SMG 2310.16

FDA Staff Manual Guide, Volume III – General Administration

Financial Management – Budget

Monetary Gift to FDA: FDA Acceptance Authority, Receipt, and Management

Effective Date: 03/13/2024

1. Purpose.

This guide establishes the policy and requirements for how FDA receives, evaluates, administers, and manages approved institutional gifts from non-federal sources to FDA. This policy applies to the receipt of unconditional monetary gifts accepted under the authority of Section 231 of the Public Health Service (PHS) Act (42 U.S.C. § 238), as amended.

FDA has authority as delegated by the Secretary of the Department of Health and Human Services (HHS), under Section 231 of PHS Act, to accept gifts, except for gifts of real property (FDA SMG 1465.9 Authority to Accept Gifts Under Title XXI [sic] of the PHS Act).

This Staff Manual Guide (SMG) supplements Gifts to FDA: Evaluation and Acceptance: Guidance for the Public and FDA Staff by providing the policy for receipt, administration, and management of monetary gifts once approved for acceptance.

This SMG applies to all personnel within FDA who wish to receive a gift from non-federal sources given to FDA as an institution, including to FDA employees in their official capacity.

This policy does not apply to the transfer of funds between federal agencies; gifts for the benefit of multiple federal agencies; resources provided under Cooperative Research and Development Agreements, co-sponsorship

agreements, Material Transfer and Data Transfer Agreements, or existing fellowship authorities; samples taken by FDA during inspections; gifts of services, including gratuitous services of experts, consultants, researchers, or volunteers; data or information submitted to FDA as part of an application for market authorization or clearance, samples submitted for lot release testing, comments to the Agency on regulatory policy or proposal, or information sharing and general collaboration intended to assist the Agency in the development of regulations, policy, and procedures; or unsolicited gifts offered to individual employees, including those addressed by the Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR § 2635), that are not intended for the benefit of FDA as an institution.

2. Background.

As a rule, an agency may not augment its appropriation from an outside source without specific statutory authority to do so. The miscellaneous receipts statute, 31 U.S.C. § 3302 (b), provides that an "official or agent of the Government receiving money for the Government from any source shall deposit the money in the [general fund of the] Treasury as soon as practicable without deduction for any charge or claim." Therefore, if an agency official receives money from any source other than an appropriation from Congress, those funds must be deposited into the general fund ("miscellaneous receipts") of the Treasury without delay and without deduction, unless the agency has specific statutory authority to retain the funds to the credit of an agency appropriation.

Pursuant to the Secretary's delegation of authority under Section 231 of the PHS Act, the Commissioner of FDA has statutory authority to accept monetary gifts for the benefit of the Public Health Service or for carrying out any of its functions. Accordingly, any gift funds accepted pursuant to the authority of Section 231 of PHS Act do not have to be deposited into the Treasury as miscellaneous receipts and may be retained by FDA. The decision to accept gifts offered to FDA is addressed by Gifts to FDA: Evaluation and Acceptance: Guidance for the Public and FDA Staff.

3. Reference/Authority.

FDA policy is consistent with applicable provisions of the U.S. Code, and with guidance provided by the Government Accountability Office (GAO), and HHS policies and procedures for the receipt and management of monetary gifts. These include:

A. "Public Health Service Act," Title 42 U.S. Code Section 238 (http://uscode.house.gov/view.xhtml?req=(title:42%20section:238%20edition:prelim)

B. "Exemptions," Title 31 U.S. Code Section 1516 (http://uscode.house.gov/view.xhtml?req=granuleid%3AUSC-prelim-title31-

chapter15-subchapter2&saved=%7CKHRpdGxlOjMxIHNlY3Rpb246MTUxNiBlZGl0aW9uOnByZWxpbSkgT1lgKGdyYW51bGVpZDpVU0MtcHJlbGltLXRpdGxlMzEtc2VjdGlvbjE1MTYp%7CdHJlZXNvcnQ%3D%7C%7C0%7Cfalse%7Cprelim&edition=prelim)

