DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
National Cancer Institute
Freedom of Information / Privacy Act Office
Bldg. 31, Room 10A48
9000 Rockville Pike, MSC 2580
Bethesda, Maryland 20892-2580
Ph: (301) 496-2999 Fax: (301) 435-2931

Kerry Donahue
Bellinger & Donahue
6295 Emerald Parkway
Dublin, OH 43016

Re: NCI 08-057, FOIA Case No. 34965

Dear Mr. Donahue:

This is our final response to your April 25, 2008 Freedom of Information Act (FOIA) request. You requested copies of the following:

1. Meeting notices issued by party of parties unknown to potential meeting attendees, including Dr. Alison Martin, Dr. Howard Streicher, and other NCI employees to discuss (a) issues related to the Provenge Advisory Committee meeting of March 29,2007; (b) the recommendations that issued from that meeting in the form of the two votes taken on Safety and Efficacy; and (c) the contents of the letter being developed by Drs. Streicher and Martin, among others, that was subsequently conveyed to the FDA, disparaging Provenge and urging the FDA *not* to approve the drug at that time.

2. Documents containing meeting notices that indicated the locations of said meetings (by agency, address, and room number(s)).

3. Correspondence from or to Alison Martin and Howard Streicher from or to persons or employees at the FDA concerning the March 29th Advisory Committee meeting on the Dendreon BLA for Provenge during the time period of March 15, 2007 to May 15, 2007.

4. Documents containing meeting notices or e-mails that indicated the times, locations, and expected duration of said meetings involving NCI employees with the FDA or others concerning Provenge between March 15, 2007 and May 15, 2007.

5. Documents containing lists prepared at or subsequent to said meetings called to discuss items cited in #1 above, listing attendees at said meetings, including their names, affiliations, and e-mail addresses.

6. Documents prepared at or issued subsequent to meetings called to discuss items cited in #1 above, including notes and minutes taken by participants at meetings called to discuss items cited in #1 above or correspondence related to the meeting.

7. Documents containing action items that resulted from meetings called to discuss items cited in #1 above.

8. Documents containing recommendations that issued from meetings called to discuss items cited in #1 above.

9. All correspondence to or from Howard Streicher and Alison Martin to each other or to or from Dr. Maha Hussain or Dr. Howard 1. Scher or Dr. Richard Pazdur from January 1, 2007 to December 31, 2007.

On April 28, 2008, you amended your request pertaining to Item 9 stating that it need not include any communications between the individuals that clearly have nothing to do with Dendreon's Provenge (also known as sipuleucil-T) BLA or AC.

Enclosed are 10 pages responsive to Item #9 of your request. The National Cancer Institute searched its files and no records responsive to Items# 1-8 of your request were located. While we believe that an adequate search of appropriate files was conducted for the records you requested, you have the right to appeal this determination that no records exist which would be responsive to your request. Should you wish to do so, you must send your appeal within 30 days of receipt of this letter to the Assistant Secretary for Public Affairs (Media), Department of Health and Human Services, Room 17A-46, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, following the procedures outlined in Subpart C of the enclosed regulations, 45 C.F.R. Part 5. Please mark both the envelope and the appeal letter "FOIA Appeal."

Provisions of the Department of Health and Human Services FOIA Regulations allow us to recover part of the cost of responding to your request. Enclosed is an invoice for **$80.25** to cover the costs associated with our response. Thank you for your interest in the National Cancer Institute.

Sincerely,

Suzanne Milliard
Freedom of Information Coordinator
NCI/FOIA/OPAR

Enclosure(s):

- Responsive documents (10 pages)
- Fee invoice
- FOIA Regulations

National Institutes of Health

Invoice of Fees for Freedom of Information Services

NIH Case NO.
34965

Date of Invoice
07/30/2008

Instructions:

1. Please write the case number, shown at the top of this form, on your check or money order.
2. Make your check or money order payable to DHHS/NIH.
3. Return one copy of this form with your remittance.
4. Mail to:
   NIH
   Bldg. 31, Room 5B35, "FOIA"
   9000 Rockville Pike
   Bethesda, MD 20892
5. Payment is due within 30 days from the date of this invoice. Interest will be charged after the due date.

Requestor's Name and Address

Kerry Donahue
Bellinger & Donahue
6295 Emerald Parkway
Dublin, OH 43016

Category

☐ P ☐ N ☐ O

SERVICE			No. of items or hours	Price per item or hour	Subtotal	Allowance	Total
Reproduction	Standard Pages (8 ½ X 11 or 8 ½ X 14)		**10**	**$.10**	**$1.00**	**$0.00**	**$1.00**
	Other Reproduction						
Search Costs	Rate 1						
	Rate 2						
	Rate 3		**.25**	**$77.00**	**$19.25**	**$0.00**	**$19.25**
Review Costs	Rate 1						
	Rate 2		**.50**	**$43.00**	**$21.50**	**$0.00**	**$21.50**
	Rate 3		**.50**	**$77.00**	**$38.50**	**$0.00**	**$38.50**
Computer Costs	Machine time, materials						
	Operator's time or search time	Rate 1					
		Rate 2					
		Rate 3					
Certification							
Special Mailing Charges							
						Pay Total of:	**$80.25**

Person Preparing Invoice	Phone No.	BID
Vontella Mills	**301-496-2999**	**NCI**

Mauer, Joan (NIH/NCI) [E]

From: Streicher, Howard (NIH/NCI) [E]
Sent: Sunday, April 01, 2007 2:35 PM
To: Martin, Alison (NIH/NCI) [E]
Subject: RE: Dendrion

To?
The web site I sent has a presentation made last november if I understand it at all it suggests that the vaccine group suvival is intirely attributable to subsequent taxotere treatment - 50 pts os 34mo if avg vaccine is 25 mo then av os for the other half is around 15 mo? None of this was even mentioned at the meeting-- except that 75% of the placebo group got salvage vaccine- and now somewhere a booster is stuck into one eof the graphs - what are all the quotes lies damn lies and statistic, or as my father used to say figures never lie but liars always figure or maybe it is all ok and we should brach out into other tumor types right away Howard

-----Original Message-----
From: Martin, Alison (NIH/NCI) [E]
Sent: Sunday, April 01, 2007 2:03 PM
To: Streicher, Howard (NIH/NCI) [E]
Subject: RE: Dendrion

Maybe you should write a letter, too.

-----Original Message-----
From: Streicher, Howard (NIH/NCI) [E]
Sent: Sunday, April 01, 2007 1:40 PM
To: Martin, Alison (NIH/NCI) [E]
Subject: RE: Dendrion

Very interesting-- I was thinking of doing one of my own on the broader implications of having the FDA forum become the arbitor of what works; without even full disclosure of all of the evidence I must believe this process is deeply flawed- whether or not the FDA deceided that it shouldn't wait for the larger study disclosure of all of the data- in addition ot compromising appproval standard, I am concerned with what this process says about how we are doing clinical research--the concern of the company but also of the research community represnted by the advisors seems to be more of achieving approval than questioning the validity and implications of the results. We must have lost our way if we are depending on the compnay and agency to tell us what these results should mean.
Howard

-----Original Message-----
From: Martin, Alison (NIH/NCI) [E]
Sent: Saturday, March 31, 2007 4:20 PM
To: Streicher, Howard (NIH/NCI) [E]
Subject: FW: Dendrion

Consider this confidential, please...but I wanted you to know.

-----Original Message-----
From: Scher, Howard
Sent: Saturday, March 31, 2007 4:19 PM
To: Martin, Alison (NIH/NCI) [E]
Subject: Re: With your blessings - will circulate to authors this week.

That will be one of the "suggestions" in the letter. Got a minute for a quick question related to FDA processes?

