GENERAL MANAGEMENT AND ADMINISTRATION

GUIDE TO ISSUANCE OF DIRECTIVES IN THE CENTER FOR DRUG EVALUATION AND RESEARCH

CONTENTS

PURPOSE This MAPP establishes a system for issuing~~directives~~ MAPPs within the Center for Drug Evaluation and Research (CDER) and disseminating Center policy and procedures to all Center employees. It specifies policy, responsibilities, and procedures for the origination, update, clearance, maintenance, and issuance of policies and procedures within the Center.

BACKGROUND

- The Federal Managers' Financial Integrity Act of 1982 (FMFIA) requires management to establish and maintain adequate systems of internal control for accounting and administrative activities.

- The Office of Management and Budget (OMB) states that internal control documentation shall include system documentation of policies and procedures, organization charts, manuals, memoranda, flow charts, and related written materials necessary to describe organizational structure, operating procedures, and administrative practices. The documentation shall communicate responsibilities and authorities for accomplishing programs and activities. Maintaining the Center's Manual of Policies and Procedures (MAPP) helps to strengthen internal controls by documenting the policies and procedures required by FMFIA, the General Accounting Office, and OMB.

REFERENCES

- Federal Managers' Financial Integrity Act of 1982 (PL-97-255).
- *Standards for Internal Controls in the Federal Government*, U.S. Government Accounting Office.
- *Circular A-123, Revised, Internal Control Systems*, Office of Management and Budget.

DEFINITIONS

- **Directive (i.e., MAPP)**. A written statement issued by CDER management to prescribe policies, responsibilities, or procedures to be applied within the Center in the conduct of its work or daily operations. ~~Directives~~ MAPPs may be issued by any CDER administrative level (Center, Office, Division, Staff, Branch or Section).
- **Interim Directive**. A directive with a stipulated termination date, usually one year from date of issuance, which may be issued as a memorandum with a formal cover sheet to identify the contents as a directive. The termination date will appear on the cover sheet. (See Attachment B.)
- **Manual of Policies and Procedures**. The CDER Manual of Policies and Procedures (MAPP) consists of specific and interim directives issued for Center administration and management as well as for program areas. ~~Directives~~ MAPPs are available electronically to all CDER employees in Videotext, the ORA Gold Disk and on Internet. In addition, hard copies are printed on yellow paper and maintained in a CDER manual binder available in each CDER organization down to the Division level.

- **Sponsor**. The person, usually a management-level individual, who directs the development or revision a particular ~~directive~~ MAPP.

- **Originator, Drafter**. The individual who actually develops or revises a particular ~~directive~~ MAPP and who may, or may not, be the sponsor. For the purposes of this ~~directive~~ MAPP, the terms originator and drafter are synonymous.

- **MAPP point of contact.** The individual at each management-level (down to the division level) that is responsible for maintaining the hard copy of the MAPP. This individual is appointed by the Office/Division Director.

POLICY

- Office, Division, and Center-wide operating policies and procedures will be published as ~~directives~~ MAPPs in the CDER Manual of Policies and Procedures and will remain in effect until their termination date is reached, or they are rescinded or superseded.

- The system and format prescribed in this ~~directive~~ MAPP will be used to issue all ~~directives~~ MAPPs in the Center.

- ~~Directives~~ MAPPs will be written, cleared, published, and updated on a timely basis and according to the responsibilities and procedures stated in this ~~directive~~ MAPP.

- A complete manual of CDER guides will be maintained in each organizational unit at the Division level and made available electronically to all CDER personnel. See Attachment F for a list of the MAPP points of contact.

- Interim directives will not be made publicly available because the policies and procedures are temporary.

RESPONSIBILITIES

The Associate Director of Policy or his/her designee

- Reviews and concurs on all proposed and revised ~~directives~~ MAPPs of Center-wide significance.

- Monitors ~~directives~~ MAPPs issued at the Office and Division level to ensure accuracy and consistency of content and format and that ~~directives~~ MAPPs with

Center-wide significance are developed with appropriate Center-wide coordination.

- Archives all expired ~~directives~~ MAPPs.
- Consults with originators of proposed ~~directives~~ MAPPs on format and content.
- Coordinates the clearance of proposed ~~directives~~ MAPPs in the Center.
- Assigns identification numbers and prepares final copy of ~~directives~~ MAPPs for publication.
- Maintains record copies of all ~~directives~~ MAPPs.
- Maintains electronic files of the finalized MAPPs on Videotex, the common CDER shared drive (x:\cdermapp), the ORA Gold Disk, and Internet. (Refer to Attachment E for specific instructions on locating electronic copies of MAPPs.)
- Ensures that ~~directives~~ MAPPs are reviewed every five years and updated as necessary to reflect current policy, operating procedures, and methods.

Office and Division Directors, and other Sponsors (e.g., Staff Directors)

- Originate ~~directives~~ MAPPs to reflect policy and procedures within their organizational areas for inclusion in the CDER MAPP, and notify the Associate Director for Policy of the initiation of a ~~directive~~ MAPP.
- Appoint a person as MAPP point of contact.
- Coordinate with the Associate Director for Policy to obtain concurrence of affected units when MAPPs ~~directives~~ cross organizational lines.

Supervisors

- Ensure that all subordinates understand their responsibilities to become familiar with the MAPPs ~~directives~~ related to their positions.

Drafters of MAPPs

- Ensure that content of the ~~directive~~ MAPP is accurate and current.

- Review all pertinent references to ensure consistency with existing policy.
- Ensure that the content is clear, complete, concise, and in the prescribed format.
- Ensure that the draft MAPP is reviewed by the appropriate parties (see below) and that sufficient time is allotted for the review (usually 10 business days).
- For Team-specific, Division-specific, or Staff-specific ~~directives~~ MAPPs, route the ~~directive~~ MAPP through the Team Leader, Division Director, or Staff Director who will check the ~~directive~~ MAPP for accuracy, endorse it, and return it to the drafter.
- For Office-wide ~~directives~~ MAPPs, route the ~~directive~~ MAPP through the Office Director who will check the ~~directive~~ MAPP for accuracy, endorse it, and return it to the drafter.
- For Center-wide ~~directives~~ MAPPs or those that cross-Office lines, route the ~~directive~~ MAPP through the Associate Director for Policy for distribution to the appropriate Office/Division Directors and coordinating committee chairs for clearance.
- Revise the proposed ~~directive~~ MAPP to incorporate appropriate comments made by reviewers and preparing a final package containing the revised draft and all memoranda or comments relating to important controversies and their resolution.
- Submit a clean, hard copy of the draft ~~directive~~ MAPP to the Associate Director for Policy or his/her designees and place an electronic copy on the CDER common shared drive (x:\transfer\mapp).
- Identify key words for indexing and hypertext links.

The MAPP Point of Contact

- Reviews and updates existing MAPPs, or develops new MAPPs as needed to reflect current policies and operating procedures, and appropriate methods to ensure current information within their organizational units;
- Maintains the hard copy of the MAPP in their organizational unit.

PROCEDURES

For new MAPPs ~~directives~~:

- Clearance of Office and Division MAPPs~~directives~~:

  1. Upon receipt of the draft and approval of content and format, the Associate Director for Policy or his/her designee will attach a clearance record and return the draft for signature by the management of the originating component.

  2. The Director of the originating Office or Division will indicate approval of the draft MAPP by signing and dating the clearance record and returning them with the draft to the Associate Director for Policy or his/her designee for distribution. An Office or Division-specific~~directive~~ is then ready for publication and distribution.

- Clearance of Center MAPPs ~~directives~~:

  1. Upon receipt of the draft and approval of content and format, the Associate Director for Policy or his/her designee will attach a clearance record and obtain the signature of the management of the originating component, or lead on the specific issue (e.g., Chair of responsible coordinating committee, working group).