C. "FDA Staff Manual Guide 2310.11 Receiving and Depositing Checks", Effective Date: March 6, 2009 (https://www.fda.gov/media/80339/download)

D. FDA Staff Manual Guide 1465.9 Delegations of Authority to Accept Gifts Under Title XXI [sic] of the PHS Act, Effective Date: January 8, 2010. (https://www.fda.gov/media/81695/download)

E. Gifts to FDA: Evaluation and Acceptance: Guidance for the Public and FDA Staff, Effective Date: December 2016. (https://www.fda.gov/RegulatoryInformation/Guidances/ucm509353.htm)

F. "FDA Staff Manual Guide 1410.10 Delegations of Authority to the Commissioner of Food and Drugs", Effective Date: August 26, 2016. (https://www.fda.gov/media/81983/download)

4. Definitions.

A. Gift: A voluntary transfer of resources of pecuniary value, including funds for either general or specific purposes, data, materials, items, information, or services to the FDA without compensation.

B. Unconditional Gift: A unilateral transfer to FDA where FDA is not obligated to provide anything in return and there is no continuing relationship with the donor related to the gift. (Example: The gift is for FDA to perform its mission or one (1) or more of the general purposes of any part of the FDA).

C. Cash, Monies, Funds: For purposes of this policy, these terms refer to a money order, electronic funds transfer, cashier check, or personal check.

5. Policy.

A. General Policy

A. General Requirements: As used in this SMG, "gifts" means resources of pecuniary value, including funds for either general or specific purposes, data, materials, items, information, or services. It does not, however, include resources that the Agency is authorized to accept in the ordinary course of exercising our regulatory responsibilities, including the resources identified below. Nothing in this SMG is intended to expand the number of situations in which a resource provided to the Agency would be considered a "gift."

Resources not considered to be gifts to the Agency, as defined in this SMG, and therefore not covered by this SMG, include:

- Unsolicited gifts offered to individual employees, which are governed by various statutory and regulatory requirements, including the Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR § 2635).

- Resources provided under Cooperative Research and Develop Agreements, co-sponsorship agreements, Material Transfer and Data Transfer Agreement authorities, and existing fellowship authorities (e.g., Reagan-Udall Foundation).

- Samples FDA takes during inspections.[1]

- The submission of data or information to FDA as part of:

    - an application for market authorization or clearance,

    - manufacturers submitting samples for lot release-testing,

    - comments to the Agency on a regulatory policy or proposal through a public docket or otherwise, or

    - information sharing and general collaboration that is intended to assist the Agency in the development of regulations, policy, and procedures.

    Such submissions are part of the normal course of business for regulatory agencies such as FDA and should not be considered as gifts, even in situations in which FDA may have an active interest in obtaining the data or may even request it.

- The acceptance of outside resources for travel, which is covered in its entirety by statue or guidelines.[2]

- Personal services including volunteering.

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[1] The taking of samples during FDA inspections is contemplated by the Federal Food, Drug, and Cosmetic Act, see 704(c) and (d). While FDA does offer to pay for samples, and the owners of the facilities being inspected can choose to request payment or not, FDA has never considered a decision not to request payment to be a gift to the Agency, and this Standard Operating Procedure (SOP) does not change that position. FDA is not taking the samples for its own benefit, but rather to be analyzed in order to determine whether or not the facility in question is responsible for a violation of the statute.

[2] See: 5 USC § 4111, 5 USC § 5707, 5 USC § 7342, 31 USC § 1353, 42 USC § 3506, 5 CFR Part 2635, 5 CFR Subpart E, 41 CFR Chapter 304, FDA SMG on Travel, HHS 2012 Travel Manual.