-----Original Message-----
From: Martin, Alison (NIH/NCI) [E] <martina@ctep.nci.nih.gov>

To: Scher, Howard I./Medicine
Sent: Sat Mar 31 16:15:05 2007
Subject: RE: With your blessings - will circulate to authors this week.

Glad to hear letter is being drafted. If that division's vote suggests it be considered for approval, I was wondering if it then could go to ODAC, which is more clinically savy, i.e., this is just a step in a process.

-----Original Message-----
From: Scher, Howard
Sent: Saturday, March 31, 2007 8:49 AM
To: Martin, Alison (NIH/NCI) [E]
Cc: Scher, Howard
Subject:

[Personal Information - Withheld]

Howard I. Scher, M.D.
D. Wayne Calloway Chair in Urologic Oncology
Chief, Genitourinary Oncology Service
Department of Medicine
Sidney Kimmel Center for Prostate and Urologic Cancers
Memorial Sloan-Kettering Cancer Center
1275 York Ave.
New York, N.Y. 10021
Tel: Administrative: 646-422-4323
Clinical: 646-422-4330
FAX: 212-988-0851
E-mail: Scherh@mskcc.org

-----Original Message-----
From: Martin, Alison (NIH/NCI) [E] [mailto:martina@ctep.nci.nih.gov]
Sent: Friday, March 30, 2007 9:49 PM
To: Scher, Howard I./Medicine
Subject: Re: With your blessings - will circulate to authors this week.

Couldn't go but it is quite the buzz at NCI - not sure we understand - not sure it meant it would be approved. You were there - please tell me if you were convinced.

Alison Martin
Sent from my BlackBerry Wireless Handheld

----- Original Message -----
From: Scher, Howard
To: Martin, Alison (NIH/NCI) [E]

Sent: Fri Mar 30 21:14:28 2007
Subject: Re: With your blessings - will circulate to authors this week.

What did you think of the ODAC.

-----Original Message-----
From: Martin, Alison (NIH/NCI) [E] <martina@ctep.nci.nih.gov>
To: Scher, Howard I./Medicine
Sent: Fri Mar 30 20:13:37 2007
Subject: Re: With your blessings - will circulate to authors this week.

That will be interesting - especially if you took out phase 2 from the title!

Alison Martin
Sent from my BlackBerry Wireless Handheld

----- Original Message -----
From: Scher, Howard
To: Martin, Alison (NIH/NCI) [E]
Sent: Fri Mar 30 13:03:52 2007
Subject: RE: With your blessings - will circulate to authors this week.

Absolutely - gave it to Rick Pazdur and Robert Kane yesterday.

-----Original Message-----
From: Martin, Alison (NIH/NCI) [E] [mailto:martina@ctep.nci.nih.gov]
Sent: Friday, March 30, 2007 1:00 PM
To: Scher, Howard I./Medicine
Subject: RE: With your blessings - will circulate to authors this week.

Howard,

OK with me to circulate, but I haven't had a chance to read for fine points. Can I read it next week when the authors are also reading?

A

-----Original Message-----
From: Scher, Howard
Sent: Monday, March 26, 2007 8:30 AM
To: Hussain, Maha H.A.; Ian.Tannock@uhn.on.ca; Martin, Alison (NIH/NCI) [E]
Cc: Scher, Howard; lafferth@mskcc.org; byczekb@mskcc.org
Subject: With your blessings - will circulate to authors this week.

<<Fig5_PCWG2_v2.tif>> <<Bubley2HS032307v8.doc>>
<<Fig1_PCWG2_v2.tif>> <<Fig2_PCWG2.tif>> <<Fig3_PCWG2.tif>>
<<Fig4_PCWG2_v3.tif>>
The message is ready to be sent with the following file or link attachments:

Fig5_PCWG2_v2
Bubley2HS032307v8
Fig1_PCWG2_v2
Fig2_PCWG2
Fig3_PCWG2
Fig4_PCWG2_v3

Note: To protect against computer viruses, e-mail programs may prevent sending or receiving certain types of file attachments. Check your e-mail security settings to determine how attachments are handled.

1

Mauer, Joan (NIH/NCI) [E]

From: Streicher, Howard (NIH/NCI) [E]
Sent: Monday, November 19, 2007 9:16 AM
To: Martin, Alison (NIH/NCI) [E]
Subject: FW: INTERVIEW REQUEST: cancer drug meeting

Alison do you know who our contact is in the press office?
Howard

-----Original Message-----
From: Julie Weisberg [mailto:juliew@rawstory.com]
Sent: Sunday, November 18, 2007 7:09 PM
To: Streicher, Howard (NIH/NCI) [E]
Subject: Re: INTERVIEW REQUEST: cancer drug meeting

Dr. Streicher,

I just wanted to point out that I made an error below when I stated that the advisory panel met in May. It did, in fact, meet in March. I just wanted to make that correction. The FDA's ruling came in May, and so I had inadvertently switched the dates. Sorry about the confusion.

Have a good evening.

Julie Weisberg
(203)-304-1297
juliew@rawstory.com
www.rawstory.com
tips@rawstory.com
RS DC: (202) 536-4203

The contents of this email are off the record and not for publication unless otherwise agreed to by the author.

Julie Weisberg wrote:
> Dr. Streicher,
>
> I am a reporter on assignment for RawStory.com, an online news and
> information site. I am working on a story about the cancer drug
> candidate Provenge.
>
> And so, I was hoping to speak with you about an FDA meeting that you
> attended after the May advisory committee meeting on Provenge, during
> a short phone interview sometime early this week.
>
> My deadline for this story is this Wednesday, Nov 21, at 5 pm.
>
> Thank you for your time and assistance. And I look forward to speaking
> with you soon.
>
> Have a good evening.
> ---
> Julie Weisberg
> (203)-304-1297
> juliew@rawstory.com
> www.rawstory.com
> tips@rawstory.com
> RS DC: (202) 536-4203
>
> ---
> The contents of this email are off the record and not for publication

> unless otherwise agreed to by the author.
> ---
>
>
>
>

Mauer, Joan (NIH/NCI) [E]

From: Streicher, Howard (NIH/NCI) [E]
Sent: Friday, July 13, 2007 8:45 AM
To: Martin, Alison (NIH/NCI) [E]
Subject: RE:
Attachments: Provenge_draft.doc

anything we can combine?

From: Pugach, David (NIH/NCI) [E]
Sent: Thursday, July 12, 2007 6:18 PM
To: Martin, Alison (NIH/NCI) [E]; Streicher, Howard (NIH/NCI) [E]
Cc: Cramer, Lindsay (NIH/NCI) [E]
Subject:

Drs. Martin and Streicher,

Thank you for your help with the prostate cancer correspondence. Information on the clinical trials you provided is incorporated into this letter.

Attached is a draft of the response that will go to Dr. Niederhuber for his signature. The letter is due on Monday. Please review and let me know if CTEP any edits.

Thanks again for your help.

David Pugach

David J. Pugach
National Cancer Institute
31 Center Drive, Room 10A48
Bethesda, MD 20892-2580

301.496.5217 (P)
301.402.1225 (F)

pugachd@mail.nih.gov

The Honorable Daniel Inouye
United States Senate
Washington, DC 208510

Dear Senator Inouye:

Thank you for your letter dated June 1, 2007 regarding the status of the prostate cancer vaccine, "Provenge." As you may be aware from recent news articles, Provenge is currently under scientific review by the Food and Drug Administration (FDA). The National Cancer Institute (NCI) is not supporting any research on this specific vaccine. Please contact the FDA for specific information pertaining to the approval process and the status of the Dendron Corp. application for Provenge.