  2. For Center-wide ~~directives~~ MAPPs, the Associate Director for Policy or his/her designee will distribute copies to all **affected** Office Directors for final clearance. Generally, 15 working days will be provided for concurrence, and the draft should be returned to the Associate Director for Policy or his/her designee with the signed clearance form and any comments attached.

  3. Any CDER component that has not responded within the 15-day time limit will be considered as having concurred. If circumstances require a longer-than-normal time frame, a 15-day extension of the time limit may be requested from the Associate Director for Policy.

- Correction and Final Package Preparation:

  1. The Associate Director for Policy or his/her designee will compile all comments received and forward them to the originator via memorandum signed by the Associate Director for Policy or his/her designee.

2. The originator will revise the proposed ~~directive~~ to incorporate appropriate comments made by reviewers, prepare a final package containing the revised draft and all memoranda or comments relating to important controversies and their resolution, and submit it to the Associate Director for Policy or his/her designee. The originator will attempt to reconcile disparate comments/concerns through discussions/meetings.

3. As needed, the Associate Director for Policy or his/her designee will circulate the revised draft and its comments for clearance to the Office Directors as described above.

- Conflict Resolution.

  1. Any reviewing Office Director who identifies a conflict or controversy in a draft ~~program directive~~ MAPP during the comment period will resolve the issue with the originating Office Director. Conflicts still unresolved one month after the clearance process ends will be directed to the Associate Director for Policy for final resolution.

  2. If necessary, the Associate Director for Policy may choose to initiate the following conflict resolution procedures:

     - The controversy will be presented to the CDER Deputy Director or Associate Director that has responsibility for the issue for resolution, or, for cross-cutting issues, to appropriate members of the CDER management team. If this is successful, the results will be returned through the Associate Director for Policy to the originating Office Director.

     - Any controversy/conflict that cannot be resolved through the Deputy or Associate Directors will be decided by the Director, Center for Drug Evaluation and Research, within one month from date of receipt of the package.

- Copy Preparation, Publication, and Distribution.

  Upon receipt of an approved Policy and Procedure, the Associate Director for Policy or his/her designee will prepare final copy and arrange for its publication and distribution.

Updating/Revising Existing CDER MAPPs ~~Directives~~:

- Sponsors will periodically evaluate ~~directives~~ MAPPs originated within their organizations to ensure that ~~directives~~ MAPPs are up to date. They will ensure that ~~directives~~ MAPPs are updated promptly when Center policy, procedures, methods, or subject areas have changed significantly, or when current procedures or methods are ineffective in accomplishing the Center's diverse functions in a satisfactory and timely manner.

- Originators will review their ~~directives~~ MAPPs periodically and update if necessary.

- The Associate Director for Policy or his/her designee will work with programs to monitor the accuracy and currency of ~~directives~~ MAPPs.

- The Associate Director for Policy or his/her designee will process revised ~~directives~~ MAPPs in the same manner as new MAPP ~~directives~~ MAPPs.

Format: The format used for text, outlines, headers, footers, and tables of contents will follow the format demonstrated throughout this guidance (See Attachment C). A blank format is available electronically (in WordPerfect) on the CDER common shared drive (x:\transfer\mapp\template.doc).

Identification and Numbering of ~~Directives~~ MAPPs: The Associate Director for Policy or his/her designee will assign identification numbers to all ~~directives~~ MAPPs issued in the Center. This numbering system consists of a three-part symbol (e.g., MAPP XXXX.X) which identifies:

- The manual acronym (MAPP).

- A four-digit subject category number or sub-category number assigned by the Associate Director for Policy or his/her designee (XXXX).

- sequential number (.X).

Transmittal: The Associate Director for Policy or his/her designee will distribute all ~~directives~~ MAPPs under transmittals which reference superseded material, provide filing instructions, and an explanation of changes. (See Attachment D.)

Filing:

- Policies and Procedures will be filed behind the appropriate tabs in numerical order by the MAPP point of contact. Specific filing instructions will appear on the transmittals.

- Existing Policies and Procedures are to be retained until canceled or superseded.

Table of Contents Update: Tables of Contents are provided for the MAPP and for each chapter. Tables are periodically updated to provide a listing of current ~~directives~~ MAPPs for ready reference. A consolidated Table of Contents shows the ~~directive~~ MAPP identification number, title, and date of issuance.

Effective Date: The effective date for all ~~directives~~ MAPPs will be the date of issuance on the transmittal.

For Interim Directives: Originators should follow the procedures for new MAPPs ~~directives~~ with the following additions:

- Originators should inform the Associate Director for Policy of the expiration date of the Interim Directive.

- The Associate Director for Policy will attach a cover memo (see Attachment B) to the Interim Directive.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

Attachment 1

SUBJECT CATEGORIES

4000 GENERAL MANAGEMENT AND ADMINISTRATION

- 4010 Delegations of Authority
- 4020 Organization
  - 4021 CDER Organizational Charts
- ~~4030 Priorities~~
- ~~4040 Resolution of Disputes~~

4100 CENTER DIRECTOR

- 4110 Executive Operations
  - 4111 Project Management
  - 4112 Executive Secretariat
  - 4113 Program Management
- 4120 Equal Employment Opportunity
- 4130 Drug Marketing, Advertising and Communications
- 4140 Regulatory Policy
  - 4141 Federal Register Documents
  - 4142 Citizen's Petitions
  - 4143 Debarment
- 4150 Ombudsman
  - 4151 Dispute Resolution

4500 TRAINING AND COMMUNICATIONS

- 4501 Program Management
- 4510 Communications
  - 4511 Communications within CDER
  - 4512 Communications with Regulated Industry
  - 4513 Communications with other FDA Organizations
  - 4514 Communications with Other Governmental Organizations
  - 4515 Communications with Foreign Countries

4720 Prescription Drug Compliance and Surveillance
- 4721 Case Management
- 4722 Compliance Evaluation
- 4723 Post-Market Surveillance

4730 Manufacturing and Product Quality
- 4731 Foreign Inspections
- 4732 Investigations and Preapproval Compliance
- 4733 Case Management and Guidance

4740 Scientific Investigations
- 4741 Bioequivalence
- 4742 Narcotic Treatment Monitoring
- 4743 Bioresearch Monitoring
- 4744 Human Subject Protection
- 4745 Clinical Investigations
- 4746 Non-Clinical Laboratory Studies

5000 PHARMACEUTICAL SCIENCES

5010 Formulations Research

5015 Chemistry Function

5020 Operations

5030 Compendial Operations

5100 CLINICAL PHARMACOLOGY AND BIOPHARMACEUTICS
- 5110 Pharmacometrics
- 5120 Pharmaceutical Evaluation

5200 GENERIC DRUGS
- 5210 Bioequivalence
- 5220 Chemistry
  - 5221 Analytical Methods
  - 5222 Drug Master Files
  - 5223 Drug Product
  - 5224 Drug Substance
  - 5225 Packaging
  - 5226 Stability
- 5230 Labeling

5240 Program Support

5300 NEW DRUG CHEMISTRY
5310 Chemistry
5320 Microbiology

5400 TESTING AND RESEARCH
5410 Clinical Pharmacology
5420 Drug Analysis
5430 Research and Testing

6000 REVIEW MANAGEMENT

6001 Advisors and Consultants
6002 Program Management
6003 Project Management
6004 Reports Data Management

6010 New Drug Application Procedures

6020 New Drug Application Policies

6030 Investigational New Drug Applications

6040 Institutional Review Boards

6050 User Fees

6100 OFFICE OF DRUG EVALUATION I
6101 Program Management
6102 Project Management

6110 Cardio-Renal Drug Products
6111 Program Management
6112 ~~Points To Consider~~
6113 Project Management

6120 Neuropharmacological Drug Products
6121 Program Management
6122 ~~Points To Consider~~
6123 Project Management

6130 Oncology Drug Products
6131 Program Management
6132 ~~Points To Consider~~
6133 Project Management

6200 OFFICE OF DRUG EVALUATION II
6201 Program Management
6202 Project Management

6210 Metabolism and Endocrine Drug Products
6211 Program Management
6212 ~~Points To Consider~~
6213 Project Management

6230 Pulmonary Drug Products
6231 Program Management
6232 ~~Points To Consider~~
6233 Project Management

6300 OFFICE OF DRUG EVALUATION III
6301 Program Management
6302 Project Management

6310 Anesthetic, Critical Care and Scheduled Drug Products
6311 Program Management
6312 ~~Points To Consider~~
6313 Project Management