- Real property, i.e., land and the improvements thereto, including buildings.[3] Authority to accept gifts of real property is expressly not within the Agency's delegated authority.[3]

  Competitively awarded grants from non-federal sources, previously processed as Cooperative Research and Develop Agreements (CRADA) Grants, are gifts and are subject to this SMG.

  FDA's Gift Acceptance & Authority (GAA) is not applicable if other authorities apply. GAA cannot be used to accept resources covered by another authority financial mechanism (e.g., sponsored travel authorities, CRADA, co-sponsorship agreements, Material Transfer Agreement and Data Transfer Agreement authorities, and existing fellowship authorities such as the Reagan-Udall Foundation).

  FDA reserves the right to reevaluate any gift.

B. Solicitation: The Agency should not solicit gifts unless there are exceptional public health circumstances for which no other solution could be achieved in the time available. In such cases, the solicitation can be made by the Commissioner or his/her delegate to achieve a specific, clearly defined outcome. The following circumstances are not considered solicitation for the purpose of this guidance:

   1. Applications for competitive grants open to a wide range of applicants from organizations such as foundations, non-profit groups, academic organizations, et al.

   2. Discussions of an unsolicited gift are underway with a potential donor, so FDA can ensure 1) the terms of the gift meet all legal and ethical requirements, 2) the gift will promote public health and the FDA mission, and 3) the gift is practical for FDA to accept and use.

C. Non-endorsement: The written agreement memorializing the gift should include a non-endorsement provision. The non-endorsement provision will state that the donor may not suggest or imply that the gift indicates any further partnership between FDA and the donor. It also will state that the donor may not suggest or imply any tacit or explicit endorsement by FDA of any activities or products of the donor because of the gift.

D. Opt-out provision: FDA retains the ability to reevaluate any gift. FDA retains the ability to halt use of a gift at any time after acceptance for any reason.

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[3] FDA Staff Manual Guides, Volume II - Delegations of Authority. SMG 1410.10. Section 1, Paragraph 19. FDA. 2016. http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/StaffManualGuides/UCM273771.pdf

E. Delegation of Authority: The authority to accept a gift valued over $5,000 is vested solely in the Commissioner, but other officials may decline any gift of any value. A decision by a Center Director or Deputy Commissioner to reject a gift is final. The Commissioner may delegate only the authority to accept unconditional gifts valued at $5,000 or less.[4]

F. Donor Status and Eligibility

1. General: In general, FDA may accept a gift from an "eligible donor" if the benefits of the gift to FDA's mission and the public health outweigh any real and/or apparent risks and conflicts of interest.

   The term "eligible donor," for the purposes of this SOP, may include any non-governmental entity, such as a company, public interest group, nonprofit organization, organization that receives funding from or has members that are regulated industry (e.g., a consortium), or any other interested party, that is not debarred from doing business with FDA at the time the offer is made.

   Generally, gift offers undergo a balancing test, a critical evaluation process that considers all information, including possible risks, to arrive at an informed position whether a gift is appropriate to accept. When applying this balancing test, FDA should consider the factors set forth in the Review Criteria Section.

2. Regulated Industry: FDA may consider gifts from regulated industry. Such gifts undergo the balancing test mentioned above and have an additional evaluation burden, described here:

   Gifts from regulated industry may be accepted only if they address exceptional circumstances in the field of public health for which no other solution could be achieved in the time available. Such a case must be one in which the magnitude of the public health benefit overrides other concerns. The authority to identify such exceptional circumstances is held by the Commissioner.[5] The Commissioner should identify such an exceptional circumstance in writing before or concurrent with accepting a gift from regulated industry.