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NCI has a robust research portfolio in prostate cancer and provided $293.2 million in FY 2006 and support is estimated to remain at this level for FY 2007 and FY 2008. Included in this amount are a range of studies designed to improve men's health and the outcome for those diagnosed with prostate cancer. NCI supports prostate cancer clinical trials through several large funding mechanisms, including the NCI Specialized Programs of Research Excellence (SPORE) and the NCI-supported Cooperative Groups.

The multidisciplinary translational research teams of the Prostate Cancer SPOREs play a leading role in translating scientific discoveries relevant to prostate cancer into early phase clinical studies, evaluating their usefulness in assessing and quantifying risk or intervening to modulate risks. NCI has expanded the prostate cancer SPORE program from two funded SPOREs when the program began in 1992 to eleven SPOREs today. This expansion has resulted in several new scientific approaches for the early detection, diagnosis, prognosis, and treatment of human prostate cancer.

One research project being supported by the NCI SPORE program is a project in early phase clinical trials that is testing several combinations of targeted therapies either developed or acquired by scientists in the SPORE program. NCI is also supporting the development of biomarkers for prostate cancer through the Inter-Prostate SPORE Biomarker Study (IPBS), which is a multi-institutional study among all 11 prostate SPOREs. There are many other areas of prostate cancer research currently being conducted by the Prostate Cancer SPOREs, exploring a range of prevention and treatment strategies, including laboratory and clinical testing of gene therapy approaches; development of prostate imaging; population-based studies evaluating specific genetic changes in relation to disease progression and mortality; expansion of extensive work in prostate cancer genomics, including gene expression profiles that can predict the course of disease and response to chemotherapy; and, projects related to gene therapy, new anti-angiogenesis targets, and novel molecular links between obesity and development of prostate cancer.

NCI is also supporting other clinical trials for prostate cancer treatments that are studying a range of treatments for prostate cancer. One, an early stage vaccine trial, uses a prostate cancer vaccine combination developed by NCI that targets the Prostate Specific-

Deleted: uses

Antigen (PSA). Follou-up trials are using, the vaccine together with hormonal and chemotherapy.

Deleted: Another clinical train

Deleted: uses

Deleted: a combination of

Deleted: drugs and

The prostate cancer research supported by NCI is very promising. I hope these few examples highlight the broad strategy that NCI is taking to understanding how to better prevent, screen, and treat this disease. Please do not hesitate to let me know should you have any additional questions regarding prostate cancer or any other area of cancer research.

Sincerely,

John E. Niederhuber, M.D.
Director
National Cancer Institute

Mauer, Joan (NIH/NCI) [E]

From: Streicher, Howard (NIH/NCI) [E]
Sent: Sunday, July 15, 2007 12:16 PM
To: Martin, Alison (NIH/NCI) [E]
Subject: FW:

fyi for now

From: Streicher, Howard (NIH/NCI) [E]
Sent: Sunday, July 15, 2007 12:15 PM
To: Schlom, Jeffrey (NIH/NCI) [E]
Subject:

I noticed in the Post today a large Ad taken out by Provenge supporters
citing the July 1, 2007 Cancer Research Artile Schlom et al. Cancer Vaccines Moving Beyond Curernt Paradigms" and quoting sections on the provenge trials – although only as support for recognition of the statistical signigcance in survival in the two trials.
The ad is inside the Outlook section page B4 and is not subtle entitled "Dysfunction at he FDA".
Thought you should know about it.
Howard

Code of Federal Regulations
Title 45, Volume 1, Parts 1 to 199
Revised as of October 1, 1997
From the U.S. Government Printing Office via GPO Access
Cite: 45CFR5

[Page 18-32]

Title 45 -- Public Welfare

Subtitle A -- Department of Health and Human Services

Part 5 -- Freedom of Information Regulations

Subpart A -- Basic Policy

Sec.

Subpart B -- Obtaining a Record

Subpart C -- Release and Denial of Records

Subpart D -- Fees

Subpart E -- Records Available for Public Inspection

Subpart F -- Reasons for Withholding Some Records

Authority: 5 U.S.C. 552, 18 U.S.C. 1905, 31 U.S.C. 9701, 42 U.S.C. 1306(c), E.O. 12600.

Source: 53 FR 47700, Nov. 25, 1988, unless otherwise noted.

Subpart A -- Basic Policy

Sec. 5.1 Purpose.

This part contains the rules that the Department of Health and Human Services (HHS) follows in handling requests for records under the Freedom of Information Act (FOIA). It describes how to make a FOIA request; who can release records and who can decide not to release; how much time it should take to make a determination regarding release; what fees may be charged; what records are available for public inspection; why some records are not released; and your right to appeal and then go to court if we refuse to release records.

Sec. 5.2 Policy.

As a general policy, HHS follows a balanced approach in administering FOIA. We not only recognize the right of public access to information in the possession of the Department, but also protect the integrity of internal processes. In addition, we recognize the legitimate interests of organizations or persons who have submitted records to the Department or who would otherwise be affected by release of records. For example, we have no discretion to release certain records, such as trade secrets and confidential commercial information, prohibited from release by law. This policy calls for the fullest responsible disclosure consistent with those requirements of administrative necessity and confidentiality which are recognized in the Freedom of Information Act.

Sec. 5.3 Scope.

These rules apply to all components of the Department. Some units may establish additional rules because of unique program requirements, but such rules must be consistent with these rules and must have the concurrence of the Assistant Secretary for Public Affairs. Existing implementing rules remain in effect to the extent that they are consistent with the new Departmental regulation. If additional rules are issued, they will be published in the Federal Register, and you may get copies from our Freedom of information Officers.

Sec. 5.4 Relationship between the FOIA and the Privacy Act of 1974.

1. **Coverage.** The FOIA and this rule apply to all HHS records. The Privacy Act, 5 U.S.C. 552a, applies to records that are about individuals, but only if the records are in a system of records. "Individuals" and "system of records" are defined in the Privacy Act and in our Privacy Act regulation, part 5b of this title.
2. **Requesting your own records.** If you are an individual and request records, then to the extent you are requesting your own records in a system of records, we will handle your request under the Privacy Act and part 5b. If there is any record that we need not release to you under those provisions, we will also consider your request under the FOIA and this rule, and we will release the record to you if the FOIA requires it.
3. **Requesting another individual's record.** Whether or not you are an individual, if you request records that are about an individual (other than yourself) and that are in a system of records, we will handle your

request under the FOIA and this rule. (However, if our disclosure in response to your request would be permitted by the Privacy Act's disclosure provision, 5 U.S.C. 552a(b), for reasons other than the requirements of the FOIA, and if we decide to make the disclosure, then we will not handle your request under the FOIA and this rule. For example, when we make routine use disclosures pursuant to requests, we do not handle them under the FOIA and this rule. "Routine use" is defined in the Privacy Act and in Part 5b). If we handle your request under the FOIA and this rule and the FOIA does not require releasing the record to you, then the Privacy Act may prohibit the release and remove our discretion to release.

Sec. 5.5 Definitions.

As used in this part,

Agency means any executive department, military department, government corporation, government controlled corporation, or other establishment in the executive branch of the Federal Government, or any independent regulatory agency. Thus, HHS is an agency. A private organization is not an agency even if it is performing work under contract with the Government or is receiving Federal financial assistance. Grantee and contractor records are not subject to the FOIA unless they are in the possession or under the control of HHS or its agents, such as Medicare health insurance carriers and intermediaries.

Commercial use means, when referring to a request, that the request is from or on behalf of one who seeks information for a use or purpose that furthers the commercial, trade, or profit interests of the requester or of a person on whose behalf the request is made. Whether a request is for a commercial use depends on the purpose of the request and the use to which the records will be put; the identity of the requester (individual, non-profit corporation, for-profit corporation), on the nature of the records, while in some cases indicative of that purpose or use, is not necessarily determinative. When a request is from a representative of the news media, a purpose or use supporting the requester's news dissemination function is not a commercial use.

