained through a private entity to fund the travel and related expenses.

- Follow the Sponsored Travel approval and reporting process for payment by a Non-Federal source, using Federal grant or contract funds. The following signatures are required within ConcurGov: Traveler, and Deputy Ethics Officer/Ethics Official.

- Funds from a Non-Federal source may not be accepted as a form of payment for travel, transportation, and subsistence expenses.

    - For more information regarding the approval process for accepting payment from Non-Federal sources see SMG 2340.1 Acceptance of Payment for Travel Expenses from Non-Federal Sources.

System Requirements. The following system requirements must be followed:

- **FDA Conference Approval System (CAS)** – Center/Office POCs must send requests for CAS access to the FDA Conference Approval mailbox, FDA-Conference-Approvals@fda.hhs.gov.

- **Concur Government Edition (ConcurGov)** – The FDA CAR Team must send conference names to the Program Support Center (PSC) so that they can be entered into the FDA travel system, ConcurGov.

    - All conference names submitted to PSC should not exceed 100 characters due to ConcurGov field/space restraints.

B. Evaluation of FDA Hosted Meetings and Events

FDA Hosted meetings and events require evaluation to determine if it meets the definition of a reportable Scientific or Non-Scientific as defined in Section 4.

- Center/Office POCs are required to complete the FDA Meeting/Event Exemption Determination Checklist in accordance with the instructions provided in the checklist. The Center/Office POC submits the completed and EO signed checklist to FDA Conference Approval Mailbox. The form is available in Appendix G: FDA Form 4076 FDA Conference Approval Request for Hosting An FDA Conference.

- If the FDA CAR team determines that the completed determination meets the definition of a reportable conference and is not exempt, the team will contact the Center/Office POC to review and resolve the variance in determination.

C. Conference Approval Request Submission Requirements

Conference approval requests will be submitted to the FDA CAR Team via CAS. All Conference Approval Request Forms are available in Appendix F: FDA Form 4075 FDA Conference Approval Request for Attending.

Conference submissions must include the following information:

- Requestor name, Center/Office, and location of requestor.
- Written delegation of authority if applicable
- Purpose of conference and impact on FDA's mission.
- Conference name using standard naming convention (See Appendix D)
- Location and date of the conference.
- Estimated conference costs broken down by expense type.
- Cost justifications and explanations.
- Written Center/Office approval by the EO or their delegated authority.
- Role of attendees in the conference.

Conferences that are FDA Sponsored/Co-Sponsored or attended with Non-FDA funding must include the additional submission requirements below:

- Amount of funding provided by another Federal agency.
- Amount of funding provided by Non-Federal agency.
- Completed Sponsored Travel Documentation when accepting payment in kind (i.e. waived registration fees, transportation fees, lodging fees etc. See Appendix C).

Submission Timeline Requirements. The following submission timeline should be followed to allow FDA to achieve substantial savings for early conference registration and to allow adequate time for the review and approval process:

- Conference approval requests should be submitted to the FDA CAR Team at least sixty (60) calendar days prior to the start of the conference, or the early registration deadline if applicable.
- The FDA CAR Team will notify Center/Office POCs of incomplete or invalid submissions within five (5) calendar days of receiving the request package.

D. Requirements for Approval of Conference Approval Requests

Review of Conference Approval Requests Submission in CAS. The FDA CAR Team must review requests submitted via CAS for completeness and reasonableness. The review must be comprised of a validation that the information required is included in the request, the costs are reasonable and in compliance with per diem rates, and the request is consistent with GSA guidance.

FDA Approving Officials. All conference approval requests must be reviewed and approved by an FDA approving official. The FDA approving official is determined based on the estimated conference cost thresholds provided below:

- **Center/Office Level Approval.** All conference approval requests must be approved by the corresponding Center/Office EO or delegated authority. For conferences with estimated costs greater than or equal to $20,000, the Center/Office must submit the request to the FDA CAR Team via CAS.
    - Requests with estimated costs less than $100,000 must be approved by the corresponding Center/Office Executive Officer or delegated authority.
    - Requests with estimated costs greater than or equal to

$100,000 must be approved by the corresponding Executive Officer (Non-delegable).