3. Debarred Entities: FDA will reject individuals and companies that are currently debarred from participation in federal government activity and are giving a gift to the FDA. FDA will reject accepting gifts from debarred individuals and companies for as long as they are debarred; after that period, any gift they

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[4] FDA Staff Manual Guides, Volume II - Delegations of Authority. SMG 1410.10. Section 1, Paragraph 23. FDA. 2023. http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/StaffManualGuides/UCM273771.pdf

[5] The Commissioner identifying exceptional circumstances for the purpose of this policy does not constitute any declaration or designation of an emergency or crisis as described in statute. Identification of exceptional circumstances by the Commissioner does not conflict with or preempt any existing public health authority.

propose would be subject to the balancing test described in this Memo. If a company has a relationship with a debarred company (e.g., is a parent or subsidiary company), but is not itself debarred, any proposed gift would be evaluated under the balancing test, which should take into account the company's relationship with the debarred company.

G. Review Criteria:

The benefits of the gift to FDA's mission and the public health must outweigh any real and/or apparent risks and conflicts of interest. FDA will not accept any gift if: (1) the eligible donor imposes conditions that are illegal, contrary to public policy, unreasonable to administer, contrary to FDA's current policies and procedures, or contrary to generally accepted public standards, or (2) acceptance of the gift would require the Agency to provide the eligible donor with some privilege, concession, or other present or future benefit in return for the gift.

The following are prudential factors to consider in applying this balancing test:

1. What is the nature and magnitude of the public health benefit expected from the gift?

    a. Is the gift consistent with the public health mission and goals of FDA?

    b. How significant is the need?

    c. How closely does the gift target the need? In what ways is the gift expected to ameliorate the crisis? Is the tie to the crisis obvious and direct?

    d. Would an alternative approach to attaining the benefit be feasible and more appropriate?

    e. Would another federal agency be a more appropriate recipient? Would the Centers for Disease Control and Prevention (CDC) or the Federal Emergency Management Agency (FEMA) be more appropriate recipients, and/or are other federal emergency resources available to meet the need?

2. What is the nature and magnitude of any real or apparent personal or institutional conflict of interest?[6]

    a. Would accepting the gift compromise or appear to compromise the independence, integrity, or impartiality of the Agency? Would accepting

[6] See: 18 USC § 208 and 5 U.S.C. app. 4 §§ 101-111, 401-408, 501-505 (https://www.govinfo.gov/content/pkg/USCODE-2012-title5/html/USCODE-2012-title5-app-ethicsing-titleI.htm)

the gift diminish public trust by reflecting unfavorably upon the ability of the Agency to carry out its responsibilities in a fair and objective manner?

b. Can public perception of any conflict be adequately managed?

c. Does the timing of the gift raise any concerns?

d. Does the size of the gift raise any concerns?

e. Do the circumstances indicate that the gift is voluntary, and not an attempt to influence decision making, obtain an advantage, or the result of coercion?

3. Donor characteristics to consider:

a. Is this donor regulated by the Agency? If so, the gift cannot be accepted unless it is intended to address an exceptional circumstance in the field of public health for which no other solution could be achieved in the time available. To determine whether the donor is a Significantly Regulated Organization (SRO), visit FDA's SRO List.

b. What is the effect of the outcome of the gift on the donor? What is the nature and magnitude of the benefit to the donor, if any? Is the donor willing to waive or transfer rights or ownership of any associated intellectual property that is generated because of the gift?

c. Has the donor made contributions to the Agency on such a frequent basis as to create an appearance of impropriety? Might the accumulation of accepted gifts over a period of time result in diminishing the appearance of FDA's independence, integrity, and impartiality?

d. Is the donor engaged in criminal, civil, or administrative litigation with the U.S. Government, or has the donor been suspended or terminated for cause or default by the U.S. Government?

e. Is FDA aware of the donor presently exhibiting poor or questionable contract or grant performance that may lead to the initiation of an adverse action against the donor or lead one to question the donor's integrity or raise a concern regarding the Government's affiliation with that donor? Contractor Performance Assessment Reporting System (CPARS) may be an appropriate resource.

f. Is the donor an interested party in pre-award activities surrounding an acquisition, grant, cooperative agreement, or other type of obligating instrument?

g. Is the donor a company that has a corporate relationship with a debarred company (e.g., is a parent or subsidiary company)? Is the donor a member of any consortium to which a debarred company belongs?

h. Consider the full scope of the donor's relationship to the Agency, Department, and sister agencies.

i. Are there any matters in which FDA may exercise subjective judgement that would have a significant financial impact on the donor?