Department or *HHS* means the Department of Health and Human Services. It includes Medicare health insurance carriers and intermediaries to the extent they are performing functions under agreements entered into under sections 1816 and 1842 of the Social Security Act, 42 U.S.C. 1395h, 1395u.

Duplication means the process of making a copy of a record and sending it to the requester, to the extent necessary to respond to the request. Such copies include paper copy, microform, audio-visual materials, and magnetic tapes, cards, and discs.

Educational institution means a preschool, elementary or secondary school, institution of undergraduate or graduate higher education, or institution of professional or vocational education, which operates a program of scholarly research.

Freedom of Information Act or *FOIA* means section 552 of Title 5, United States Code, as amended.

Freedom of Information Officer means an HHS official who has been delegated the authority to release or withhold records and assess, waive, or reduce fees in response to FOIA requests.

Non-commercial scientific institution means an institution that is not operated substantially for purposes of furthering its own or someone else's business, trade, or profit interests, and that is operated for purposes of conducting scientific research whose results are not intended to promote any particular product or industry.

Records means any handwritten, typed, or printed documents (such as memoranda, books, brochures, studies, writings, drafts, letters, transcripts, and minutes) and documentary material in other forms (such as punchcards; 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 exhibits, models, equipment, and duplication machines or audiovisual processing materials. Nor does it include books, magazines, pamphlets, or other

reference material in formally organized and officially designated HHS libraries, where such materials are available under the rules of the particular library.

Representative of the news media means a person actively gathering information for an entity organized and operated to publish or broadcast news to the public. News media entities include television and radio broadcasters, publishers of periodicals who distribute their products to the general public or who make their products available for purchase or subscription by the general public, and entities that may disseminate news through other media (e.g., electronic dissemination of text). We will treat freelance journalists as representatives of a new media entity if they can show a likelihood of publication through such an entity. A publication contract is such a basis, and the requester's past publication record may show such a basis.

Request means asking for records, whether or not you refer specifically to the Freedom of Information Act. Requests from Federal agencies and court orders for documents are not included within this definition. Subpoenas are requests only to the extent provided by Part 2 of this title.

Review means, when used in connection with processing records for a commercial use request, examining the records to determine what portions, if any, may be withheld, and any other processing that is necessary to prepare the records for release. It includes only the examining and processing that are done the first time we analyze whether a specific exemption applies to a particular record or portion of a record. It does not include examination done in the appeal stage with respect to an exemption that was applied at the initial request stage. However, if we initially withhold a record under one exemption, and on appeal we determine that that exemption does not apply, then examining the record in the appeal stage for the purpose of determining whether a different exemption applies is included in review. It does not include the process of researching or resolving general legal or policy issues regarding exemptions.

Search means looking for records or portions of records responsive to a request. It includes reading and interpreting a request, and also page-by-page and line-by-line examination to identify responsive portions of a document. However, it does not include line-by-line examination where merely duplicating the entire page would be a less expensive and quicker way to comply with the request.

Subpart B -- Obtaining a Record

Sec. 5.21 How to request records.

1. **General.** Our policy is to answer all requests, both oral and written, for records. However, in order to have the rights given you by the FOIA and by this regulation (for example, the right to appeal if we deny your request and the right to have our decisions reviewed in court), you must either make your request in writing or make it orally to a Freedom of Information Officer. Freedom of Information Officers and their staffs may put in writing any oral requests they receive directly.
2. **Addressing requests.** It will help us to handle your request sooner if you address it to the Freedom of Information Officer in the HHS unit that is most likely to have the records you want. (See Sec. 5.31 of this Part for a list of Freedom of Information Officers.) If you cannot determine this, send the request to: HHS Freedom of Information Officer, 645-F, Hubert H. Humphrey Building, Department of Health and Human Services, 200 Independence Avenue SW., Washington, DC 20201. Write the words "Freedom of Information Act Request" on the envelope and letter.
3. **Details in the letter.** You should provide details that will help us identify and find the records you are requesting. If there is insufficient information, we will ask you for more. Include your telephone number(s) to help us reach you if we have questions. If you are not sure how to write your request or what details to include, communicate with a Freedom of Information Officer.

Sec. 5.22 Requests not handled under the FOIA.

1. We will not handle your request under the FOIA and this regulation to the extent it asks for records that are currently available, either from HHS or from another part of the Federal Government, under a statute that

provides for charging fees for those records. For example, we will not handle your request under the FOIA and this regulation to the extent it asks for detailed earnings statements under the Social Security program, or records currently available from the Government Printing Office of the National Technical Information Service.

2. We will not handle your request under the FOIA and this regulation to the extent it asks for records that are distributed by an HHS program office as part of its regular program activity, for example, health education brochures distributed by the Public Health Service or public information leaflets distributed by the Social Security Administration.

Sec. 5.23 Referral of requests outside the Department.

If you request records that were created by, or provided to us by, another Federal agency, and if that agency asserts control over the records, we may refer the records and your request to that agency. We may likewise refer requests for classified records to the agency that classified them. In these cases, the other agency will process and respond to your request, to the extent it concerns those records, under that agency's regulation, and you need not make a separate request to that agency. We will notify you when we refer your request to another agency.

Sec. 5.24 Responding to your request.

1. **Retrieving records.** The Department is required to furnish copies of records only when they are in our possession or we can retrieve them from storage. If we have stored the records you want in the National Archives or another storage center, we will retrieve and review them for possible disclosure. However, the Federal Government destroys many old records, so sometimes it is impossible to fill requests. Various laws, regulations, and manuals give the time periods for keeping records before they may be destroyed. For example, there is information about retention of records in the Records Disposal Act of 1944, 44 U.S.C. 3301 through 3314; the Federal Property Management Regulations, 41 CFR 101- 11.4; the General Records Schedules of the National Archives and Records Administration; and in the HHS Handbook: Files Maintenance and Records Disposition.
2. **Furnishing records.** The requirement is that we furnish copies only of records that we have or can retrieve. We are not compelled to create new records. For example, we are not required to write a new program so that a computer will print information in the format you prefer. However, if the requested information is maintained in computerized form, but we can, with minimal computer instructions, produce the information on paper, we will do this if it is the only way to respond to a request. Nor are we required to perform research for you. On the other hand, we may decide to conserve government resources and at the same time supply the records you need by consolidating information from various records rather than copying them all. Moreover, we are required to furnish only one copy of a record and usually impose that limit. If information exists in different forms, we will provide the record in the form that best conserves government resources. For example, if it requires less time and expense to provide a computer record as a paper printout rather than in an electronic medium, we will provide the printout.

Subpart C -- Release and Denial of Records

Sec. 5.31 Designation of authorized officials.

1. **Freedom of Information Officers.** To provide coordination and consistency in responding to FOIA requests, only Freedom of Information Officers have the authority to release or deny records. These same officials determine fees.
    1. **HHS Freedom of Information Officer**. Only the HHS Freedom of Information Officer may determine whether to release or deny records in any of the following situations:
        1. The records you seek include records addressed to or sent from an official or office of the Office of the Secretary, including its staff offices, or of any Regional Director's Office;
        2. The records you seek include any records of the Office of Human Development Services, the Family Support Administration, or any organizational unit of HHS not specifically indentified below; or

3. The records include records of more than one of the major units identified below (PHS, HCFA, and SSA) either at headquarters or in a Regional Office.

