SMG 3297.7

FDA Staff Manual Guides, Volume III - General Administration

Information Resources Management - Privacy Program

Policy for Implementation of the Privacy Act and the FDA Privacy Program:

Privacy Act Requests and Appeals

Effective Date: September 16, 2015
Changed: May 2, 2023

NOTE: This is not guidance for industry or the public.

1. Purpose
2. Policy
3. Responsibilities
4. Procedures
5. Effective Date
6. History

Appendix A (References and Authorities)

1. Purpose

The purpose of this Staff Manual Guide (SMG) is to provide an overview of the policies and procedures that govern Privacy Act requests and appeals.

2. Policy

FDA's privacy program supports the consistent adherence to the individual access, redress and related provisions of the Privacy Act and FDA's implementing regulations, as well as the underlying principles of notice and participation.

The Privacy Act right of an individual to request notice of, have access to, or seek amendment of records about that individual applies only to records maintained in a Privacy Act System of Records. A Privacy Act "System of Records," is a group of Agency records from which the Agency retrieves information by the name of an individual or by some identifying number, symbol, or other identifying characteristic assigned to the individual. A Privacy Act System of Records Notice (SORN) is a related public document, published in the Federal Register and on FDA's website, which notifies the public of the existence of the System of Records and describes the records that are maintained in the system.

In addition, the rights provided by the Privacy Act only extend to an individual if (1)

the records are about that individual, and (2) these records are retrieved by the name of that individual or by some other information that identifies that individual. Some Privacy Act Systems of Records are exempt from the notice, access, and amendments provisions of the Privacy Act. The SORN will list any exemptions and FDA's regulations in 21 CFR 21.61 list the exempt Systems of Records.

3. Responsibilities

The following sets out the general roles and responsibilities for Agency personnel with regard to Privacy Act requests. These roles and responsibilities are largely drawn from and intended to align with HHS policy.

A. Office of the Senior Official for Privacy (SOP)

- Administer and oversee FDA's Privacy Act programs.
- Provide programmatic direction, aligning FDA's Privacy program with that recommended by the Department (HHS).
- Process all Privacy Act requests, including requests for access to records, amendment of records, and appeals of denials of access or refusals to amend records.
- Provide subject matter expertise regarding the Privacy Act.
- Ensure consistent adherence to the law, Agency regulations (including 21 CFR Part 21 (FDA implementation of the Privacy Act)), and HHS and FDA policies.
- Consider and appropriately apply exemptions[1] and withholding requirements.[2]
- Support the Agency's Privacy Act request activities (e.g., prepare reports, provide training).
- Maintain request records in accordance with applicable laws, regulations and policies (e.g., follow records retention schedules, maintain no record describing an individual's exercise of First Amendment rights (5 U.S.C. 552a(e)(7)).

[1] Some systems of records, such as those that include investigatory or law enforcement records, may be appropriate for exemption from the access, amendment, or other provisions of the Privacy Act. 5 U.S.C. 552a(j) and (k). See other portions of this Guide describing SORNs and exemptions.
[2] The Privacy Act specifies that its provisions do not allow an individual access to any information compiled in reasonable anticipation of a civil action or proceeding. 5 U.S.C. 552a(d)(5).

B. System of Records Manager and Program Management[3]

- At the request of the Privacy Act Coordinator[4] (or other member of the Office of the SOP (aka FDA Privacy Office)), conduct searches for records within a System(s) of Records.

- If records are located, securely forward them in full, without redaction, to the Privacy Act Coordinator for processing and direct response to the requester.

- Advise Privacy Act Coordinator if not records are located.

- Provide information to the Privacy Act Coordinator to assist in making the determination to amend a record.

4. Procedures

Agency offices that receive requests for access to or amendment of records, or appeals of prior responses pursuant to the Privacy Act will refer them to the Privacy Act Coordinator FDA Privacy Office (OO/OEMS/DIG/Privacy) for processing.

A. Requests for Access to Privacy Act Records from the Subject Individual

Upon receipt of a request for access to records from an individual to whom a record pertains, the Privacy Act Coordinator shall:

1. Make a record of receipt of the request and the date of receipt.

2. As promptly as possible, issue a response to the requester in accordance with 21 CFR 21.41 and 21.42.

3. In the event that a request for records about a minor child is made by a parent or guardian, or a request for records of any person is made by that person's legal representative, the Privacy Act Coordinator shall request verification of identity and verification of the relationship between the requestor and the subject of the record, consistent with 21 CFR 21.44(c), 21.72, and 21.75 (FDA).