4. Characteristics of the FDA recipient Center/Office to consider:

a. Is the value of the gift a significant percentage of the recipient Office's budget?

b. Are there mechanisms for excluding employee(s) whose work or Office benefits from the gift from matters affecting the donor (e.g., is an effective firewall possible)?

c. Is the gift reasonable to administer (in the immediate and long-term)?

The Agency may wish to require that potential donors disclose in writing relevant information such as a list of the donor's business affiliations and subsidiaries, and any matters that require the Agency's attention.

H. Approval: Approval for acceptance of gifts should be authorized in accordance with Gifts to FDA: Evaluation and Acceptance: Guidance for the Public and FDA Staff prior to receipt of the gift.

1. Financial intermediary restriction: Under federal law 31 U.S.C. § 3302(a), funds received by or for the U.S. Government or its agencies, including gifts, are deposited in, and administered through U.S. Government accounts and may not be deposited with or otherwise administered by other persons or organizations.

2. Types of funds: FDA maintains a gift fund for receiving unconditional gifts in Treasury Account Symbol (TAS) 75-X-8247.

3. Opt-out provision: FDA retains the ability to reevaluate any gift. FDA retains the ability to halt use of the gift at any time after acceptance for any reason.

I. Unconditional Gifts

1. Gifts can only be used to further authorize agency purposes in accordance with FDA's mission and the PHS Act.

2. If an unconditional gift is received, the Commissioner, in consultation with the Chief Financial Officer (CFO) and FDA leadership, will determine how to best use the gift to further the mission of FDA.

3. The Commissioner may redelegate the authority to accept unconditional gifts under $5,000. Receipt of such a gift by Office of Finance, Budget, Acquisitions, and Planning (OFBAP) may only take place if the gift has been accepted by an individual with an official delegation of this authority in accordance with requirements set out in SMG 1465.9 Authority to Accept Gifts Under Title XXI [sic] of the PHS Act.

4. Upon the determination of use for an unconditional gift, the gift will be distributed in accordance with the purpose defined by the Commissioner.

J. Monetary Gifts

1. Gift funds are generally no-year monies and, as such, are available until expended. Gift funds may be expended for any authorized purpose in the performance of FDA functions, and in accordance with other applicable federal laws.

2. Gift funds become public funds, i.e., appropriated funds, and therefore expenditures are subject to the same monitoring and audit processes as appropriated funds and should be treated in the same manner as appropriated funds.

K. Receiving and Distribution

1. Upon a determination by an authorized FDA official to accept a monetary gift pursuant to the authority of Section 231 of the PHS Act, the recipient Center/Office must create a gift plan for the funds by monthly expenses and major object class codes (OCC) and provide the gift plan to the Office of Budget (OB), Division of Budget Execution and Control (DBEC). If the gift results in the need to issue a contract, in accordance with SMG 2610.1 Request for Contract for Actions Exceeding the Simplified Acquisition Threshold and SMG 2610.7 Request for Contract for Actions Less than or Equal to the Simplified Acquisition Threshold, the Center/Office must update their Advanced Acquisition Plan (AAP) to include any contract actions greater than and equal to $25,000, as necessary for the performance of the gift, and submit the AAP to the Office of Acquisition and Grants Services (OAGS).

2. Monetary gifts do not require an apportionment request. An allowance for each gift and recipient will be created in the appropriate fund upon receipt of the gift. The allowance will include the entire amount of the gift.

3. The sub-allowances and cost centers for each gift and recipient will be created as appropriate.

4. At least one (1) Common Accounting Number (CAN) per gift will be created. If more than one (1) Center/Office is the recipient of a gift, then a separate CAN for each Center/Office will be created. If a gift's purpose is for more than one (1) project (e.g., the gift is for research to be conducted on infectious drugs and tobacco), a CAN will be created for each project.