2. **PHS Freedom of Information Officer.** If the records you seek are exclusively records of the Public Health Service or if the records you seek involve more than one health agency of the Public Health Service, including its records in the regions, only the Deputy Assistant Secretary for Health (Communications), who also is the PHS Freedom of Information Officer, may determine whether to release or deny the records, except as follows:
    1. **CDC and ATSDR Freedom of Information Officer.** If the records you seek are exclusively records of the Centers for Disease Control and/or the Agency for Toxic Substances and Disease Registry, only the Director, Office of Public Affairs, CDC, who also is the CDC and ATSDR Freedom of Information Officer, may determine whether to release or deny the records.
    2. **FDA Freedom of Information Officer.** If the records you seek are exclusively records of the Food and Drug Administration, only the Associate Commissioner for Public Affairs, FDA, who also is the FDA Freedom of Information Officer, may determine whether to release or deny the records.
    3. **NIH Freedom of Information Officer.** If the records you seek are exclusively records of the National Institutes of Health, only the Associate Director of Communications, HIH, who also is the NIH Freedom of Information Officer, may determine whether to release or deny the records.
    4. **HRSA Freedom of Information Officer.** If the records you seek are exclusively records of the Health Resources and Services Administration, only the Associate Administrator for Communications, HRSA, who also is the HRSA Freedom of Information Officer, may determine whether to release or deny the records.
    5. **ADAMHA Freedom of Information Officer.** If the records you seek are exclusively records of the Alcohol, Drug Abuse and Mental Health Administration, only the Associate Administrator for Communications and Public Affairs, ADAMHA, who is also the ADAMHA Freedom of Information Officer, may determine whether to release or deny the records.
    6. **IHS Freedom of Information Officer.** If the records you seek are exclusively records of the Indian Health Service, only the Director of Communications, IHS, who also is the IHS Freedom of Information Officer, may determine whether to release or deny the records.
3. **SSA Freedom of Information Officer.** If the records you seek are exclusively records of the Social Security Administration, including its records in the regions, only the Director, Office of Public Inquiries, SSA, who also is the SSA Freedom of Information Officer, may determine whether to release or deny the records.
4. **HCFA Freedom of Information Officer.** If the records you seek are exclusively records of the Health Care Financing Administration, including its records in the regions, only the Director, Office of Public Affairs, HCFA, who also is the HCFA Freedom of Information Officer, may determine whether to release or deny the records.

2. **Delegations.** Any of the above Freedom of Information Officers may delegate his or her authority to release or deny records and to determine fees. Any such delegation requires the concurrence of the Assistant Secretary for Public Affairs.
3. **Addresses and telephone numbers.** The addresses and telephone numbers of the Freedom of Information Officers are listed below.

Freedom of Information Officers

HHS Freedom of Information Officer, Room 645-F, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201, Tel: (202) 472-7453
SSA Freedom of Information Officer, Room 4-H-8, Annex Building, 6401 Security Boulevard, Baltimore, Maryland 21235, Tel: (301) 965-3962
HCFA Freedom of Information Officer, Room 100, Professional Building, Office of Public Affairs, 6660 Security Boulevard, Baltimore, Maryland 21207, Tel: (301) 966-5352
PHS Freedom of Information Officer, Room 13-C-24, Parklawn Building, 5600 Fishers Lane,

Rockville, Maryland 20857, Tel: (301) 443-5252
FDA Freedom of Information Officer, HFW-35, Room 12A16, Parklawn Building, 5600 Fishers Land, Rockville, Maryland 20857, Tel: (301) 443- 1813
NIH Freedom of Information Officer, National Institutes of Health, Building 31, Room 2B39, 9000 Rockville Pike, Bethesda, Maryland 20892, Tel: (301) 496-5633
CDC Freedom of Information Officer, Centers for Disease Control, 1600 Clifton Road, NE., Atlanta, Georgia 30333, Tel: (404) 329-3286
HRSA Freedom of Information Officer, Room 14-43, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Tel: (301) 443-2086
ADAMHA Freedom of Information Officer, Room 12-C-15, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Tel: (301) 443-3783
IHS Freedom of Information Officer, Room 5-A-39, Parklawn Building, 5600 Fishers Land, Rockville, Maryland 20857, Tel: (301) 443-1397.

Sec. 5.32 Release of records.

1. **Records previously released.** If we have released a record, or a part of a record, to others in the past, we will ordinarily release it to you also. However, we will not release it to you if a statute forbids this disclosure, and we will not necessarily release it to you if an exemption applies in your situation and did not apply, or applied differently, in the previous situations.
2. **Unauthorized disclosure.** The principle stated in paragraph (a) of this section, does not apply if the previous release was unauthorized.
3. **Poor copy.** If we cannot make a legible copy of a record to be released, we do not attempt to reconstruct it. Instead, we furnish the best copy possible and note its poor quality in our reply.

Sec. 5.33 Denial of requests.

1. **Information furnished.** All denials are in writing and describe in general terms the material withheld; state the reasons for the denial, including, as applicable, a reference to the specific exemption of the FOIA authorizing the withholding or deletion; explain your right to appeal the decision and identify the official to whom you should send the appeal; and are signed by the person who made the decision to deny all or part of the request.
2. **Unproductive searches.** We make a diligent search for records to satisfy your request. Nevertheless, we may not be able always to find the records you want using the information you provided, or they may not exist. If we advise you that we have been unable to find the records despite a diligent search, this does not constitute a denial of your request.

Sec. 5.34 Appeal of denials.

1. **Right of appeal.** You have the right to appeal a partial or full denial of your FOIA request. To do so, you must put your appeal in writing and send it to the review official identified in the denial letter. You must send your appeal within 30 days from the date you receive that letter or from the date you receive the records released as a partial grant of your request, whichever is later.
2. **Letter of appeal.** The appeal letter should state reasons why you believe that the FOIA exemption(s) we cited do not apply to the records that you requested, or give reasons why they should be released regardless of whether the exemption(s) apply. Because we have some discretionary authority in deciding whether to release or withhold records, you may strengthen your request by explaining your reasons for wanting the records. However, you are not required to give any explanation.
3. **Review process.** Before making a decision on an appeal of a denial, the designated review official will consult with the General Counsel to ensure that the rights and interests of all parties affected by the request are protected. Also, the concurrence of the Assistant Secretary for Public Affairs is required in all appeal decisions, including those on fees. When the review official responds to an appeal, that constitutes the Department's final action on the request. If the review official grants your appeal, we will send the records to you promptly or let you inspect them, or else we will explain the reason for any delay and the

approximate date you will receive copies or be allowed to inspect the records. If the decision is to deny your appeal, the official will state the reasons for the decision in writing and inform you of the FOIA provision for judicial review.

Sec. 5.35 Time limits.

1. **General.** FOIA sets certain time limits for us to decide whether to disclose the records you requested, and to decide appeals. If we fail to meet the deadlines, you may proceed as if we had denied your request or your appeal. We will try diligently to comply with the time limits, but if it appears that processing your request may take longer than we would wish, we will acknowledge your request and tell you its status. Since requests may be misaddressed or misrouted, you should call or write to confirm that we have the request and to learn its status if you have not heard from us in a reasonable time.
2. **Time allowed.**
    1. We will decide whether to release records within 10 working days after your request reaches the appropriate FOI office, as identified in Sec. 5.31 of this part. When we decide to release records, we will actually provide the records, or let you inspect them, as soon as possible after that decision.
    2. We will decide an appeal within 20 working days after the appeal reaches the appropriate review official
3. **Extension of time limits.** FOI Officers of review officials may extend the time limits in unusual circumstances. Extension at the request stage and at the appeal stage may total up to 10 working days. We will notify you in writing of any extension. "Unusual circumstances" include situations when we:
    1. Search for and collect records from field facilites, archives, or locations other than the office processing the request.
    2. Search for, collect, or examine a great many records in response to a single request.
    3. Consult with another office or agency that has substantial interest in the determination of the request.
    4. Conduct negotiations with submitters and requesters of information to determine the nature and extent of non-disclosable proprietary materials.

