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Regulatory Information

Freedom of Information Annual Report 2007

I. AGENCY Food and Drug Administration (FDA)

REPORT PREPARED BY Frederick J. Sadler

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ELECTRONIC ADDRESS FOR REPORT ON THE WORLD WIDE WEB:

Copies of the annual reports of a number of individual HHS Operating Divisions can be found by contacting the responsible component shown in Section II below, or by locating a FOIA link at the following Web sites:

<http://www.fda.gov/RegulatoryInformation/FOI/FOIAAnnualReports/default.htm>¹

ADDRESS FOR PAPER COPIES OF REPORT:

Food and Drug Administration
Division of Freedom of Information
5600 Fishers Lane, HFI-35, Room 6B-05
Rockville, MD 20857

II. HOW TO MAKE A FOIA REQUEST: Please see the FDA Handbook for Requesting Information and Records from FDA at:

<http://www.fda.gov/RegulatoryInformation/FOI/HowtoMakeFOIAResult/default.htm>²

A. Names, addresses, and telephone numbers of all individual agency components and offices that process FOIA requests: [Attached, at the close of this report.](#)

B. Brief description of agency's response time range(s): As indicated below.

C. Brief description of why some requests are not granted: Documents requested were protected by a statutory exemption and release would have caused harm to the interest protected by the exemption.

III. DEFINITIONS OF TERMS AND ACRONYMS USED IN REPORT:

A. Agency-specific acronyms or other terms:

HHS - U.S. Department of Health and Human Services
OPDIVs - Operating Divisions of HHS
OS - Office of the Secretary
OASPA - Office of the Assistant Secretary for Public Affairs, HHS
AoA - Administration on Aging
ACF - Administration for Children and Families
AHRQ - Agency for Healthcare Research and Quality
ATSDR - Agency for Toxic Substances and Disease Registry
CDC - Centers for Disease Control and Prevention
FDA - Food and Drug Administration
HRSA - Health Resources and Services Administration
IHS - Indian Health Service
NIH - National Institutes of Health
OPHS - Office of Public Health and Science
PHS - Public Health Service
PRO - Professional Review Organization
PSC - Program Support Center
SAMHSA - Substance Abuse and Mental Health Services Administration

B. Basic terms (from FOIA Update, Summer 1997):

FOIA/PA request - Freedom of Information/Privacy Act request. A FOIA request is generally a request for access to records concerning a third party, an organization, or a particular topic of interest. A Privacy Act request is a request for records concerning oneself. Such requests are also treated as FOIA requests. (All requests for access to records, regardless of which law is cited by the requester, are included in this report).

Initial Request - A request to a federal agency for access to records under the Freedom of Information Act.

Appeal - A request to a federal agency asking that it review at a higher administrative level a full denial or partial denial of access to records under the Freedom of Information Act, or any other FOIA determination such as a matter pertaining to fees.

Processed Request or Appeal - A request or appeal for which an agency has taken final action on the request or appeal in all respects.

Multi-track processing - A system in which simple requests requiring relatively minimal review are placed in one processing track, and more voluminous and complex requests are placed in one or more other tracks. Requests in each track are processed on a first-in/first-out basis. A requester who has an urgent need for records may request expedited processing (see below).

Expedited processing - An agency will process a FOIA request on an expedited basis when a requester has shown an exceptional need or urgency for the records which warrants prioritization of his or her request over other requests that were made earlier.

Simple request - A FOIA request that an agency using multi-track processing places in its fastest (non-expedited) track based on the volume and/or simplicity of the records requested.

records requested.

Grant - An agency decision to disclose all records in full response to a FOIA request.

Partial grant - An agency decision to disclose a record in part in response to a FOIA request, deleting information determined to be exempt under one or more of the FOIA exemptions; or a decision to disclose some records in their entireties, but to withhold others in whole or in part.

Denial - An agency decision not to release any part of a record or records in response to a FOIA request because all the information in the requested records is determined by the agency to be exempt under one or more of FOIA exemptions or for some procedural reason (such as because no record is located in response to a FOIA request).

Time Limits - The time period in the Freedom of Information Act for an agency to respond to a FOIA request (ordinarily 20 working days from proper receipt of a perfected FOIA request).

Perfected request - A FOIA request for records which adequately describes the records sought, which has been received by the FOIA office of the agency component in possession of the records, and for which there is no remaining question about the payment of applicable fees.

Exemption 3 statute - A separate federal statute prohibiting the disclosure of a certain type of information and authorizing its withholding under FOIA subsection (b)(3).