6320 Gastrointestinal and Coagulation Drug Products
6321 Program Management
6322 ~~Points To Consider~~
6323 Project Management

6330 Medical Imaging and Radiopharmaceutical Drug Products
6331 Program Management
6332 ~~Points To Consider~~
6333 Project Management

6400 OFFICE OF DRUG EVALUATION IV
6401 Program Management
6402 Project Management

6410 Anti-Infective Drug Products
6411 Program Management
6412 ~~Points To Consider~~
6413 Project Management

6420 Antiviral Drug Products
6421 Program Management
6422 ~~Points To Consider~~
6423 Project Management

6500 OFFICE OF DRUG EVALUATION V
6501 Program Management
6502 Project Management

6510 Anti-Inflammatory, Analgesic and Dental Drug Products
6511 Program Management
6512 ~~Points To Consider~~
6513 Project Management

6520 Dermatologic and Ophthalmologic Drug Products
6521 Office Procedures
6522 Project Management Procedures
6523 Pharmacology
6524 Chemistry
6525 Dermatologic Drug Product Considerations
6526 Dental Drug Product Considerations

6530 Over-the-Counter Drug Products
6531 Program Management
6532 ~~Points To Consider~~
6533 Project Management

6600 EPIDEMIOLOGY AND BIOSTATISTICS
6610 Research and Methodology
6620 Epidemiology and Surveillance
6630 Biometrics

7000 DISCIPLINE-SPECIFIC

7100 BIOPHARMACEUTICS

7200 CHEMISTRY

7211 Analytical Methods
7212 Biotechnology
7213 Drug Master Files
7214 Drug Product
7215 Drug Substance
7216 Information Technology
7217 Labeling and Nomenclature
7218 Packaging
7219 Stability

7300 MEDICAL/STATISTICAL

7400 PHARMACOLOGY AND TOXICOLOGY

7411 6/12 Month
7412 Carcinogenicity Assessment
7413 Clinical Pathology
7414 Dose Selection
7415 General Safety Pharmacology
7416 Genotoxicity
7417 Good Review Practices
7418 Herbals
7419 Immunotoxicology
7420 Inactive Ingredients
7421 Infotechnological
7422 Neurotoxicology
7423 Reproductive Toxicology
7424 Stereochemistry/Stereoisomer
7425 Structure-Activity
7426 Toxicokinetic

7500 PROJECT MANAGEMENT

7600 INFORMATION TECHNOLOGY

7610 Internet

7700 RESEARCH

7800 ADMINISTRATIVE MANAGEMENT

Attachment B

SAMPLE FORMAT FOR INTERIM DIRECTIVE COVER SHEET

MANUAL OF POLICIES AND PROCEDURES

CENTER FOR DRUG EVALUATION AND RESEARCH **MAPP XXXX.X**

INTERIM DIRECTIVE

DATE:

TO:

SUBJECT: (Title of Memorandum)

ISSUED BY: (Title of Author, Organizational Component)

EXPIRATION DATE: (Generally one year from data of memorandum)

NOT PUBLICLY AVAILABLE

Attachment C

SAMPLE FORMAT FOR POLICIES AND PROCEDURES

CONTENTS

Text and outline format should follow the format demonstrated throughout this guidance.

An blank format is available electronically (in WordPerfect) on the CDER common shared drive (x:\transfer\mapp\template.doc).

Attachment D

CENTER FOR DRUG EVALUATION AND RESEARCH
POLICY AND PROCEDURE TRANSMITTAL

(DATE)

POLICY AND PROCEDURE: CDER MAPP#:
Title:

FILING INSTRUCTIONS AND EXPLANATION OF CHANGES:

REMOVE:

INSERT:

EXPLANATION:

PEN AND INK CHANGES TO TABLE OF CONTENTS
In the Table of Contents in the front of your CDER Manual of Policies and Procedures enter:

MAPP #:

Title:

Date:

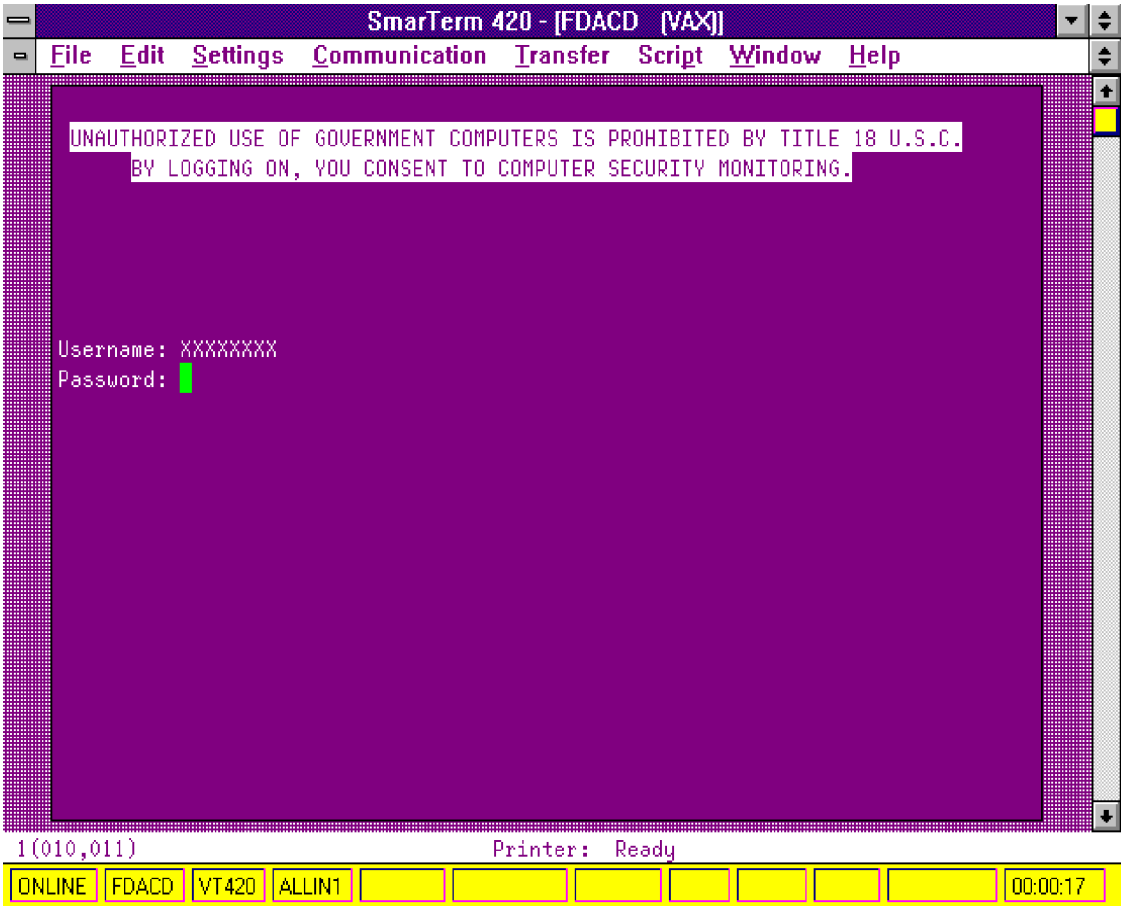
_____
Associate Director for Policy

Attachment E

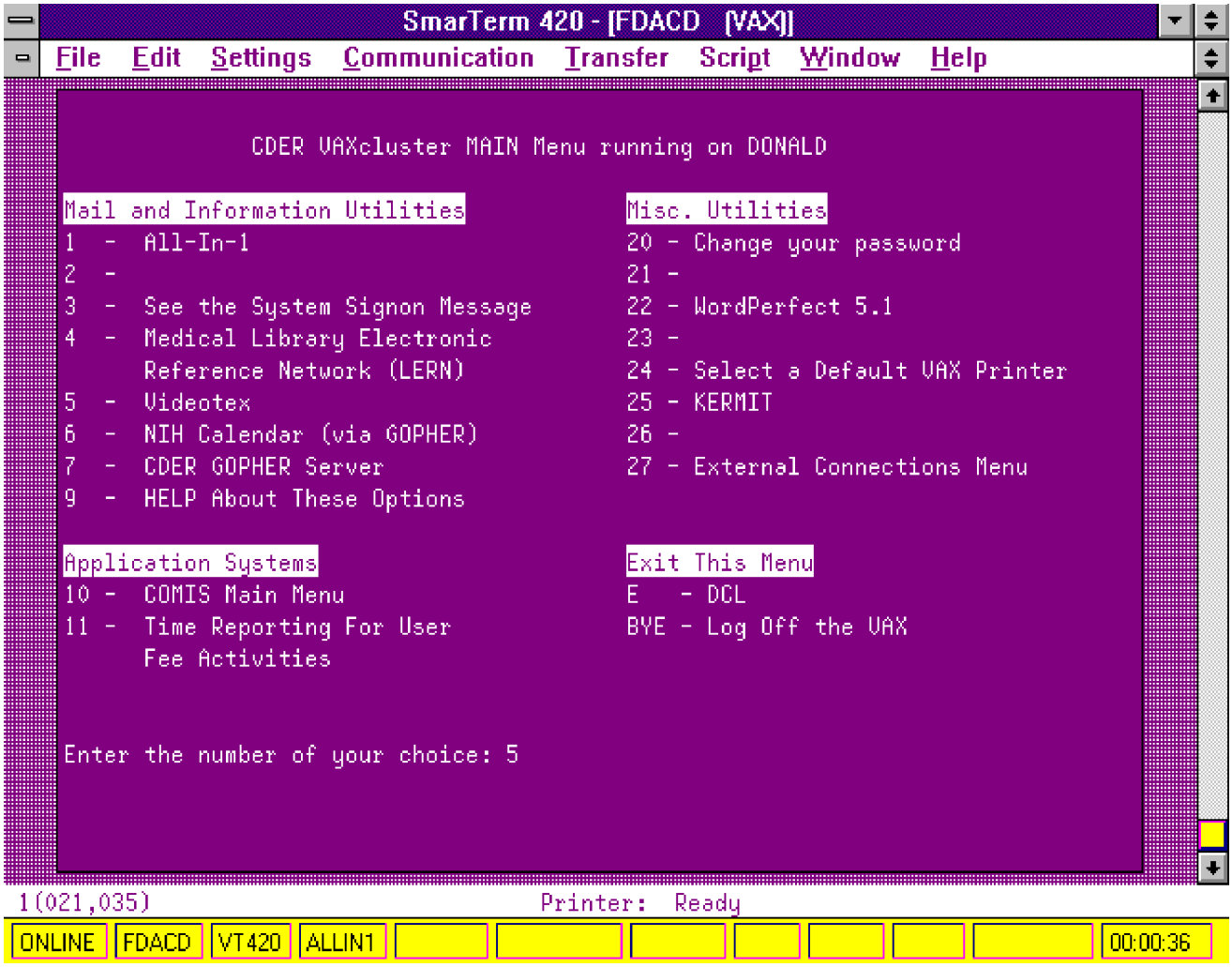
DIRECTIONS FOR FINDING ELECTRONIC COPIES OF MAPPS