4. If it is unclear whether an individual is seeking information about himself under the Privacy Act (i.e., the record is about that individual and is maintained in a System of Records from which the record is retrieved by that

[3] "Program Management" is used generally here to describe knowledgeable program level personnel who can effectively coordinate the location and production to the SOP of Privacy Act records responsive to a request for such records.

[4] The Privacy Act Coordinator position resides in the FDA Privacy Office. The role may be filled by one or more staff in the Privacy Office.

individual's name or personal identifier), or whether this is a third-party request, the Privacy Act Coordinator shall consult with the appropriate FDA Freedom of Information Act (FOIA) expert and any relevant program offices to determine whether the request should be processed under the Privacy Act, under the FOIA (as a third-party request for records maintained in a Privacy Act System of Records, or, where none of the requested records are held in a Privacy Act System or Records), or under both (e.g., under the Privacy Act for responsive records maintained in an Agency System of Records, and under FOIA for any responsive records not held in a System of Records). In some instances, it may be necessary to contact the requester to clarify the nature of the request and the specific records sought.

5. Refer the portion(s) of the request which concerns records that are not maintained in a Privacy Act System of Records to FDA's Division of Freedom of Information for assignment to the appropriate Agency component for processing under the FOIA.

6. Forward the request to the appropriate System of Records manager or similar responsible point of contact to conduct a search for records responsive to the request.

7. After the System of Records manager replies to the search request, the Privacy Act Coordinator will respond to the requester by letter in any of the following ways:

    - If no records are located about the individual that are retrieved by the individual's name or other personal identifier in a named Privacy Act System of Records, the letter will advise the individual of such and, when appropriate, indicate that the request will also be handled under the FOIA for certain potentially responsive records not retrieved by the requester's name or other personal identifier.

    - If records exist which are retrieved by the individual's name or other personal identifier, a copy of the records will be enclosed with the letter[5] or the letter will indicate that the records will be forwarded under separate cover.

    - If the records are available but a final determination has not been made with respect to access of all of the records covered by the request (e.g., searches are incomplete), the letter should explain the circumstances and indicate when a final answer will be given.

    - If the request for access to a record is denied, in whole or in part, the letter should specify the reason for the denial. Only the Associate Commissioner

[5] Response letters and records

for Public Affairs or his[6] designee[7] can deny a request for a record under the Privacy Act (except when the denial is for a personnel record(s), in which case access can only be denied by the Associate Commissioner for Management and Operations). The letter should state the right of the individual to appeal any denial as described in FDA's regulations for the protection of privacy.[8]

- If the requested records are not in the control or possession of the FDA, the Privacy Act Coordinator shall refer the request to the appropriate HHS Operating Division and inform the requester accordingly.

- If the requested records are believed to be under the control or possession of another federal agency, the Privacy Act Coordinator shall advise the requester to submit his or her request to that agency and provide the contact information for that agency.

8. If fees for duplicating records are to be assessed, the requester shall be notified prior to the processing of copies and be given an opportunity to amend his request. The Privacy Act Coordinator will also notify the Division of Financial Management (DFM) if fees are to be assessed. DFM should also be notified of any cancellation of assessed fees. Fees shall be assessed in accordance with FDA regulations (e.g., 21 CFR 21.45, Procedures for Notification of and Access to Records in Privacy Act records Systems: Fees).

B. Third-Party Requests for Access to Privacy Act Records

Upon receipt of a request for access to records from a third party (i.e., someone other than the subject individual), the Privacy Act Coordinator shall:

1. Determine whether the third-party requester is acting on behalf of, or with the written consent of, the subject individual such that responsive records would be provided to the requester under 21 CFR 21.70-75.

2. If the third-party is not entitled to the requested records under the Privacy Act, refer the request to the FDA Division of Freedom of Information for assignment to the appropriate Agency component for processing under standard FOIA procedures and FDA's regulations (21 CFR Part 20).

---

[6] "His" is used frequently in this document in keeping with the language of the FDA's regulations at 21 CFR Part 21. Use of "he," "his" and "him/her" should be read inclusively as he/she/they and his/her/their.
[7] The Director of the Division of Freedom of Information is the official designee for all denials of requests made under the FOIA and Privacy Act.
[8] See 21 CFR 21.42(b). Note that a denial of access to a Privacy Act record may consist of providing the requested record to the requester under the Freedom of Information Act, e.g., in a redacted or other partially responsive state. Requesters typically appeal such responses (e.g., seeking unredacted records) using the process available to individuals under the FOIA and FDA's related regulations at 21 CFR Part 20.