Median number - The middle number, not the average. For example, of 3, 7, and 14, the median number is 7.

Average number - The number obtained by dividing the sum of a group of numbers by the quantity of numbers in the group. For example, of 3, 7, and 14, the average number is eight.

IV. EXEMPTION 3 STATUTES:

A. List of Exemption 3 statutes relied on by the agency during report year:

1. Brief description of type(s) of information withheld under each statute:
2. Has a court upheld the use of each statute? If so, cite example:
 - 1) Ethics in Government Act (P.L. 95-521, as amended).
 - Confidential, financial disclosure reports.
 - upheld under Meyerhoff v. EPA, 958 F.2nd 1498 (9th Cir 1992).
 - 2) Public Health Security and Bioterrorism Preparedness and Response Act, 2002 (P.L. 107-188).
 - Food Registration Documents.
 - The statute has not been litigated.

V. INITIAL FOIA/PA ACCESS REQUESTS (Include all requests, 3rd or 1st party):

A. Numbers of initial requests (line 1 + line 2 - line 3 = line 4):

1. Number of requests pending at close of preceding fiscal year 19,328
2. Number of requests received during reporting fiscal year 12,320
3. Number of requests processed during reporting fiscal year 14,190
4. Number of requests pending at close of reporting fiscal year 17,458

B. Disposition of Initial Requests:

1. Number granted in full 10,365
2. Number granted in part 49
3. Number of full denials 52

a. Number of times each FOIA exemption was used:

Exemption 1	0
Exemption 2	4
Exemption 3	2
Exemption 4	56
Exemption 5	15
Exemption 6	22
Exemption 7(A)	30
Exemption 7(B)	0
Exemption 7(C)	7
Exemption 7(D)	4
Exemption 7(E)	4
Exemption 7(F)	0
Exemption 8	0
Exemption 9	0

4. Other reasons for non-disclosure (total)

- a. No records 675
- b. Referrals 11
- c. Request withdrawn 1,858
- d. Fee-related reason 96
- e. Records not reasonably described 1
- f. Not a proper FOIA request for some other reason 174
- g. Not an agency record 2
- h. Duplicate request 282
- i. Other (specify) 625

In the main, the "Other" category represents requests for records that were posted on the Agency's Internet Web site; or requests from regulated industry for copies of their own inspection reports. The agency proactively releases unredacted copies of Establishment Inspection Reports (EIRs) to the subject of the inspection, without requiring submission of a FOIA request, as both an educational tool and a method of achieving transparency.

A. Number of Appeals: N/A

Appeals to denials issued by the FDA are filed with the FOI officer for the Public Health Service, HHS, and processed within that office, after consultation with FDA.

1. Number of appeals received during the fiscal year N/A
2. Number of appeals processed during the fiscal year N/A

B. Disposition of Appeals:

1. Number completely upheld N/A
2. Number partially reversed N/A
3. Number completely reversed N/A
 - a. Number of times each FOIA exemption used (counting each exemption used once per appeal)

Exemption 1 N/A

Exemption 2 N/A

Exemption 3 N/A

Exemption 4 N/A

Exemption 5 N/A

Exemption 6 N/A

Exemption 7(A) N/A

Exemption 7(B) N/A

Exemption 7(C) N/A

Exemption 7(D) N/A

Exemption 7(E) N/A

Exemption 7(F) N/A

Exemption 8 N/A

Exemption 9 N/A

4. Other reasons for non-disclosure (total) N/A

- a. No records:
- b. Referrals:
- c. Request withdrawn:
- d. Fee-related reason:
- e. Records not reasonably described:
- f. Not a proper FOIA request for some other reason:
- g. Not an agency record:
- h. Duplicate request:
- i. Other (specify):

VII. COMPLIANCE WITH TIME LIMITS/STATUS OF PENDING REQUESTS:

A. Median Processing Time for Requests Processed During the Year

1. Simple Requests (if multiple tracks used):

- a. Number of requests processed 11,336
- b. Median number of days to process 146

2. Complex Requests:

- a. Number of requests processed 2,850
- b. Median number of days to process 653

3. Requests Accorded Expedited Processing:

- a. Number of requests processed 4
- b. Median number of days to process 84

B. Status of Pending Requests (if multiple tracks are being used, report for each track as well as totals).

1. Number of requests pending as of the end of the fiscal year covered in this report (from Line V.A.4) 17,458
2. Median number of days that such requests were pending as of that date. 311
(Medians vary greatly from OPDIV to OPDIV.)