- **Office of the Commissioner (OC) Level Approval.** Conference approval requests greater than or equal to $100,000 must receive OC level approval.

    - Requests with estimated costs greater than or equal to $100,000 and less than $500,000 must be approved by the FDA Deputy COO.

    - Requests with estimated costs greater than or equal to $500,000 must be approved by the FDA COO.

Requirements for Conferences Attended by Multiple Centers/Offices. The following list describes the requirements:

- The FDA CAR Team will identify conferences attended by multiple Centers/Offices in the previous fiscal year.

- For identified conference with costs that are equal to or exceed $100,000, the FDA CAR Team will work with each Center/Office POCs to request their Conference Approval Request Package a minimum of 90 days prior to the early registration deadline or the conference start date. This includes a written justification, approved by the Center EO, with detailed explanation to support that the conference is the most cost-effective option for achieving the intended objective. Requests submitted after the 90 days requirement, will require EO justification for the late submission.

Approval Timeline Requirements. The following approval process timeline requirements must be followed:

- The FDA CAR Team must send conference approval request review packages for OC level approval within five (5) calendar of receiving complete, accurate, and signed Conference Approval request packages. Conferences with estimated costs greater than or equal to $100,000 and less than $500,000 must be approved by the FDA Deputy COO; conferences with an estimated cost of $500,000 or greater, must be approved by the FDA COO.

- If no response has been received from Deputy COO or COO after five (5) business days, the FDA CAR Team must follow up with the Executive Assistant to receive a conference decision from the Deputy COO and/or COO.

- Once the decision on the conference approval request is provided by Deputy COO or COO, the FDA CAR Team must assign an approval decision to the conference request in CAS within one (1) business day. The Center/Office POC that submitted the conference approval request will be automatically notified of the approval/rejection decision via an automated FDA Conference Approval System email. A request can have the following outcomes:

    - **Approved –** Conference approval request with estimated cost greater than or equal to $20,000 must be reviewed by the FDA CAR Team for completeness and reasonableness prior to conference registration and travel authorization. For conference with estimated cost greater than or equal to $20,000 and below $100,000, if the FDA CAR Team has determined that conference approval request is complete, the FDA CAR Team will communicate to the Center/Office POC that the conference approval request is approved. If the estimated conference cost is at or exceeds $100,000, and the FDA CAR Team has determined that conference approval request is complete, and the Deputy COO or COO have approved the conference approval request, the FDA CAR Team will communicate to the Center/Office POC that the conference approval request is approved.

    - **Reject with Comments –** If the FDA CAR Team determines cost estimates are inaccurate/unreasonable, and/or the required information is not included in the form, the FDA CAR Team will communicate to the Center/Office POC that the conference approval request is rejected along with further instructions for resubmission. If the Deputy COO or COO has reviewed and rejected the conference approval request, the FDA CAR Team will communicate to the Center/Office POC that the conference approval request is rejected. The Deputy COO or COO must provide an explanation for the rejection. If the conference is rejected, the FDA CAR Team will include the reasons for the rejection in the ‘Comments’ section.

E. Conference Reporting Requirements

The FDA CAR Team must conduct data calls with each Center/Office POC to gather all conference activities the FDA CAR Team will aggregate all data to develop required reports.

The following five (5) reports must be developed in accordance with the required timeline:

#	Report Name	Conference Type	Expenditure Threshold	Frequency/ Submission Date	Distribution
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2	**HHS OIG Reporting of Conferences in Excess of $20,000**	• Scientific • Non-Scientific • FDA Hosted, Sponsored/Co-Sponsored	Conferences with expenditures greater than $20,000	Quarterly / 15 calendar days after end of each fiscal year quarter	Submitted to OIG via email
3	**OMB M-17-08 Annual Report**	• Scientific • Non-Scientific • FDA Hosted, Sponsored/Co-Sponsored	Conferences with expenditures greater than $100,000	Annually / January 31st of the next calendar year	Published to FDA Annual Report on Conference website and submitted to Assistant Secretary of Financial Resources (ASFR) for inclusion on HHS website
4	**HHS OIG Annual Report**	• Scientific • Non-Scientific • FDA Hosted, Sponsored/Co-Sponsored	Conferences with expenditures greater than $100,000	Annually / January 31st of the next calendar year	Submitted to OIG via email
5	**Reporting of Scientific Conferences**	• Scientific • FDA Hosted, Sponsored/Co-Sponsored • Non-FDA Conference Attended by FDA	Conferences with expenditures greater than $30,000	Annually / 90 calendar days after the end of each fiscal year	Published to FDA Annual Report on Conference website