Subpart D -- Fees

Sec. 5.41 Fees to be charged -- categories of requests.

The paragraphs below state, for each category of request, the type of fees that we will generally charge. However, for each of these categories, the fees may be limited, waived, or reduced for the reasons given in Secs. 5.42 through 5.45 or for other reasons.

1. **Commercial use request.** If your request is for a commercial use, HHS will charge you the costs of search, review, and duplication.
2. **Educational and scientific institutions and news media.** If you are an educational institution or a non-commercial scientific institution, operated primarily for scholarly or scientific research, or a representative of the news media, and your request is not for a commercial use, HHS will charge you only for the duplication of documents. Also, HHS will not charge you the copying costs for the first 100 pages of duplication.
3. **Other requesters.** If your request is not the kind described by paragraph (a) or (b) of this section, then HHS will charge you only for the search and the duplication. Also, we will not charge you for the first two hours of search time or for the copying costs of the first 100 pages of duplication.

Sec. 5.42 Fees to be charged -- general provisions.

1. We may charge search fees even if the records we find are exempt from disclosure, or even if we do not find any records at all.
2. If we are not charging you for the first two hours of search time, under Sec. 5.41(c), and those two hours are spent on a computer search, then the two free hours are the first two hours of the operator's own operation. If the operator spends less than two hours on the search, we well reduce the total search fees by

the average hourly rate for the operator's time, multipled by two.

3. If we are not charging you for the first 100 pages of duplication, under Sec. 5.41 (b) or (c), then those 100 pages are the first 100 pages of photocopies of standard size pages, or the first 100 pages of computer printout. If we cannot use this method to calculate the fee reduction, then we will reduce your total duplication fee by the normal charge for photocopying a standard size page, multiplied by 100.
4. We will not charge you any fee at all if the costs of routine collection and processing of the fee are likely to equal or exceed the amount of the fee. As of May 1987, such costs among the units HHS ranged between $6.00 and $12.50.
5. If we determine that you (acting either alone or together with others) are breaking down a single request into a series of requests in order to avoid (or reduce) the fees charged, we may aggregate all these requests for purposes of calculating the fees charged.
6. We will charge interest on unpaid bills beginning on the 31st day following the day the bill was sent. We will use the provisions of Part 30 of this Title in assessing interest, administrative costs, and penalties and in taking actions to encourage payment.
7. This subpart does not apply to requests for Social Security program records on Social Security number holders, wage earners, employers, and claimants, where the requests are governed by section 1106 of the Social Security Act, 42 U.S.C. 1306(c), and by 20 CFR 442.441.

Sec. 5.43 Fee schedule.

HHS charges the following fees:

1. **Manual searching for or reviewing of records** -- when the search or review is performed by employees at grade GS-1 through GS-8, an hourly rate based on the salary of a GS-5, step 7, employee; when done by a GS- 9 through GS-14, an hourly rate based on the salary of a GS-12, step 4, employee; and when done by a GS-15 or above, an hourly rate based on the salary of a GS-15, step 7, employee. In each case, the hourly rate will be computed by taking the current hourly rate for the specified grade and step, adding 16% of that rate to cover benefits, and rounding to the nearest whole dollar. As of November 25, 1988, these rates were $10, $20, and $37 respectively. When a search involves employees at more than one of these levels, we will charge the rate appropriate for each.
2. **Computer searching and printing** -- the actual cost of operating the computer plus charges for the time spent by the operator, at the rates given in paragraph (a) of this section.
3. **Photocopying standard size pages**-- $0.10 per page. FOI Officers may charge lower fees for particular documents where --
    1. The document has already been printed in large numbers,
    2. The program office determines that using existing stock to answer this request, and any other anticipated FOI requests, will not interfere with program requirements, and
    3. The FOI Officer determines that the lower fee is adequate to recover the prorated share of the original printing costs.
4. **Photocopying odd-size documents**(such as punchcards or blueprints), or reproducing other records (such as tapes) -- the actual costs of operating the machine, plus the actual cost of the materials used, plus charges for the time spent by the operator, at the rates given in paragraph (a) of this section.
5. **Certifying that records are true copies.** This service is not required by the FOIA. If we agree to provide it, we will charge $10 per certification.
6. **Sending records by express mail, certified mail, or other special methods.** This service is not required by the FOIA. If we agree to provide it, we will charge our actual costs.
7. **Performing any other special service that you request and we agree to**-- actual costs of operating any machinery, plus actual cost of any materials used, plus charges for the time of our employees, at the rates given in paragraph (a) of this section.

Sec. 5.44 Procedures for assessing and collecting fees.

1. **Agreement to pay.** We generally assume that when you request records you are willing to pay the fees we charge for services associated with your request. You may specify a limit on the amount you are willing to

spend. We will notify you if it appears that the fees will exceed the limit and ask whether you nevertheless want us to proceed with the search.

2. **Advance payment.** If you have failed to pay previous bills in a timely fashion, or if our initial review of your request indicates that we will charge you fees exceeding $250, we will require you to pay your past due fees and/or the estimated fees, or a deposit, before we start searching for the records you want. If so, we will let you know promptly upon receiving your request. In such cases, the administrative time limits prescribed in Sec. 5.35 of the part (i.e., ten working days from receipt of initial requests and 20 working days from receipt of appeals from initial denials, plus permissible extensions of these time limits) will begin only after we come to an agreement with you over payment of fees, or decide that fee waiver or reduction is appropriate.
3. **Billing and payment.** We will normally require you to pay all fees before we furnish the records to you. We may, at our discretion, send you a bill along with or following the furnishing of the records. For example, we may do this if you have a history of prompt payment. We may also, at our discretion, aggregate the charges for certain time periods in order to avoid sending numerous small bills to frequent requesters, or to businesses or agents representing requesters. For example, we might send a bill to such a requester once a month. Fees should be paid in accordance with the instructions furnished by the person who responds to your requests.

Sec. 5.45 Waiver or reduction of fees.

1. **Standard.** We will waive or reduce the fees we would otherwise charge if disclosure of the information meets both of the following tests:
    1. It is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government, and
    2. It is not primarily in the commercial interest of the requester. These two tests are explained in paragraphs (b) and (c) of this section.
2. **Public interest.** The disclosure passes the first test only if it furthers the specific public interest of being likely to contribute significantly to public understanding of government operations or activities, regardless of any other public interest it may further. In analyzing this question, we will consider the following factors.
    1. How, if at all, do the records to be disclosed pertain to the operations or activities of the Federal Government?
    2. Would disclosure of the records reveal any meaningful information about government operations or activities? Can one learn from these records anything about such operations that is not already public knowledge?
    3. Will the disclosure advance the understanding of the general public as distinguished from a narrow segment of interested persons? Under this factor we may consider whether the requester is in a position to contribute to public understanding. For example, we may consider whether the requester has such knowledge or expertise as may be necessary to understand the information, and whether the requester's intended use of the information would be likely to disseminate the information among the public. An unsupported claim to be doing research for a book or article does not demonstrate that likelihood, while such a claim by a representative of the news media is better evidence.
    4. Will the contribution to public understanding be a significant one? Will the public's understanding of the government's operations be substantially greater as a result of the disclosure?
3. **Not primarily in the requester's commercial interest.** If the disclosure passes the test of furthering the specific public interest described in paragraph (b) of this section, we will determine whether it also furthers the requester's commercial interest and, if so, whether this effect outweighs the advancement of that public interest. In applying this second test, we will consider the following factors:
    1. Would the disclosure further a commercial interest of the requester, or of someone on whose behalf the requester is acting? "Commercial interests" include interests relating to business, trade, and profit. Not only profit-making corporations have commercial interests--so do nonprofit corporations, individuals, unions, and other associations. The interest of a representative of the news media in using the information for news dissemination purposes will not be considered a commercial interest.
    2. If disclosure would further a commercial interest of the requester, would that effect outweigh the

advancement of the public interest defined in paragraph (b) of this section? Which effect is primary?

