FREEDOM OF INFORMATION REQUESTS

1. **Purpose:**

This document provides general information of interest to all CVM employees concerning Freedom of Information requests and describes Center procedures to be used when responding to these requests.

2. **General Information:**

a. The term "records" refers to identifiable records not normally prepared for distribution to the public, in existence and in the possession or control of the Food and Drug Administration (FDA), and made or received by the Agency in pursuance of the Federal law or in connection with the transaction of public business and preserved by the Agency as evidence of the organization, functions, policies, decisions, procedures, operations, programs, or other activities. Records include any handwritten, typed or printed documents (such as memoranda, letters, drafts, reports, brochures, books, transcripts, and minutes) and documentary material in other forms (such as electronic records, punch cards; magnetic tapes, cards or discs; paper tapes; audio or video recordings; maps; photographs; slides; microfilm; and motion pictures). It does not include objects or articles such as models or equipment, nor does it include books, magazines, or other reference material in formally organized and officially designated DHHS libraries, where such materials are available under the rules of the particular library.

b. "Freedom of Information request" is any request for existing records not prepared for routine distribution to the public. Requests must only "reasonably" describe the requested records. Documents must be described, but they do not need to be specifically identified. Requests made orally may be honored at the discretion of the FDA employee. However, if an oral request is honored, it must be put into writing before a response is made and a copy of the request with records disclosed must be sent to the FDA FOI Staff.

c. All requests for Agency records shall be sent in writing to the FDA, Division of Freedom of Information Staff (HFI-35), 5600 Fishers Lane, Rockville, MD 20857. FOI requests which are addressed to any CVM office or employee should be routed to the FOI Staff through the CVM FOI Officer (HFV-12).

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d. The Freedom of Information Act does not apply to records which are routinely prepared for public distribution, such as press releases, CVM Updates, FDA Backgrounders, information brochures, guidelines, speeches, etc. Such records will be provided promptly to any requester, without reference to the FOI Act, without referral to the FOI Staff, and without collecting any fees.

e. The Freedom of Information Act does not require the creation of new records to respond to a request. Therefore, a request for information only is not to be considered as an FOI activity. Such inquiries shall, however, be responded to promptly, without referral to the FOI Staff, as part of FDA's general effort to be responsive to the public.

f. Responses to FOI requests will be sent within 20 working days from the date of receipt by the FDA FOI Staff (HFI-35).

g. The Food and Drug Administration will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in regard to trade secrets, and the need for the Agency to promote frank internal policy deliberations and to pursue its regulatory activities without disruption. This policy includes disclosure of records where it would be in the public interest to do so, even though they might otherwise be withheld under strict interpretation of the FOI Act.

h. The Freedom of Information Act does not require that a determination of disclosure be given in response to a request for a record not in the possession of FDA or not yet in existence at the time the request is received. The Agency will, however, respond as fully as reasonably possible to such requests. In response to a request for a record which is not yet completed, indicate that the record is not complete and offer (if possible) an estimate of when the record will be completed, so that it can be requested at that time. Do not offer to provide the record when it is completed.

i. Requests that specific records be automatically and regularly sent as they are created will not be honored.

j. If any document or information is disclosed in an authorized manner to any member of the public, it must be made available to all members of the public.

k. The authority and responsibility for granting an FOI request is vested in the FOI Officer of the organizational component maintaining the records.

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l. The authority and responsibility for denying an FOI request is vested only in the Associate Commissioner for Public Affairs.

m. Some Freedom of Information requests may also be considered Privacy Act requests. If an individual requests access to a record concerning himself contained in a designated Privacy Act System of Records, the FDA employee receiving the request should mark the request "Privacy Act Request" and refer it to the Privacy Act Coordinator (HFI-35) unless the requester is a present or former FDA employee requesting a personnel record. All employee requests for personnel records should be referred to the Director, Office of Human Resources and Management Services (HFA-400).

n. If a requester requests a record concerning an individual other than himself, and it is contained in a designated Privacy Act System of Records, the request constitutes a Freedom of Information request rather than a Privacy Act request. The appropriate Freedom of Information regulations should be consulted to determine whether the record may be disclosed. If disclosure is not required by FOI regulations, then the Privacy Act prohibits the disclosure of the record. If a clearly unwarranted invasion of privacy would occur through disclosure of the record, the request should be denied. (See FDA Staff Manual Guide 3291.5, Sections 7a(1)(j) and 7a(2)(h) procedures for denial of a request.)

o. When a request specifies "any available information" or "all disclosable information," a denial is not appropriate even when there are no records that can be disclosed on the requested subject. If there are no disclosable records on a requested subject, the requester should be so informed.

p. If a record is disclosable but a legible copy of the record cannot be made, there is no requirement that the record be reconstructed. Instead, the requester should be sent the best copy that can be made, and its poor quality should be noted in the response.

q. If a request is partially releasable, the clearly disclosable records should be sent to the requester by the Center's FOI Officer or FOI Specialist and the requester informed that further response will be made by another office. A denial recommendation with copies of the nondisclosable records and copies of the records released should be sent to the FDA FOI Denials Officer.

r. The Associate Director for Executive Programs (HFV-3), will designate an employee to serve as the CVM Freedom of Information Officer. It is the responsibility of the

FOI Officer to grant Freedom of Information requests for records maintained by the Center. The FOI Officer (HFV-12) is responsible for searching for and reviewing records. The Officer may need to call upon designated contact persons in other CVM units to assist with search or location of documents.

3. **Search and Review Procedures:**

a. The FOI Officer (HFV-12) has the primary responsibility for the location and review of records. In some cases, the FOI Officer may request assistance from designated Center contacts to help locate specific document(s) and/or to determine what information may be publicly disclosed. If another unit is requested to provide assistance, the request will be made in writing and flagged "FOI." This will serve to notify the contact person of the need for expeditious handling.

b. If the requested records cannot be located, the contact person will notify the FOI Officer. Note, however, that the Agency is required to make every reasonable effort to locate requested records.

4. **Response Procedures:**

a. After reviewing the records and redacting any information that is exempt from disclosure, the FOI Officer:

1. Prepares the reply letter and sends to requester w/releasable records.

2. Computes applicable charges.

3. Imports a copy of the reply letter and a copy of the enclosures to the Agency Information Management Systems (AIMS) Disclosure: FOI Repository.

b. If the requested records are exempt from disclosure, the FOI Officer will prepare the Denial Recommendation memorandum and will forward the recommendation to the Denials Officer (HFI-30).

c. If the requested records do not exist or cannot be located, the FOI Officer will notify the requester in writing of that fact.

5. **References**

Additional guidance on handling Freedom of Information requests can be found in the

following:

a. Freedom of Information Act. Section 552 of Title 5, United States Code, as amended by Public Law 93-502.

b. HHS Public Information Regulations.

(1) August 1974

(2) June 1975

(3) May 1, 1975

c. FDA Public Information Regulations.

(1) December 24, 1974.

(2) January 14, 1977.

d. Code of Federal Regulations. Title 21, Part 20 - Public Information and Title 21, sections 514.11, 514.12 and 571.1(h).

e. FDA Staff Manual Guide - FDA 3291.5 - Procedures for Implementing the Freedom of Information (FOI) Act

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