Data Call Requirements. The following notification timelines must be followed:

- The FDA CAR Team will send data call notification via email to Center/Office POCs by 20th of each month.

- Center/Office POC will send conference activities to the FDA CAR Team via email within five (5) business days of the end of the month. Center/Office must maintain supporting documentation of all conference and associated travel actual costs that is reported.

- If the FDA CAR Team does not receive the conference activities from the Center/Office POC within the five (5) business day timeframe, then the FDA CAR Team will follow-up within one (1) business day with the Center/Office EO copied on the follow-up email.

- If the information provided by the Center/Office POC does not include all the information the FDA CAR Team requested, the FDA CAR Team will follow-up with the Center/Office POC and allow for one (1) business day for the Center/Office POC to provide the missing information.

6. Responsibilities.

The minimum required responsibilities of all FDA employees in the CAR process are listed below.

A. Responsibilities of Center/Office POC

1. Evaluates the need for conference-related travel and the use of travel substitutes such as telephone, teleconference, etc.

2. Coordinates with conference attendee or conference planner to calculate estimated costs based on applicable conference expenses defined in Appendix B – Conference Expenses.

3. Evaluates if the costs are reasonable and in compliance with per diem rates, and the request is consistent with GSA guidance.

4. Certifies that conference approval request is the most cost-effective option.

5. Obtains approval from corresponding Center/Office EO or delegated authority.

6. Coordinate the completion of conference approval requests with conference attendee or conference planner.

7. Submits request to the FDA CAR Team via CAS, once approved by the EO or delegated authority, within required timelines.

8. Coordinate with conference attendee or conference planner to track conference expenditures. Maintain supporting documentation of all conference and associated travel expenditures that is reported. Respond to data call notifications and provide conference activities within the required timeline for inclusion in monthly FDA Conference Expense Report. (Note: Conferences should be reported for the month that the conference ends.)

9. Notifies the FDA CAR Team when Center/Office POCs or EO's change.

B. Responsibilities of Center/Office EO or delegated authority

1. Reviews and approves all conference approval requests prior to submission of request to the FDA CAR Team.

   a. Requests with estimated costs less than $100,000 must be approved by the corresponding Center/Office EO or delegated authority.

   b. Requests with estimated costs greater than or equal to $100,000 must be approved by the Center/Office EO (Non-delegable).

2. Evaluates request to determine if the conference is aligned to FDA's mission and represents an appropriate use of Federal funds.

3. Establishes additional approval and reporting requirements for their respective Center/Office, if deemed necessary.

4. When delegating authority, EO should provide the delegation of authority in writing.

C. Responsibilities of FDA CAR Team

1. Reviews conference approval requests with estimated costs greater than or equal to $20,000 submitted via CAS for completeness and reasonableness.

2. Coordinates the development of FDA-wide Conference Approval Request Packages and submits for OC level approvals, to include an FDA-wide data call at the beginning of the fiscal year to the Center/Office POCs to request anticipated attendance.

3. Initiates data calls to all Center/Office POCs to obtain conference information for monthly, quarterly, annual reports, or as needed.

4. Conducts annual refresh of Center/Office POC list.

5. Aggregate estimated costs for each conference and monitor costs to identify conferences that meet the approval thresholds.

6. For conference approval requests with estimated costs greater than or equal to $100,000, the FDA CAR Team coordinates the development of the Deputy COO/COO review packages and submits the request to the Deputy COO/COO for review and approval.

7. For conference requests that have attendees from multiple FDA Centers/Offices and have an estimated cost of $100,000 or greater, the FDA CAR Team coordinates with the Center/Office POCs, to provide a justification that the conference is the most cost-effective option.