4. **Deciding between waiver and reduction.** If the disclosure passes both tests, we will normally waive fees. However, in some cases we may decide only to reduce the fees. For example, we may do this when disclosure of some but not all of the requested records passes the tests.
5. **Procedure for requesting a waiver or reduction.** You must make your request for a waiver or reduction at the same time you make your request for records. You should explain why you believe a waiver or reduction is proper under the analysis in paragraphs (a) through (d) of this section. Only FOI Officers may make the decision whether to waive, or reduce, the fees. If we do not completely grant your request for a waiver or reduction, the denial letter will designate a review official. You may appeal the denial to that official. In your appeal letter, you should discuss whatever reasons are given in our denial letter. The process prescribed in Sec. 5.34(c) of this part will also apply to these appeals.

Subpart E -- Records Available for Public Inspection

Sec. 5.51 Records available.

1. **Records of general interest.** We will make the following records of general interest available for your inspection and copying. Before releasing them, however, we may delete the names of people, or information that would identify them, if release would invade their personal privacy to a clearly unwarranted degree. (See Sec. 5.67 of this part.)
    1. Orders and final opinions, including concurring and dissenting opinions in adjudications, such as Letters of Finding issued by the Office for Civil Rights in civil rights complaints, and Social Security Rulings. (See Sec. 5.66 of this part for availability of internal memoranda, including attorney opinions and advice.)
    2. Statements of policy and interpretations that we have adopted but have not published in the Federal Register.
    3. Administrative staff manuals and instructions to staff that affect the public. (We will not make available, however, manuals or instructions that reveal investigative or audit procedures as described in Secs. 5.63 and 5.68 of this part.)
2. **Other records.** In addition to such records as those described in paragraph (a) of this section, we will make available to any person a copy of all other agency records, unless we determine that such records should be withheld from disclosure under subsection (b) of the Act and Subpart F of this regulation.

Sec. 5.52 Indexes of records.

1. **Inspection and copying.** We will maintain and provide for your inspection and copying current indexes of the records described in Sec. 5.51(a). We will also publish and distribute copies of the indexes unless we announce in the Federal Register that it is unnecessary or impracticable to do so. For assistance in locating indexes maintained in the Department, you may contact the HHS Freedom of Information Officer at the address and telephone number in Sec. 5.31(c).
2. **Record citation as precedent.** We will not use or cite any record described in Sec. 5.51(a) as a precedent for an action against a person unless we have indexed the record and published it or made it available, or unless the person has timely notice of the record.

Subpart F -- Reasons for Withholding Some Records

Sec. 5.61 General.

Section 552(b) of the Freedom of Information Act contains nine exemptions to the mandatory disclosure of records. We describe these exemptions below and explain how this Department applies them to disclosure determinations. (In some cases more than one exemption may apply to the same document.) Information obtained by the Department from any individual or organization, furnished in reliance on a provision for confidentiality authorized by applicable statute or regulation, will not be disclosed, to the extent it can be withheld under one of these exemptions. This section does not itself authorize the giving of any pledge of

confidentiality by any officer or employee of the Department.

Sec. 5.62 Exemption one: National defense and foreign policy.

We are not required to release records that, as provided by FOIA, are "(a) specifically authorized under criteria established by an Executive Order to be kept secret in the interest of national defense or foreign policy and (b) are in fact properly classified pursuant to such Executive Order." Executive Order No. 12356 (1982) provides for such classification. When the release of certain records may adversely affect U.S. relations with foreign countries, we usually consult with officials of those countries or officials of the Department of State. Also, we may on occasion have in our possession records classified by some other agency. We may refer your request for such records to the agency that classified them and notify you that we have done so, as explained in Sec. 5.23.

Sec. 5.63 Exemption two: Internal personnel rules and practices.

We are not required to release records that are "related solely to the internal personnel rules and practices of an agency." Under this exemption, we may withhold routine internal agency practices and procedures. For example, we may withhold guard schedules and rules governing parking facilities or lunch periods. Also under this exemption, we may withhold internal records whose release would help some persons circumvent the law or agency regulations. For example, we ordinarily do not disclose manuals that instruct our investigators or auditors how to investigate possible violations of law, to the extent that this release would help some persons circumvent the law.

Sec. 5.64 Exemption three: Records exempted by other statutes.

We are not required to release records if another statute specifically allows us to withhold them. We may use another statute to justify withholding only if it absolutely prohibits disclosure or if it sets forth criteria to guide our decision on releasing or identifies particular types of material to be withheld.

Sec. 5.65 Exemption four: Trade secrets and confidential commercial or financial information.

We will withhold trade secrets and commercial or financial information that is obtained from a person and is privileged or confidential.

1. **Trade secrets.** A trade secret is a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process.
2. **Commercial or financial information.** We will not disclose records whose information is "commercial or financial," is obtained from a person, and is "privileged or confidential."
    1. Information is "commercial or financial" if it relates to businesses, commerce, trade, employment, profits, or finances (including personal finances). We interpret this category broadly.
    2. Information is "obtained from a person" if HHS or another agency has obtained it from someone outside the Federal Government or from someone within the Government who has a commercial or financial interest in the information. "Person" includes an individual, partnership, corporation, association, state or foreign government, or other organization. Information is not "obtained from a person" if it is generated by HHS or another federal agency. However, information is "obtained from a person" if it is provided by someone, including but not limited to an agency employee, who retains a commercial or financial interest in the information.
    3. Information is "privileged" if it would ordinarily be protected from disclosure in civil discovery by a recognized evidentiary privilege, such as the attorney-client privilege or the work product privilege. Information may be privileged for this purpose under a privilege belonging to a person outside the government, unless the providing of the information to the government rendered the information no longer protectable in civil discovery.
    4. Information is "confidential" if it meets one of the following tests:

1. Disclosure may impair the government's ability to obtain necessary information in the future;
2. Disclosure would substantially harm the competitive position of the person who submitted the information;
3. Disclosure would impair other government interests, such as program effectiveness and compliance;
   or
4. Disclosure would impair other private interests, such as an interest in controlling availability of intrinsically valuable records, which are sold in the market by their owner.

The following questions may be relevant in analyzing whether a record meets one or more of the above tests: Is the information of a type customarily held in strict confidence and not disclosed to the public by the person to whom it belongs? What is the general custom or usage with respect to such information in the relevant occupation or business? How many, and what types of, individuals have access to the information? What kind and degree of financial injury can be expected if the information is disclosed?