TO ACCESS MAPPs ON VIDEOTEX

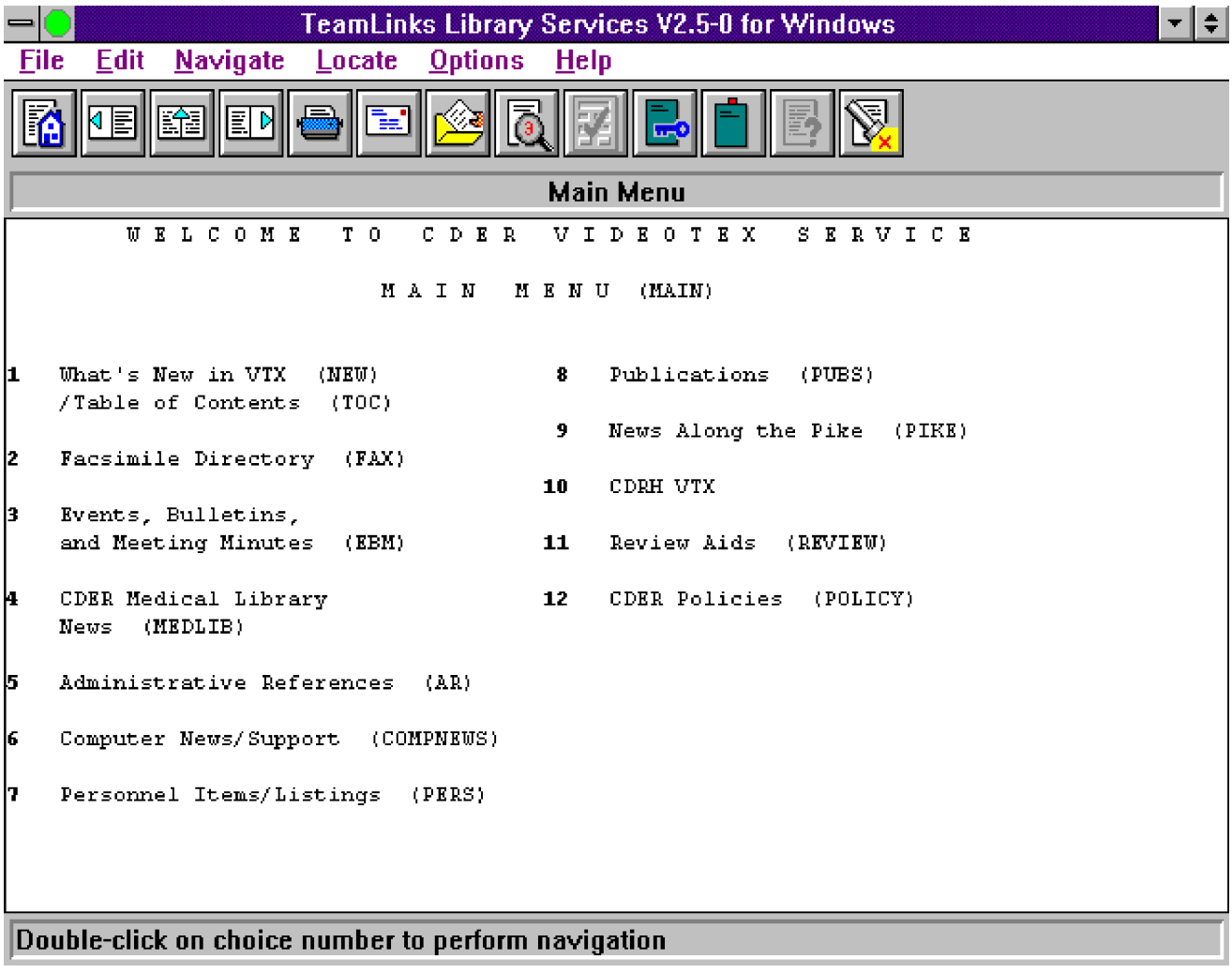
1. Log on to the CDER VAX



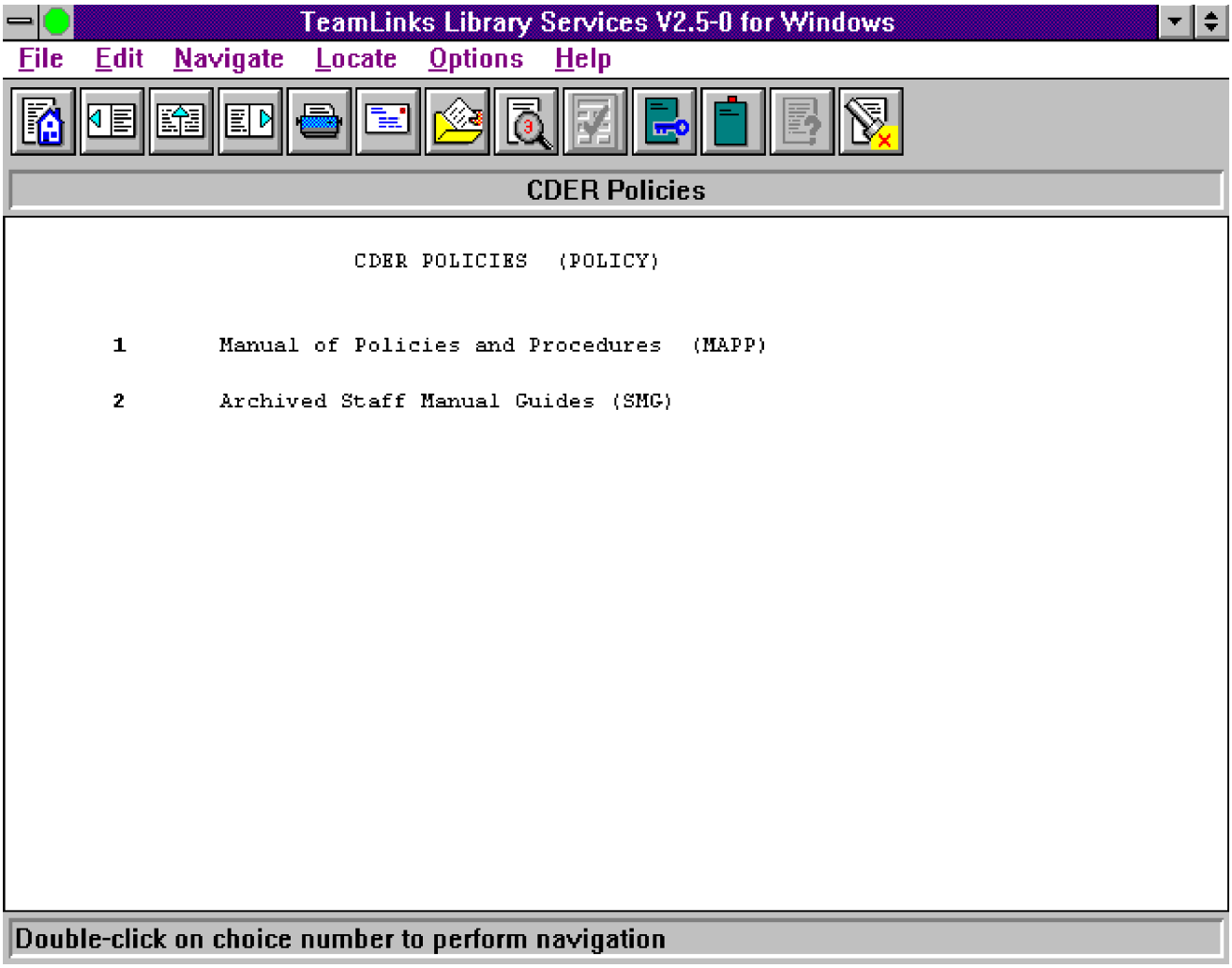
2. From the Main Menu, enter “5", for Videotex