8. Develops and reviews required conference reports and submits reports in accordance with HHS, OMB and FDA policies.

9. Obtains the conference names from the approved conference requests in CAS.

10. Submits approved conference names to Program Support Center (PSC) on a weekly basis.

11. Establishes and maintains FDA policy, procedures, and internal controls regarding conference approval and reporting.

D. Responsibilities of FDA Deputy COO

1. Reviews and approves all conference approval requests with estimated costs greater than or equal to $100,000 and less than $500,000 and reviews requests exceeding $500,000.

2. Evaluates request to determine if conference is aligned to FDA mission and represents an appropriate use of Federal funds.

E. Responsibilities of FDA COO

1. Reviews and approves all conference approval requests with estimated costs greater than or equal to $500,000.

2. Evaluates request to determine if conference is aligned to FDA mission and represents an appropriate use of Federal funds.

3. Approves the provided Center/Office conference justification statement as the rationale to be posted on the FDA website.

7. Procedures.

A. Conference Approval and Meeting Review Request Submission and Approval

1. Center/Office POC submits conference approval request to Center/Office EO or delegated authority.

2. Center/Office EO or delegated authority reviews and approves conference approval request at the Center/Office.

3. Center/Office POC submits/updates conference approval request with estimated cost greater than or equal to $20,000 to the FDA CAR Team via CAS.

4. The FDA CAR Team reviews request to ensure that all required information has been provided and verifies the estimated conference costs calculations.

5. The FDA CAR Team monitors estimated conference costs to identify conferences that meet OC approval thresholds.

6. The FDA CAR Team submits conference approval package to Deputy COO or COO based on below thresholds:

    a. Conferences with estimated costs equal to or greater than $100,000 and less than $500,000 are submitted to the Deputy COO for approval.

    b. Conferences with estimated costs equal to or greater than $500,000 are submitted to the COO for approval.

7. FDA Deputy COO or COO makes the approval decision with respect to the following criteria:

    a. Alignment of conference to FDA mission.
    b. Appropriateness of using Federal funds for conference.

8. The FDA CAR Team sends approval decision and justification to the Center/Office POC.

9. The FDA CAR Team sends list of approved conferences to PSC.

B. Monthly Conference Internal Reporting

1. The FDA CAR Team sends data call notification and reporting template to applicable Center/Office POCs to submit conference activities.

2. Center/Office POCs submits conference activities, justifications and supporting documentation to the FDA CAR Team.

3. The FDA CAR Team reviews conference activities, reconciles and aggregates all data.

4. The FDA CAR Team generates and reviews FDA Conference Expense Report.

5. The FDA CAR Team submits FDA Conference Expense Report to the Deputy Chief Financial Officer (DCFO) via email.

C. Quarterly OIG Conference Public Reporting

1. The FDA CAR Team aggregates applicable data from the monthly reports.

2. The FDA CAR Team generates and reviews the Quarterly OIG Conference Report.

3. The FDA CAR Team submits Quarterly OIG Conference Report to OIG via email.

D. Annual Conference Public Reporting

1. The FDA CAR Team aggregates applicable data from the monthly reports.

2. The FDA CAR Team generates and reviews public annual reports.

3. The FDA CAR Team sends draft public annual reports to DCFO for review and approval.

4. The FDA CAR Team sends the file with approved reports to the Office of External Affairs who will make the report 508-compliant (accessible) and post to FDA.Gov:

    a. OMB M-17-08 Annual Report – Published to FDA Annual Report on Conference website and submitted to ASFR for inclusion on HHS website.

    b. Report for Scientific Conferences - Published to FDA Annual Report on Conference website

    c. OIG Annual Report - Submitted to OIG via email.

E. Monitoring of Conference Reporting

1. The FDA CAR Team will perform verification of Center/Office reported

expenses to assess the completeness, timeliness, and accuracy of the FDA Conference reports and compliance with DHHS, OMB, OIG, and FDA reporting requirements.

2. The FDA CAR Team will request supporting documentation from Centers/Offices related to selected testing samples to verify detailed, timely, and accurate information in its monthly reports.