3. **Designation of certain confidential information.** A person who submits records to the government may designate part or all of the information in such records as exempt from disclosure under Exemption 4 of the FOIA. The person may make this designation either at the time the records are submitted to the government or within a reasonable time thereafter. The designation must be in writing. Where a legend is required by a request for proposals or request for quotations, pursuant to 48 CFR 352.215-12, then that legend is necessary for this purpose. Any such designation will expire ten years after the records were submitted to the government.
4. **Predisclosure notification.** The procedures in this paragraph apply to records on which the submitter has designated information as provided in paragraph (c) of this section. They also apply to records that were submitted to the government where we have substantial reason to believe that information in the records could reasonably be considered exempt under Exemption 4. Certain exceptions to these procedures are stated in paragraph (e) of this section.
   1. When we receive a request for such records, and we determine that we may be required to disclose them, we will make reasonable efforts to notify the submitter about these facts. The notice will include a copy of the request, and it will inform the submitter about the procedures and time limits for submission and consideration of objections to disclosure. If we must notify a large number of submitters, we may do this by posting or publishing a notice in a place where the submitters are reasonably likely to become aware of it.
   2. The submitter has five working days from receipt of the notice to object to disclosure of any part of the records and to state all bases for its objections.
   3. We will give consideration to all bases that have been timely stated by the submitter. If we decide to disclose the records, we will notify the submitter in writing. This notice will briefly explain why we did not sustain its objections. We will include with the notice a copy of the records about which the submitter objected, as we propose to disclose them. The notice will state that we intend to disclose the records five working days after the submitter receives the notice unless we are ordered by a United States District Court not to release them.
   4. When a requester files suit under the FOIA to obtain records covered by this paragraph, we will promptly notify the submitter.
   5. Whenever we send a notice to a submitter under paragraph (d)(1) of this section, we will notify the requester that we are giving the submitter a notice and an opportunity to object. Whenever we send a notice to a submitter under paragraph (d)(3) of this section, we will notify the requester of this fact.
5. **Exceptions to predisclosure notification.** The notice requirements in paragraph (d) of this section do not apply in the following situations:
   1. We decided not to disclose the records;
   2. The information has previously been published or made generally available;
   3. Disclosure is required by a regulation, issued after notice and opportunity for public comment, that specifies narrow categories of records that are to be disclosed under the FOIA, but in this case a submitter may still designate records as described in paragraph (c) of this section, and in exceptional cases, we may, at our discretion, follow the notice procedures in paragraph (d) of this section; or
   4. The designation appears to be obviously frivolous, but in this case we will still give the submitter the

written notice required by paragraph (d)(3) of this section (although this notice need not explain our decision or include a copy of the records), and we will notify the requester as described in paragraph (d)(5) of this section.

Sec. 5.66 Exemption five: Internal memoranda.

This exemption covers internal government communications and notes that fall within a generally recognized evidentiary privilege. Internal government communications include an agency's communications with an outside consultant or other outside person, with a court, or with Congress, when those communications are for a purpose similar to the purpose of privileged intra-agency communications. Some of the most- commonly applicable privileges are described in the following paragraphs.

1. **Deliberative process privilege.** This privilege protects predecisional deliberative communications. A communication is protected under this privilege if it was made before a final decision was reached on some question of policy and if it expressed recommendations or opinions on that question. The purpose of the privilege is to prevent injury to the quality of the agency decisionmaking process by encouraging open and frank internal policy discussions, by avoiding premature disclosure of policies not yet adopted, and by avoiding the public confusion that might result from disclosing reasons that were not in fact the ultimate grounds for an agency's decision. Purely factual material in a deliberative document is within this privilege only if it is inextricably intertwined with the deliberative portions so that it cannot reasonably be segregated, if it would reveal the nature of the deliberative portions, or if its disclosure would in some other way make possible an intrusion into the decisionmaking process. We will release purely factual material in a deliberative document unless that material is otherwise exempt. The privilege continues to protect predecisional documents even after a decision is made.
2. **Attorney work product privilege.** This privilege protects documents prepared by or for an agency, or by or for its representative (typically, HHS attorneys) in anticipation of litigation or for trial. It includes documents prepared for purposes of administrative adjudications as well as court litigation. It includes documents prepared by program offices as well as by attorneys. It includes factual material in such documents as well as material revealing opinions and tactics. Finally, the privilege continues to protect the documents even after the litigation is closed.
3. **Attorney-client communication privilege.** This privilege protects confidential communications between a lawyer and an employee or agent of the government where there is an attorney-client relationship between them (typically, where the lawyer is acting as attorney for the agency and the employee is communicating on behalf of the agency) and where the employee has communicated information to the attorney in confidence in order to obtain legal advice or assistance.

Sec. 5.67 Exemption six: Clearly unwarranted invasion of personal privacy.

1. **Documents affected.** We may withhold records about individuals if disclosure would constitute a clearly unwarranted invasion of their personal privacy.
2. **Balancing test.** In deciding whether to release records to you that contain personal or private information about someone else, we weigh the foreseeable harm of invading that person's privacy against the public benefit that would result from the release. If you were seeking information for a purely commercial venture, for example, we might not think that disclosure would primarily benefit the public and we would deny your request. On the other hand, we would be more inclined to release information if you were working on a research project that gave promise of providing valuable information to a wide audience. However, in our evaluation of requests for records we attempt to guard against the release of information that might involve a violation of personal privacy because of a requester being able to ``read between the lines" or piece together items that would constitute information that normally would be exempt from mandatory disclosure under Exemption Six.
3. **Examples.** Some of the information that we frequently withhold under Exemption Six is: Home addresses, ages, and minority group status of our employees or former employees; social security numbers; medical information about individuals participating in clinical research studies; names and addresses of individual beneficiaries of our programs, or benefits such individuals receive; earning records, claim files, and other

personal information maintained by the Social Security Administration, the Public Health Service, and the Health Care Financing Administration.

Sec. 5.68 Exemption seven: Law enforcement.

We are not required to disclose information or records that the government has compiled for law enforcement purposes. The records may apply to actual or potential violations of either criminal or civil laws or regulations. We can withhold these records only to the extent that releasing them would cause harm in at least one of the following situations:

1. **Enforcement proceedings.** We may withhold information whose release could reasonably be expected to interfere with prospective or ongoing law enforcement proceedings. Investigations of fraud and mismanagement, employee misconduct, and civil rights violations may fall into this category. In certain cases--such as when a fraud investigation is likely--we may refuse to confirm or deny the existence of records that relate to the violations in order not to disclose that an investigation is in progress, or may be conducted.
2. **Fair trial or impartial adjudication.** We may withhold records whose release would deprive a person of a fair trial or an impartial adjudication because of prejudicial publicity.
3. **Personal privacy.** We are careful not to disclose information that could reasonably be expected to constitute an unwarranted invasion of personal privacy. When a name surfaces in an investigation, that person is likely to be vulnerable to innuendo, rumor, harassment, and retaliation.
4. **Confidential sources and information.** We may withhold records whose release could reasonably be expected to disclose the identity of a confidential source of information. A confidential source may be an individual; a state, local, or foreign government agency; or any private organization. The exemption applies whether the source provides information under an express promise of confidentiality or under circumstances from which such an assurance could be reasonably inferred. Also, where the record, or information in it, has been compiled by a criminal law enforcement authority conducting a criminal investigation, or by an agency conducting a lawful national security investigation, the exemption also protects all information supplied by a confidential source. Also protected from mandatory disclosure is any information which, if disclosed, could reasonably be expected to jeopardize the system of confidentiality that assures a flow of information from sources to investigatory agencies.
5. **Techniques and procedures.** We may withhold records reflecting special techniques or procedures of investigation or prosecution, not otherwise generally known to the public. In some cases, it is not possible to describe even in general terms those techniques without disclosing the very material to be withheld. We may also withhold records whose release would disclose guidelines for law enforcement investigations or prosecutions if this disclosure could reasonably be expected to create a risk that someone could circumvent requirements of law or of regulation.
6. **Life and physical safety.** We may withhold records whose disclosure could reasonably be expected to endanger the life or physical safety of any individual. This protection extends to threats and harassment as well as to physical violence.

Sec. 5.69 Exemptions 8 and 9: Records on financial institutions; records on wells.

Exemption eight permits us to withhold records about regulation or supervision of financial institutions. Exemption nine permits the withholding of geological and geophysical information and data, including maps, concerning wells.