5. The Internal Revenue Service (IRS) Tax Form 8283, Noncash Charitable Contributions, is required to be filled out and provided to the donor. See Appendix A.

L. Expenditure of Gift Funds

1. Total obligations and expenditures for performance of the purpose of the gift may not exceed the amount of the gift.

2. Gift funds may not be used to pay in whole or in part for permanent full-time equivalents (FTEs). Gift funds may be used to pay for a fellow or other temporary position whose entire role and associated responsibilities are to support the purpose of the gift.

M. Monitoring and Reporting

1. Monthly reporting is to be performed on all gifts. Monthly reporting is to include monthly expenditures by Object Class Code (OCC), the current balance, and the expiration of the gift. Monthly reporting must be certified by the Budget Officer at the recipient Center/Office and provided to DBEC.

2. DBEC will monitor gift expenditures at the allowance level monthly.

3. If progress reporting on the project or use of the gift is required by the terms and conditions of the gift, the Project Lead for the Center/Office recipient and Center/Office Executive must sign off on the progress report.

4. Reporting of all gifts will be provided to HHS via the SF-133.

N. Refunds and Close-Out

1. If the period of performance (PoP) for a project funded from the unconditional gift fund has expired, the Center/Office recipient may request an extension from the Commissioner. If the extension is not approved, the funds will be repurposed.

2. If a project funded by the unconditional gift fund has been completed and excess funds remain, then all excess funds will be repurposed. The Center/Office recipient may not expend the funds on another project, unless approved by the Commissioner or delegate.

3. Upon completion of a project, expenditure of all allocated funds, or expiration of the PoP, any allowances and/or CANs created for the gift will be end-dated and will not be rolled over to the next fiscal year.

6. Responsibilities.

A. Responsibilities of the Commissioner or Delegate

1. Review and approve gift (monetary and/or non-monetary) offers and confirm written agreement includes a non-endorsement provision. Determine how unconditional gifts should be distributed within FDA in consultation with the CFO and other FDA leadership, as appropriate.

2. Assign monetary or non-monetary gifts to the recipient Center/Office.

3. Delegate the authority to accept unconditional gifts under $5,000, as deemed appropriate by the Commissioner.

B. Responsibilities of the Office of Budget (OB), Division of Budget Execution and Control (DBEC)

1. Receive the letter of acceptance and any other associated documentation of an approved gift and provide copies to Division of Accounting (DA) and the recipient Center(s)/Office(s).

2. In coordination with DA, Financial Systems Support Staff (FSSS), and the recipient Center/Office, create the necessary segments and CAN(s) for the gift. A segment includes the funds, allowances, sub-allowances, and cost centers.

3. Approve CAN and segment requests.

4. Create the CAN and segments in Unified Financial Management System (UFMS) and inform the Center/Office Budget Officers that the CAN and segments have been created.

5. Notify the Center(s)/Office(s) that the funds are deposited into the FDA fund, and the segments and CAN(s) are created.

6. Allow and monitor gift funds accounts.

7. Publish monthly reports.

8. Ensure a gift fund status of funds report is available to the Center(s)/Office(s).

9. Work with Office of Financial Management (OFM) to ensure the appropriate reports are available for proper management of the gift.

10. Allow funds once all documentation for a gift fund deposit is received and the receipt is verified in the UFMS.

11. Monitor expenditures each month by Object Class Codes (OCC) at the allowance level.

C. Responsibilities of the Office of Financial Management, Division of Accounting

1. Receive gift letter of acceptance and associated documentation from DBEC.

2. Approve CAN and segment requests.

3. Report on FDA gifts to HHS.

4. Perform reconciliations for gift funds.

5. Deputy Chief Financial Officer (DCFO) signs the Noncash Charitable Contributions form.

6. Work with OB to ensure the appropriate reports are available for proper management of the gift.

D. Responsibilities of the Office of Financial Management, Operations Support Staff (OSS) and Division of Accounting

1. OSS receives gift letter of acceptance and associated documentation from DBEC
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2. OSS receives checks for gift funds, deposits the check, and notifies the appropriate parties within FDA (refer to SMG 2310.11, Receiving and Depositing Checks).