8. Effective Date.

The effective date of this guide is August 7, 2020.

9. Document History, SMG 2350.5, "Conference Approval and Reporting"

Status (I, R, C)	Date Approved	Location of Change History	Contact	Approving Official
Initial	02/24/2020	N/a	OO/OFBA/OFM	Sahra I. Torres-Rivera, Director, OFM
Revised	08/06/2020	N/a	OO/OFBA/OFM	Sahra I. Torres-Rivera, Director, OFM

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Appendix A – Exceptions to Conferences

1. Mission (Operational)

   a. Federal Employee's day-to-day operational or managerial activities that may in certain instances involve limited travel.
   b. Hearings such as before governing oversight boards, appeals boards, courts, etc.
   c. Site and Technical Assistance visits of a specific site or series of sites to fulfill a specific program's oversight or assistance requirements. Inspections of a specific site or series of sites to fulfill a specific program's oversight requirements.
   d. Audits to fulfill a specific oversight or enforcement requirements.
   e. Investigations to fulfill a specific oversight or enforcement requirement.
   f. Examinations to fulfill a specific oversight or enforcement requirements.
   g. National / Federal Advisory Council meetings governed under the Federal Advisory Committee Act (FACA).
   h. General staff meetings that are a daily or regular occurrence and within the normal course of business [that may in certain instances involve limited travel], such as a meeting that takes place bi-weekly to discuss the previous week's events and/and where certain employees from another region attend to weigh in on the specific topic. Program Review/Kickoffs if with a specific grantee or contractor regarding a

specific program, grant, or contract.

i. Peer Review meetings if conducted to fulfill a statutory requirement to review grant application.
j. Evaluation Panel meetings if conducted to fulfill regulatory requirement to evaluate contractor proposals.
k. Solicitation / Funding Opportunity Announcement Review Board meetings between the awarding agency and only those individuals selected to serve on a particular review board.
l. Industry Days, Pre-solicitation, and Preproposal conferences, to the extent they involve official Federal attendee travel, are considered conferences.
m. Tribal Compact or Contract Negotiation meetings if held with one Tribe or Confederation of Tribes regarding that Tribe's specific compact or contract.
n. Trade or Third-Party/International Negotiations regarding a specific agreement.
o. Scientific meetings with a specific investigator or investigating team regarding a specific item, area of scientific inquiry, or public health need.

2. Special Agency Mission

    a. Security missions conducted for specific, programmatic purposes.
    b. Emergency response/recovery such as civil, natural disasters, evacuation, catastrophic events.
    c. Technical assistance or regulatory oversight or monitoring meetings to fulfill a specific program's oversight, monitoring, or training requirements such as to send subject matter experts to state, local, and international sites to provide and share expertise in disease intervention, public health practices, research, etc.
    d. Evaluations such as to fulfill a specific program's oversight or monitoring requirements.
    e. Assessments such as to fulfill a specific program's oversight or monitoring requirements

3. Training (Non-Conference)

    a. Classroom or instructor-based certification and/or job training of Federal staff to become proficient or qualified in one or more areas of responsibility.
    b. Classroom or instructor-based certification and/or job training of Federal staff to receive instruction or education, in scientific, professional, technical, mechanical, trade, clerical, fiscal, administrative, or other fields.

The preparer could seek the input and advice of the FDA CAR Team before making a determination on the applicability, if any, of the exemptions listed above.

Appendix B – Conference Expenses

The total cost of a conference is aggregate of the allowable and applicable conference expenses. The Center/Office POC must include the following cost elements when estimating and calculating the total cost of a conference:

- Amount of the total expenditure from a contract, order or any formalized agreement associated with the conference (only applicable for Sponsored/Co-Sponsored conferences)
- Any food or beverages
- Audiovisual use
- Computer and telephone access fees
- Contractor support
- Federal attendee travel and per diem expenses
- Ground transportation
- Hire of rooms for official business
- Non-Federal attendee travel and per diem expenses
- Other costs (shipping, supplies, etc.)
- Other expenses as defined by the FTR Sec. 301-2.2 (per diem, transportation and miscellaneous expenses)
- Printing Costs
- Promotional Marketing
- Registration Fees
- Speaker Fees
- Training Materials