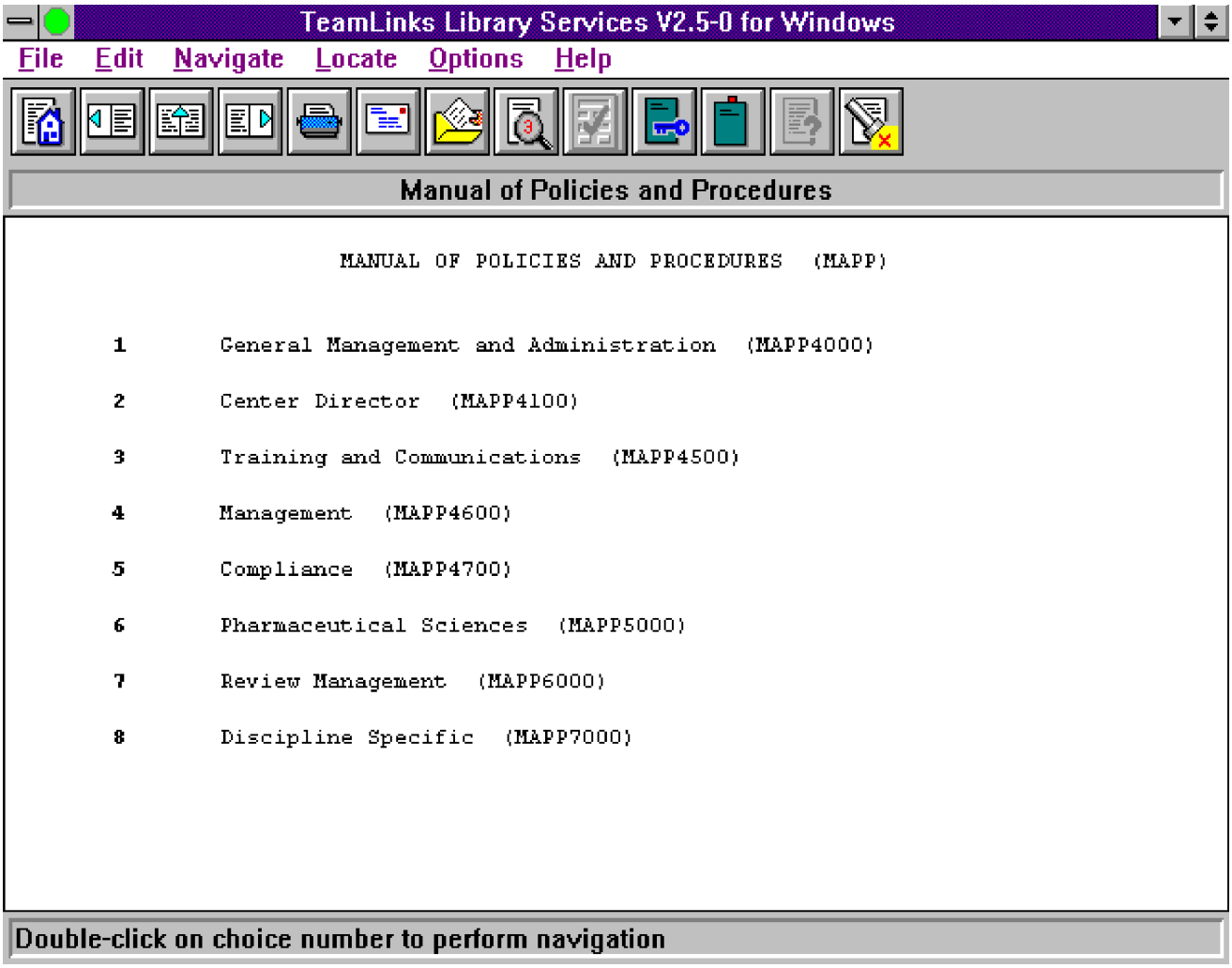
3. Enter “12", for CDER Policies



4. Enter “1", for the Manual of Policies and Procedures



5. Enter the Appropriate Category

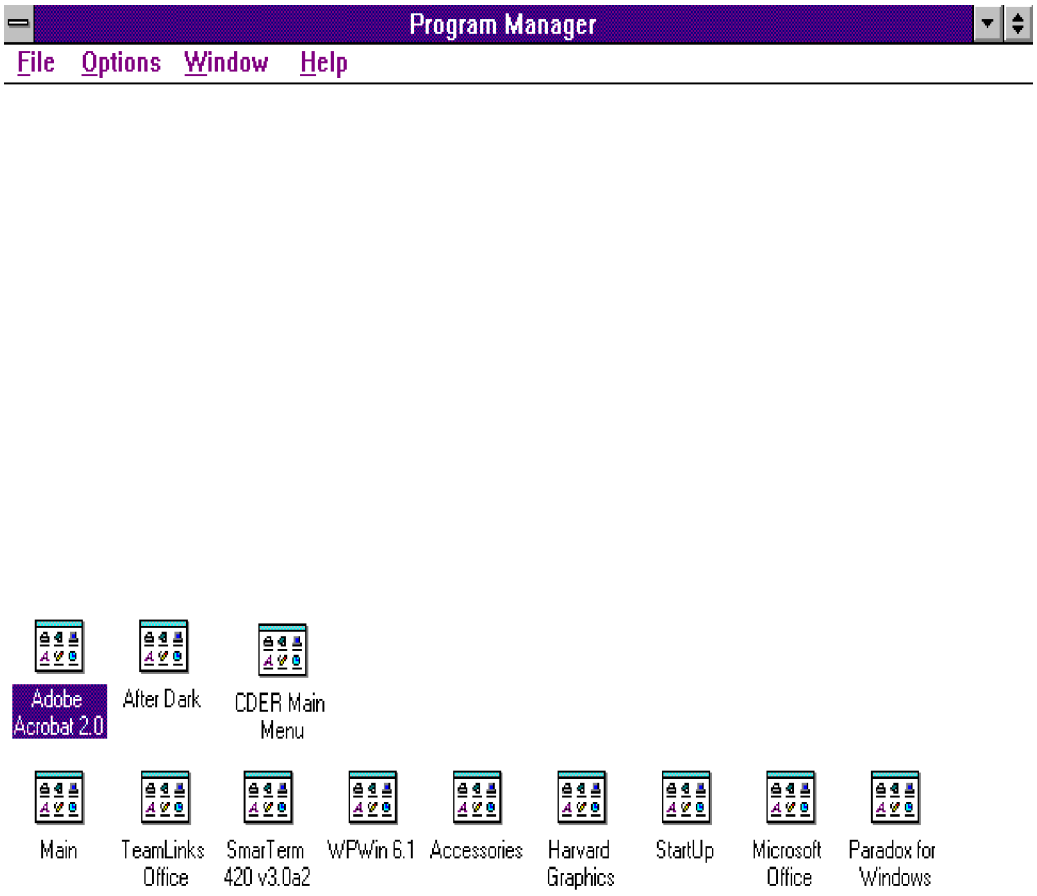


Each item leads you through a menu of the subject categories.

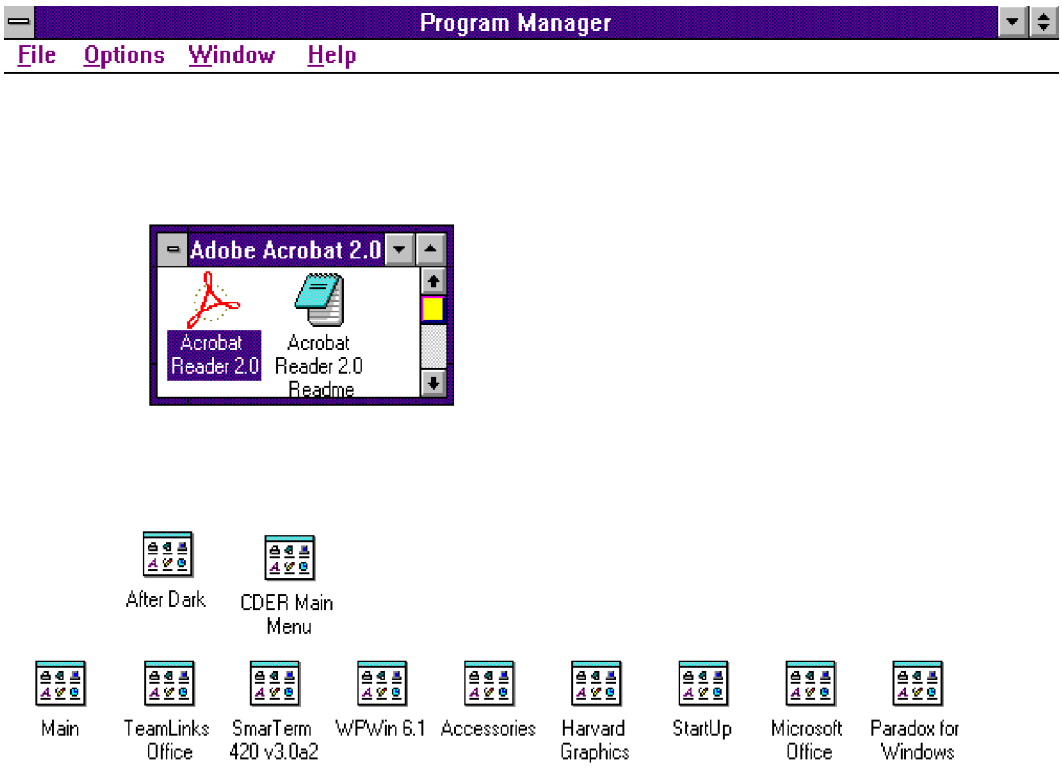
TO ACCESS MAPPS ON THE CDER COMMON SHARED DRIVE (X:\CDERMAPP)

MAPPs are in pdf format and should be accessed via the Adobe Acrobat Reader. (Contact the DISD Help Desk for information on installing the software).

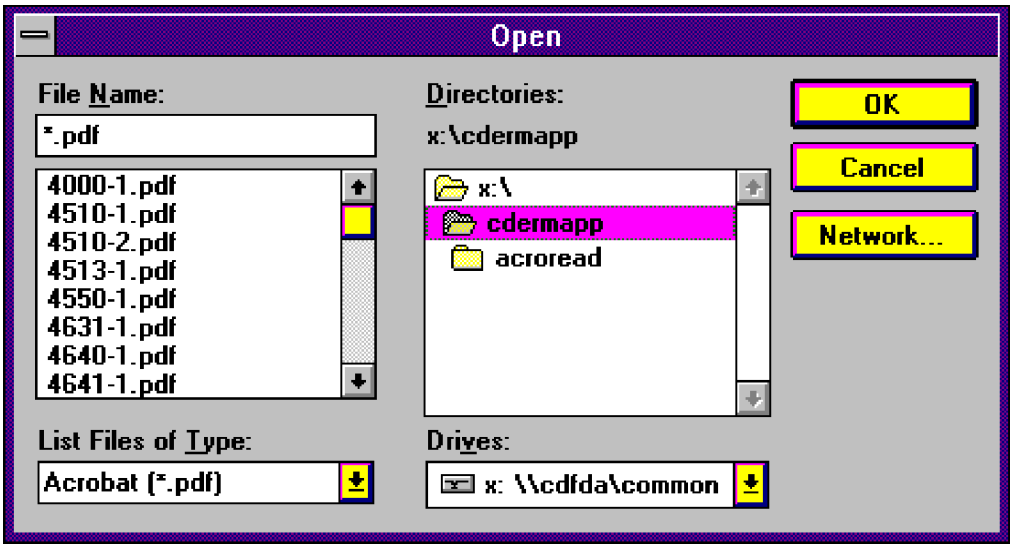
1. Double-Click on the "ADOBE ACROBAT" Icon