E. Responsibilities of the Center/Office Executive Officer or designee

1. Maintain copies of letters from donors and provide copies of documentation to DBEC.

2. Maintain the gift fund files on site in accordance with FDA records retention policy (see FDA Staff Manual Guide 3291.1 Records Management Policy).

F. Responsibilities of the Center/Office Budget Officer

1. Coordinate with DA to receive through Pay.gov and approve CAN and segments required for the gift.

2. Approve requisitions and purchase orders (POs) for expenditures from gift funds.

3. Develop the Center/Office annual gift plan and provide the plan to DBEC. This plan should include proposed obligations by object class code and month.

4. Work with the acquisition staff in the Center/Office to update the AAP to include contract actions greater than and equal to $25,000 that are impacted by the expenditure of gift funds.

5. Confirm the deposit of funds into the gift fund via the status of funds report.

6. Report to DBEC the monthly expenditures by Object Class Code (OCC), the open balance, and date of expiration of funds.

G. Responsibilities of the Project Lead or Director of Research Group or Lead Scientist, Center/Office

1. Provide information as required to develop the gift plan to the Center/Office Budget Officer.

2. Monitor expenditures in accordance with the FDA-designated purpose of the gift. If the period of performance for a project funded from the unconditional gift fund has expired, the Center/Office recipient may request an extension from the Commissioner. If the extension is not approved, the funds will be repurposed (see Section 5.F.1).

7. Procedures.

The procedures section of the document describes the activities performed during the gift acceptance process from the time a gift is offered or a grant is awarded to when the Commissioner accepts or declines the offer. The content below provides a high-level view of the business activities and information needed to support these procedures. The following steps should be taken for each request. Generally, the Center/Office of jurisdiction (the Center/Office that would operationalize the gift) is responsible for the feedback, review, and package assembly processes. Any questions regarding the procedures set forth below may be directed to the Office of Policy, Legislation, and International Affairs (OPLIA), Office of Policy (OP).

A. Processing

1. The receiver of the offer routes the request to the Center/Office of jurisdiction if the original offer recipient is not said Center/Office.

2. The Center/Office of jurisdiction will prepare a Gift Review Package[7] that contains all information relevant to applying a balancing test if the Office wishes to pursue the gift.

3. The Center/Office of jurisdiction will request that the OAGS share whether the potential donor is debarred. FDA should not accept gifts from debarred individuals and companies for as long as they are debarred.

4. The Center/Office will solicit feedback from OAGS, OB, OFM, and Office of the Chief Counsel (OCC).

5. The Center Director is responsible for assessing the potential gift, assessing the public health impact, determining if the potential gift is from a regulated industry, performing the balancing test, and clearing or rejecting the gift. The process ends if the Center Director rejects the gift. The Center Director clears the gift by signing off on the package.

6. The Center Director is responsible for forwarding the cleared Gift Proposal Package to OP via the Policy Mailbox (OPPolicyReviewTeam@fda.hhs.gov).

B. Reviewing

1. The OP is responsible for reviewing the Gift Proposal Package submitted to the Policy Mailbox (OPPolicyReviewTeam@fda.hhs.gov) for completeness. A Gift Proposal Package is complete when it addresses all foreseeable effects and impacts of accepting a gift.

2. The OP is responsible for assessing the public health impact, determining if the potential gift is from a regulated industry, and performing the balancing test.

3. If the gift offer is from regulated industry or if the OP has specific questions, OP will submit questions to the Center/Office, OB, OFM, OAGS, and/or the Office of the Chief Counsel (OCC).