3. If the Agency will assess fees for duplicating records in response to a request for Privacy Act records, they shall be assessed as indicated for the subject individual as per section 4.a.8, above.

C. Requests for Amendment of Privacy Act Records

Upon receipt of a request to amend a record from an individual to whom a record pertains under the Privacy Act, the Privacy Act Coordinator shall:

1. Make a record of receipt of the request and the date of receipt.

2. Acknowledge receipt of the request within ten working days. No acknowledgement need be made if the request can be reviewed, processed, and the individual notified of FDA's determination within the ten day period. The period for taking action may be extended an additional 30 days if notice is provided to the individual explaining the circumstances of the delay. The acknowledgment will also include, if necessary, a request for adequate verification of the requester's identity.

3. Take action to see that amendment is made to any portion of the record which FDA has determined, based upon a preponderance of the evidence, is not accurate.

4. Inform the individual of the refusal to amend any portion of the record in the manner requested, the reason for the refusal, and the opportunity for administrative appeal.

5. If the accuracy, relevancy, timeliness, or completeness of the records may be contested in any other pending or imminent FDA proceedings, refer the individual to the other proceeding as the appropriate means for obtaining relief.

6. If the accuracy, relevance, timeliness, or completeness of a record is, or has been, an issue in another FDA proceeding, the request will be handled in accordance with the decision in the other proceedings barring unusual circumstances.

7. Where another HHS Operating Division was the source of and has control of the record, refer the request to that Operating Division and inform the requester accordingly.

8. Where another federal agency was the source of and has control of the record, advise the requester to submit his request to that agency and provide the contact information for that agency.

D. Appeals of Denials of Access to, or Refusals to Amend Records

An individual may appeal FDA's denial of access to, or the refusal to amend a record about that individual under the Privacy Act.[9] A final determination regarding refusals to amend a record shall be made within 30 working days unless it is decided to extend the period for good cause. Upon receipt of the appeal, the Privacy Act Coordinator will:

1. Make a record of receipt of the appeal and the date of receipt.

2. Send a letter to the appellant acknowledging receipt and informing the appellant of the reasons for any delay, if necessary, and the approximate date on which a decision of the appeal can be expected.

3. Review the facts of the appeal, including any additional information supplied by the appellant and appropriate program office.

4. Prepare the response letter for the appropriate individual for signature. This letter will inform the appellant of FDA's final determination regarding the Privacy Act request, including any additional disclosures or FDA's decision to uphold the appeal. The response letter will inform the individual making the request of the following:

    - The final decision regarding the request and the reasons supporting that decision.

    - If the appeal is upheld, the letter will inform the appellant of his right to file a concise statement of the appellant's reasons for disagreeing with FDA's decision not to amend the record as requested.

    - That any statement of disagreement provided by the appellant will be made available to any person who has received the disputed record in the past or to whom it is disclosed in the future along with a brief statement summarizing FDA's reasons for refusing to amend the record.

    - If the appeal is upheld, the letter will inform the appellant of his right to seek judicial review of the refusal to grant access to, or amend, the record.

5. Forward the draft response letter to the Office of Chief Counsel (OCC) for legal review.

6. Upon receipt of OCC's review response, the Privacy Act Coordinator shall make any necessary edits and finalize the letter.

7. Forward the final letter to the appropriate individual for signature.

[9] See 21 CFR Part 21.

5. Effective Date

The effective date of this guide is September 16, 2015.

6. Document History - SMG 3297.7, "Privacy Act Requests and Appeals"

Status (I, R, C)	Date Approved	Location of Change History	Contact	Approving Official
Initial	09/16/2015	N/A	OC/OES/ DFOI/Privacy	Sarah Kotler, Director, DFOI
Change	04/26/2023	organizational information and cited authorities	OEMS/DIG/Privacy	Tiffany Branch, Director, OEMS

APPENDIX A

References and Authorities

Statutes

- Privacy Act of 1974, as amended, 5 U.S.C. 552a

Regulations

- HHS Privacy Act Regulations, 45 CFR Part 5b
- FDA Public Information and Privacy Act Regulations, 21 CFR Parts 20 and 21

Other

- OMB Circular A-108, Federal Agency Responsibilities for Review, Reporting, and Publication Under the Privacy Act (2016)