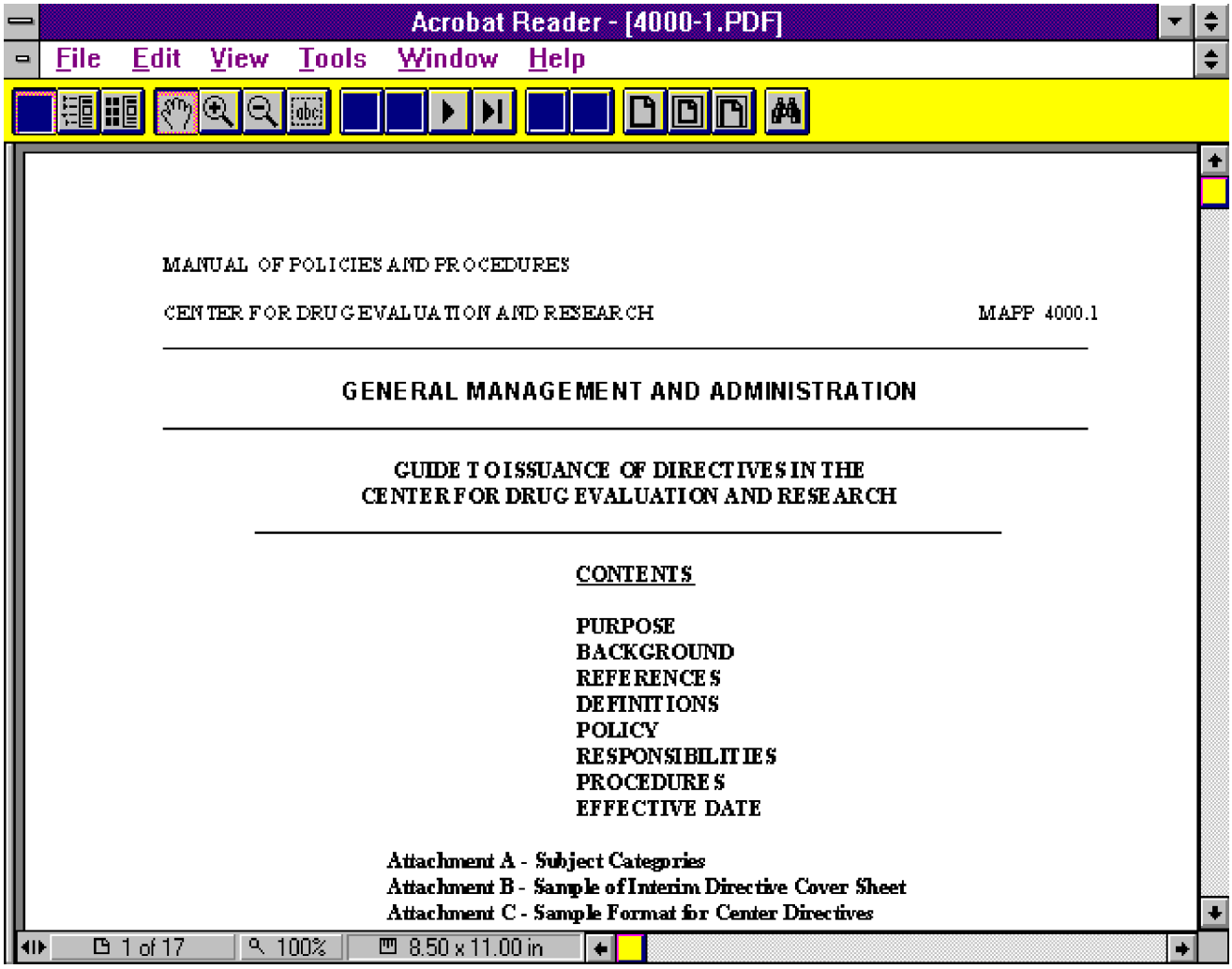
2. Double-Click on the “Acrobat Reader 2.0" Icon