4. OFBAP is responsible for sending the final package to the Commissioner for final review and approval. The final package includes recommendations to the

[7] Examples of reviewed and cleared Gift Review Packages (https://fda.sharepoint.com/:f:/s/OC-Intranet-OC-OO-OFBA/EvtQEknOzSJImA_kdRD_8fEBOGCVc4Wc5Q59U50zDU2Pzg?e=RxFeTG)

Commissioner. The Center/Office is then notified of the Commissioner's decision.

C. Receiving and Distribution

1. Once a gift has been approved for acceptance by FDA in accordance with Gifts to FDA: Evaluation and Acceptance: Guidance for the Public and FDA Staff, any documentation accompanying the gift including the letter of acceptance to the donor, will be provided to DBEC. Documentation will be reviewed by DBEC to ensure all information necessary to process receipt of the gift is included.

2. The IRS Tax Form 8283, Noncash Charitable Contributions, should be filled out and provided to the donor. See Appendix A.

3. The Center/Office recipient(s) will create the gift plan for the funds, which includes the planned expenses by month and major Object Class Codes (OCC). The Center/Office recipient(s) will update their AAP to include contract actions greater than and equal to $25,000, as necessary for performance of the gift.

4. Based on what FDA approves the gift should be used for and the recipient(s) gift plan for the funds, the necessary segments and CAN structure will be created. An allowance will be created for each gift and each recipient. At least one (1) CAN per project for each Center/Office recipient will be created.

5. Monetary gifts should be sent electronically to FDA through Pay.gov – FDA Payment Submission Form (Non-User Fee). Note: FDA no longer accepts mailed checks.

6. The Center/Office recipient(s) will coordinate with FSSS, DA, and DBEC to create the segments and CANs necessary for performance of the gift.

7. DBEC will allow the gift funds into the appropriate Center/Office allowance in the gift fund.

8. The Center/Office of jurisdiction will provide OFM with all materials needed to execute the financial mechanisms of receiving the gift.

D. Monitoring and Reporting

1. DBEC will monitor the obligations and expenditures of monthly funds by Object Class Codes (OCC) on all gifts at the allowance level.

2. The Center/Office recipient will monitor expenditures monthly, justify any variances between the gift plan and actuals to DBEC, and report monthly

expenditures by Object Class Codes (OCC), current balance, and expiration of funds. The Center/Office will continuously monitor the use of the gift in accordance with the FDA-designated purpose for the gift. They will also raise any concerns that the terms or nature of the gift arrangement have changed and therefore might influence the acceptability of the gift under the balancing test to the OP and OFM.

3. Annual reporting on the yearly obligations and carry forward balances for all gifts is provided to HHS.

E. Refunds and Close-Out

1. Upon completion of the purpose of a gift, expenditure of all monies, expiration of the period of performance, or other event that would end the use of a gift, a certification of close-out will be prepared by the Center/Office recipient. The certification of close-out will be reviewed and signed by the Project Lead, Director of Research Group, or Lead Scientist and the Center/Office Executive, as required.

2. The Center/Office Executive will provide a copy of the certification of close-out to OFBAP.

3. If any monies remain at the close-out of a project, the funds will be transferred to the unconditional gift fund.

4. Upon completion of a project, the CANs and segments will be end-dated and will not be rolled over to the next fiscal year.

8. Effective Date.

This policy is effective starting on 03/13/2024.

9. Document History – SMG 2310.16, "Monetary Gifts to FDA: Acceptance Authority, Receipt, and Management"

Status (I, R, C)	Date Approved	Location of Change History	Contact	Approving Official
Initial	03/05/2024	N/A	OC/OO/ OFBAP/OFM	Sahra I. Torres-Rivera, OFM

Appendix A – Form 8283, Noncash Charitable Contributions (https://www.irs.gov/pub/irs-pdf/f8283.pdf)