VIII. COMPARISONS WITH PREVIOUS YEAR(S) (Optional)

IX. COSTS/FOIA STAFFING:

A. Staffing levels:

1. Number of full-time FOIA personnel 69
2. Number of personnel with part-time or occasional FOIA duties (in total work-years) 24.61
3. Total number of personnel (in work years) 93.61

B. Total costs (including staff and all resources):

1. FOIA processing (including appeals) \$14,588,882.47
2. Litigation-related activities (estimated) \$99,500.00
3. Total costs \$14,688,382.47
4. Comparison with previous year(s) (including percentage of change) (optional)

X. FEES:

XI. FOIA REGULATIONS:

The Food and Drug Administration's implementing regulations are found in 21 CFR Part 20, and may be viewed on the Internet in the Agency's Electronic Reading Room at: http://www.access.gpo.gov/nara/cfr/waisidx_04/21cfr20_04.html³.

XII. Report on FOIA Executive Order Implementation

Please refer to the DHHS Annual Report: www.hhs.gov/foia/reports/07anlrpt.html⁴.

FDA HEADQUARTERS COMPONENT FREEDOM OF INFORMATION/PRIVACY ACT OFFICERS AND CONTACTS

Food and Drug Administration Staff
Division of Freedom of Information (DFOI)
5600 Fishers Lane, Parklawn (PKLN) Building
HFI-35, Room 6B-05
Rockville, MD 20857
Telephone (301) 827-6500
Fax (301) 443-1726
Confirm Fax Received (301) 443-2414

*Address all FOIA correspondence to the Division of Freedom of Information at address given above.

Component FOIA Offices***Office of Chief Counsel**

(301) 827-1181 PkIn, Room 6-89

Advisory Committee Oversight & Management Staff

(301) 827-1220 PkIn, Room 15A-12

Office of the Ombudsman

(301) 827-3390 PkIn, Room 14-72

Office of Women's Health

(301) 827-0350 PkIn, Room 16-65

Office of Internal Affairs

One Church Street,
Church Building
Room 700
Rockville, MD 20850
(301) 827-0243

Office of External Relations

(301) 827-4402 PkIn, Room 14-72

Office of Special Health Issues

(301) 827-4460 PkIn, Room 9-49

Office of Equal Opportunity

(301) 827-4835 PkIn, Room 8-72

Office of Policy

(301) 827-3360 PkIn, Room 14-101

Office of Science

(301) 827-3038, PkIn, Room 14C-06

Office of Orphan Products Development

(301) 827-3666 PkIn, Room 6A-55

Office of the Commissioner and Executive Secretariat

(301) 827-4433 PkIn, Room 16-70

Office of Executive Operations

(301) 827-3394 PkIn, Room 11-101

Office of the Chief Information Officer

(301) 827-4655 PkIn, Room 16B-45

Office of Financial Management

(301) 827-5045 PkIn, Room 11-68

5630 Fishers Lane, Room 2030
Rockville, MD 20857
(301) 827-7056

Paperwork Reduction Act & Records Management Branch

(301) 827-1476 PkIn, Room 6A08

Ethics & Integrity Staff

(301) 827-5511 PkIn, Room 4-72

Division of Dockets Management

5630 Fishers Lane, Room 1061
Rockville, MD 20857
(301) 827-6860

Office of Aquisitions and Grant Services

5630 Fishers Lane, Room 2035
Rockville, MD 20857
(301) 827-7009

Office of Crisis Management

(301) 796-8240 or 1-866-300-4374 PkIn, Room 12A-55

Office of Regulatory Affairs

15800 Crabbs Branch Way, Suite 130
Rockville, MD 20850
(240) 632-6860

Office of Criminal Investigations

7500 Standish Place,
MPN #2, Room 250N
Rockville, MD 20855
(301) 294-4030

Center for Drug Evaluation and Research (CDER)

15400 Calhoun Drive, Room 2100
Rockville, MD 20855
(240) 453-6666

Office of International Programs Policy, Europe, Trade & Harmonization Staff

(301) 827-3363 PkIn, Room 15A-55

Office of Combination Products

15800 Crabbs Branch Way
Room 200
Rockville, MD 20855
(301) 427-1934

Office Public Affairs

(301) 827-6242 PkIn, Room 15-05

Center for Biologics Evaluation and Research (CBER)

11400 Rockville Pike,
Rockwall Building, Room 601
Rockville, MD 20857
(301) 827-2000

Office of Planning

(301) 827-5292 PkIn, Room 14-101

Center for Food Safety and Applied Nutrition (CFSAN)

5100 Paint Branch Pkwy
Room 4B-023
College Park, MD 20740-3835
(301) 436-1590

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