Appendix C – Sponsored Travel

Authorization job aid:

https://www.psc.gov/transportation-services/travel-training/job-aids/creating-an-authorization-for-sponsored-travel

Voucher job aid:

https://www.psc.gov/transportation-services/travel-training/job-aids/creating-a-voucher-for-sponsored-travel

HHS Policy Chapter 7:

https://www.psc.gov/transportation-services/resources/HHS-Travel-Policy-Manual.pdf

Sponsored travel web link, information and all forms needed:

http://inside.fda.gov:9003/Administrative/Travel/TravelInformation/ucm538771.htm

Appendix D – Standard Naming Convention

Conference Names should be reflected as seen on the conference website and put in the following format: 'FDA-Calendar Year-Conference Title'

Appendix E – Conference Activities for Public Reporting

FDA Conference Expense Report

In developing the FDA Conference Expense Report, the following information must be included for each conference included in the report:

- Conference Title
- Venue Name
- City, State or Country
- Start and End Date
- Purpose of Conference
- Total Estimated Cost to HHS
- Total number of Conference Attendees
- Total number of Federal Attendees
- Total number of Non-Federal Attendees (on Travel Reimbursed by HHS)
- Purpose of the conference to include a brief explanation how the conference advanced the mission of the agency
- Include Contracting Procedures if applicable
- Include Cost Comparison Method if applicable
- A breakout of the costs for:
  - Contractor support
  - Audio-visual services
  - Food or beverages (which should be $0, see the January 3, 2012 policy on the Use of Appropriated Funds for Food)
  - Federal attendee travel, per diem, and registration
  - Non-Federal attendee travel, per diem, and registration
  - The total number of attendees
  - A discussion of the methodology used to determine which costs relate to the conference
  - A description of the contracting procedures used to include discussions of:
    - Whether contracts were awarded on a competitive basis
    - Any cost comparison conducted in evaluating potential contractors for the conference

Reporting of Scientific Conferences

In developing the Reporting of Scientific Conferences Report, the following information must be included for each conference included in the report:

- Conference Title
- Total agency cost of the meeting
- Location of the conference
- Start and End Date
- Total number of individuals whose travel expenses were paid by HHS
- A brief explanation of how conference advanced the mission of HHS
- A general description of the scientific meeting activities
- If expenses exceed $150,000 a description of the circumstances must be provided

OMB M-17-08 Annual Report

In developing the OMB M-17-08 Annual Report, the following information must be included for each conference included in the report:

- A narrative report that includes information on conference expenses for the fiscal year
- A general report about conference activities throughout the year
- Expenses over $500,000 include agency approving official note
- Conference Title
- Total agency cost of the Conference
- Location of the conference
- Start and End Date
- A brief explanation of how the conference advanced the mission of the agency
- Total number of individuals whose travel expenses were paid by the agency

OIG Annual Report

In developing the OIG Annual Report, the following information must be included for each conference included in the report:

- Conference Title
- Venue Name
- City, State or Country
- Start and End Date
- Purpose of Conference
- Total Estimated Cost to HHS
- Total number of Conference Attendees
- Total number of Federal Attendees

- Total number of Non-Federal Attendees (on Travel Reimbursed by HHS)
- Purpose of the conference to include a brief explanation how the conference advanced the mission of the agency
- Include Contracting Procedures if applicable
- Include Cost Comparison Method if applicable
- A breakout of the costs for:
    - Contractor support
    - Audio-visual services
    - Food or beverages (which should be $0, see the January 3, 2012 policy on the Use of Appropriated Funds for Food)
    - Federal attendee travel, per diem, and registration
    - Non-Federal attendee travel, per diem, and registration
    - The total number of attendees
    - A discussion of the methodology used to determine which costs relate to the conference
    - A description of the contracting procedures used to include discussions of:
        - Whether contracts were awarded on a competitive basis
        - Any cost comparison conducted in evaluating potential contractors for the conference

Regarding the OIG Annual Report requirements on contracting and cost comparison procedures, the following options listed below show the standard descriptions to be used in the reports:

Contracting Procedures:

The preparer should seek confirmation and advice of the cognizant CO/CS before reporting on any of the following Contracting Procedures:

1. Competed under Federal Supply Schedule Ordering Procedures of FAR 8.405
2. Competed under Simplified Acquisition Procedures of FAR Part 13
3. Full and Open Competition under FAR Part 15
4. Fair Opportunity under Multiple Award Contract, including previously competed strategic sources, under FAR 16.505(b)(1)
5. Full and Open Competition after exclusion of sources (Small Business Set Aside) under FAR 19.5
6. Other than Full and Open Competition based on Circumstances under FAR 6.302
7. Solicited from a single source using Federal Supply Schedule Ordering Procedures under FAR 8.405-6
8. Solicited from a single source using simplified acquisitions under FAR 13.106-1(b) or 13.501
9. Exception to Fair Opportunity under FAR 16.505(b)(2)
10. 8(a) Directed Source under FAR 19.8
11. Exercise of Option under FAR 17.207

12. N/A - Conference was supported by a Grant, Cooperative Agreement, Interagency Agreement, or Co-sponsorship Agreement
13. N/A – Contractor support was not used
14. Other (provide brief explanation)

Cost Comparison Method

The preparer will also provide details on the cost comparison method used when reporting on conferences contract activities the OIG Annual Report:

1. Single Offer – Cost/price analysis performed in accordance with FAR 13 or FAR 15 as applicable
   Note – use this description if selecting 1 through 6 from the selection above and only one offer was received, or if selecting choices 7 through 10 above.
2. Trade-Off or Best Value Comparison – Multiple offers compared on combination of cost/price and technical factors, award based on best value continuum
   Note – use this description if selecting choices 1 through 6 above and a best value source selection approach was used.
3. Low Price Technically Acceptable (LPTA) Comparison – Multiple offers compared on combination of either cost or price and technical factors, award made to the technically acceptable offer at the lowest price
   Note – use this description if selecting choices1 through 6 above and a LPTA source selection approach was used
4. Determination that Option Exercise is the most advantageous method of fulfilling the Government's needs
   Note – use this description if selecting choice 11 from the above listing
5. N/A – Conference was supported by a Grant, Cooperative Agreement, Interagency Agreement, or Co-sponsorship Agreement
   Note – use this description if selecting choice 12 from the above listing
6. N/A – Conference was not supported by a contractor
   Note – use this description if selecting choice 13 from the above listing

OIG Reporting of Conferences in Excess of $20,000

In developing the OIG Reporting of Conferences in Excess of $20,000 Report, the following information must be included for each conference included in the report:

- Conference Title
- Venue Name
- City, State or Country
- Start and End Date
- Purpose of Conference
- Total Estimated Cost to HHS
- Total number of Conference Attendees
- Total number of Federal Attendees
- Total number of Non-Federal Attendees (on Travel Reimbursed by HHS)

- Purpose of the conference to include a brief explanation how the conference advanced the mission of the agency
- Include Contracting Procedures if applicable
- Include Cost Comparison Method if applicable
- A breakout of the costs for:
- Contractor support
- Audio-visual services
- Food or beverages (which should be $0, see the January 3, 2012 policy on the Use of Appropriated Funds for Food)
- Federal attendee travel, per diem, and registration
- Non-Federal attendee travel, per diem, and registration
- The total number of attendees
- A discussion of the methodology used to determine which costs relate to the conference
- A description of the contracting procedures used, including discussions of:
  - Whether contracts were awarded on a competitive basis
  - Any cost comparison conducted in evaluating potential contractors for the conference

Appendix F – FDA Conference Request and Approval Form Attending

http://inside.fda.gov:9003/downloads/Administrative/Forms/FDA/UCM646319.pdf (Inside.FDA Forms)

https://www.fda.gov/media/135204/download (FDA.gov Forms)

Appendix G – FDA Conference Request and Approval Form Hosting

http://inside.fda.gov:9003/downloads/Administrative/Forms/FDA/UCM646321.pdf (Inside.FDA Forms)

https://www.fda.gov/media/135203/download (FDA.gov Forms)