3. Files are located under x:\cdermapp directory

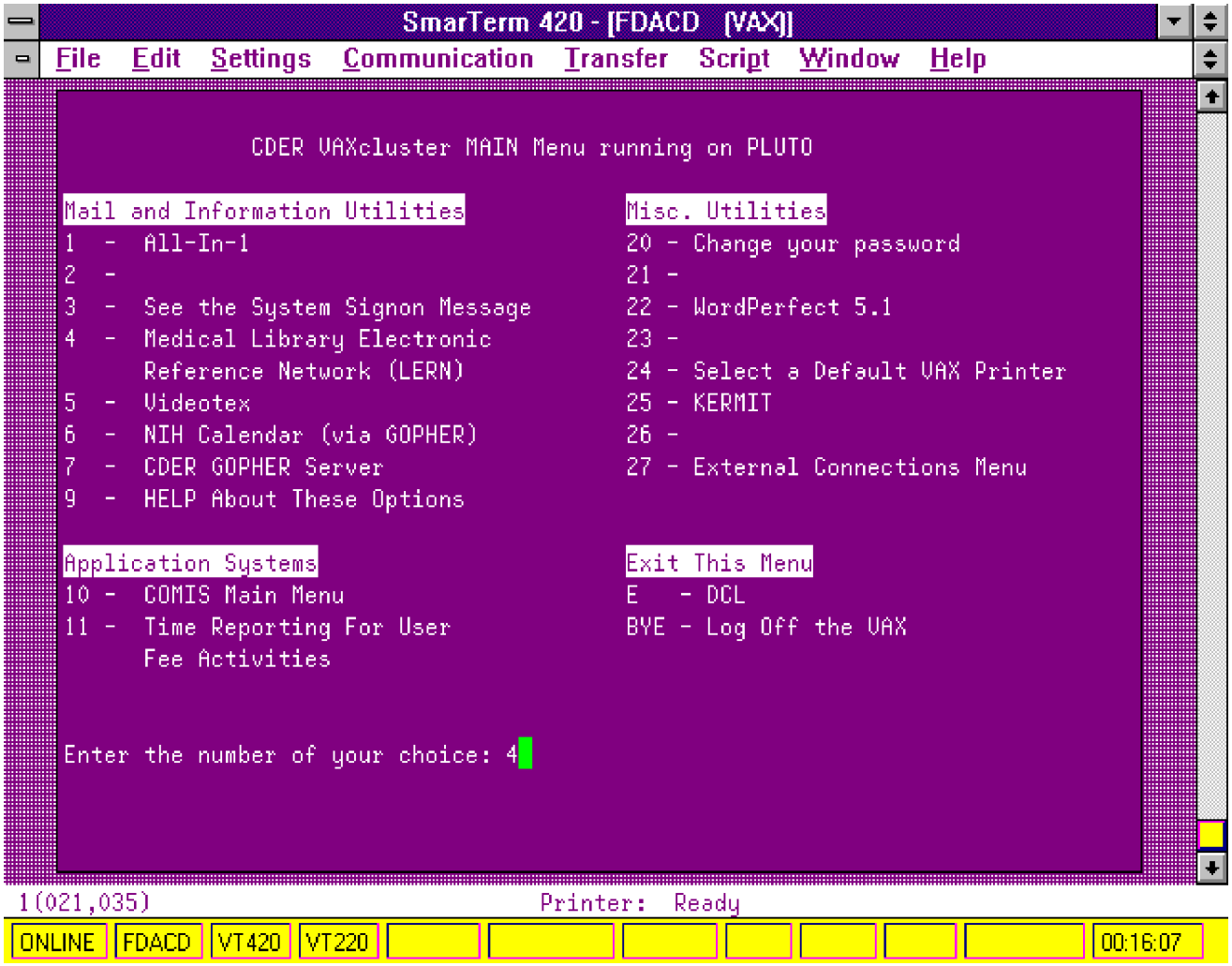


4. MAPPs are filed by MAPP Number. Choose the file you would like to view (e.g., 4000-1):

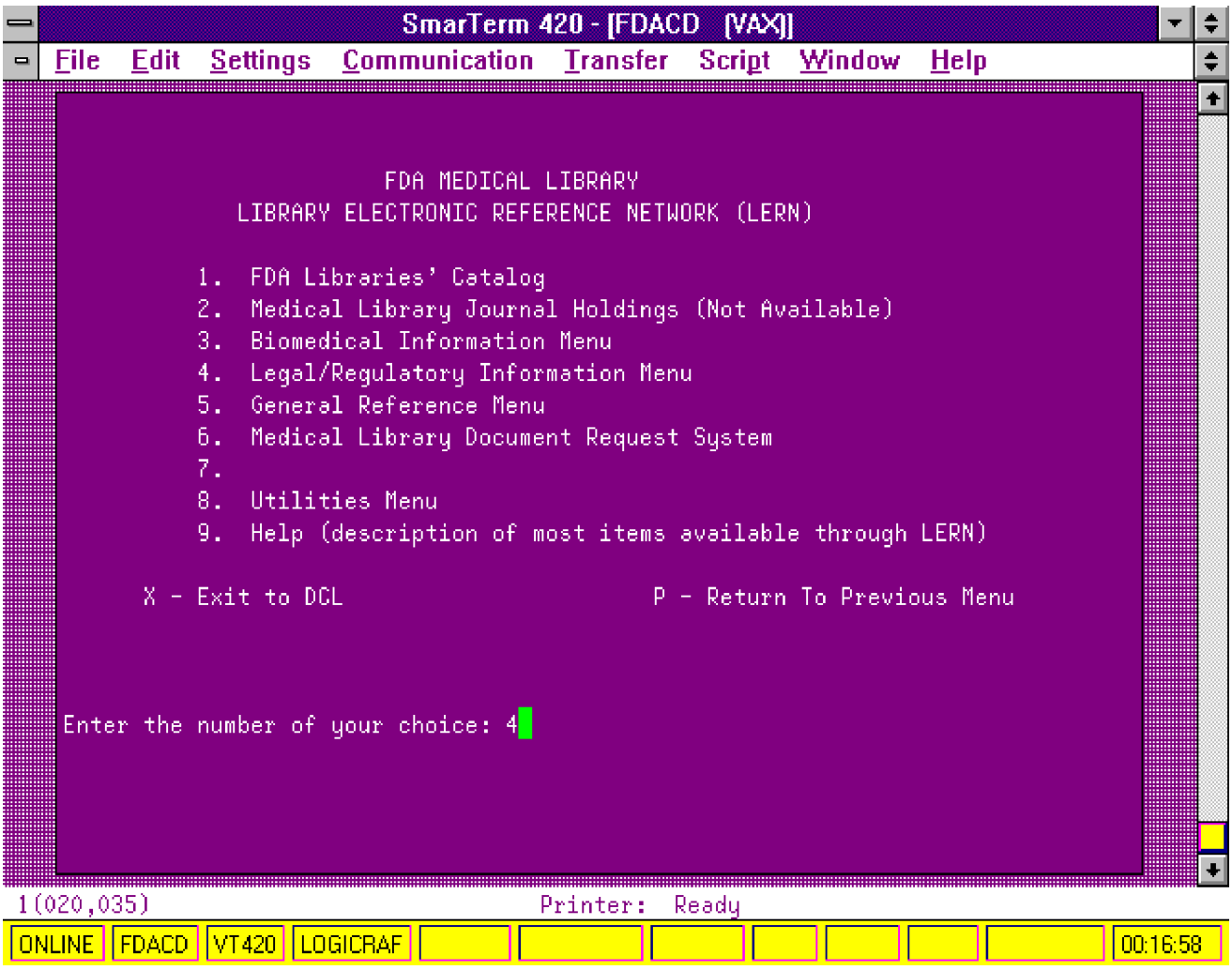


TO ACCESS MAPPs on ORA GOLD DISK

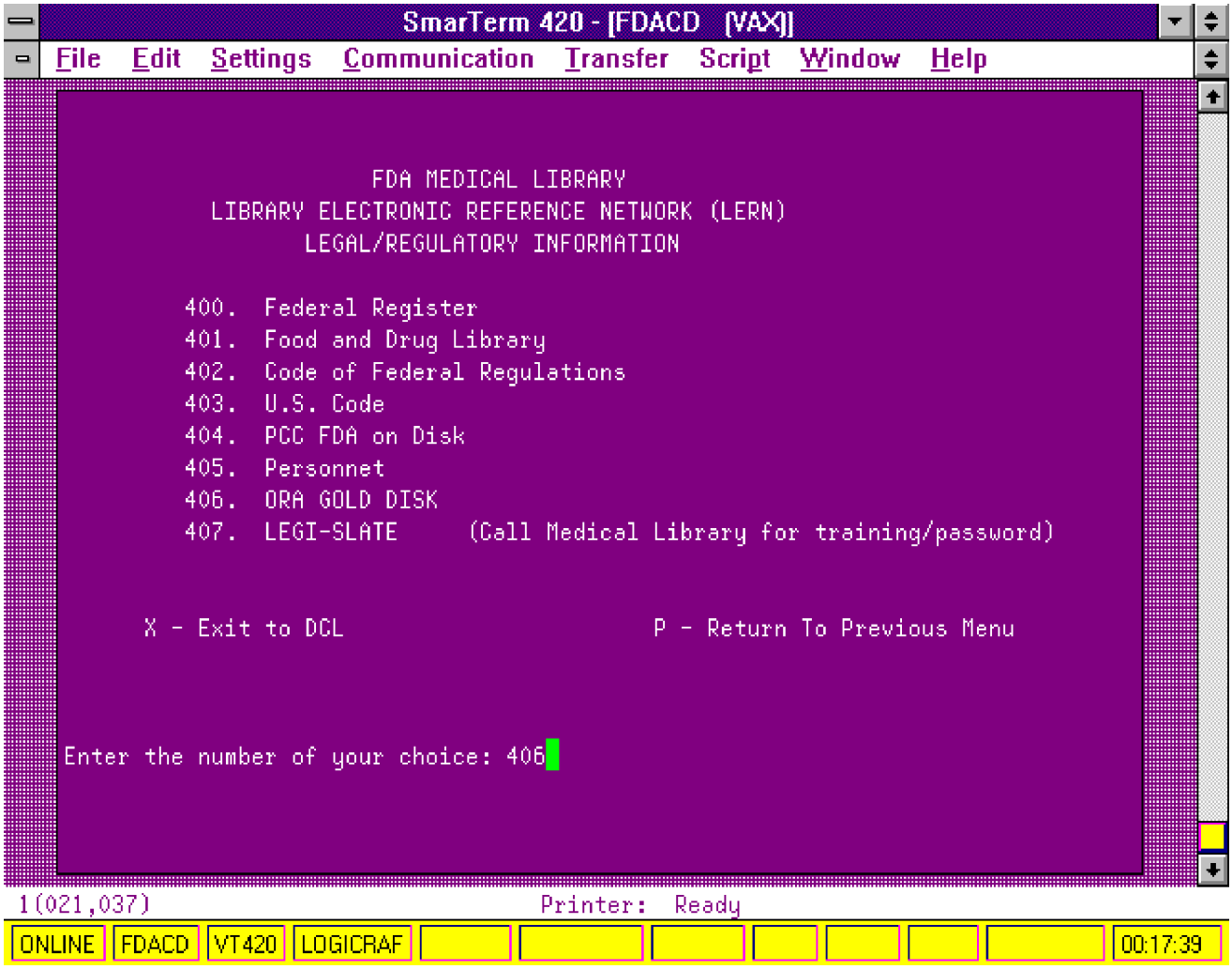
1. Log on to the CDER Vax
2. Enter “4", for the Medical Library Electronic Reference Network (LERN)



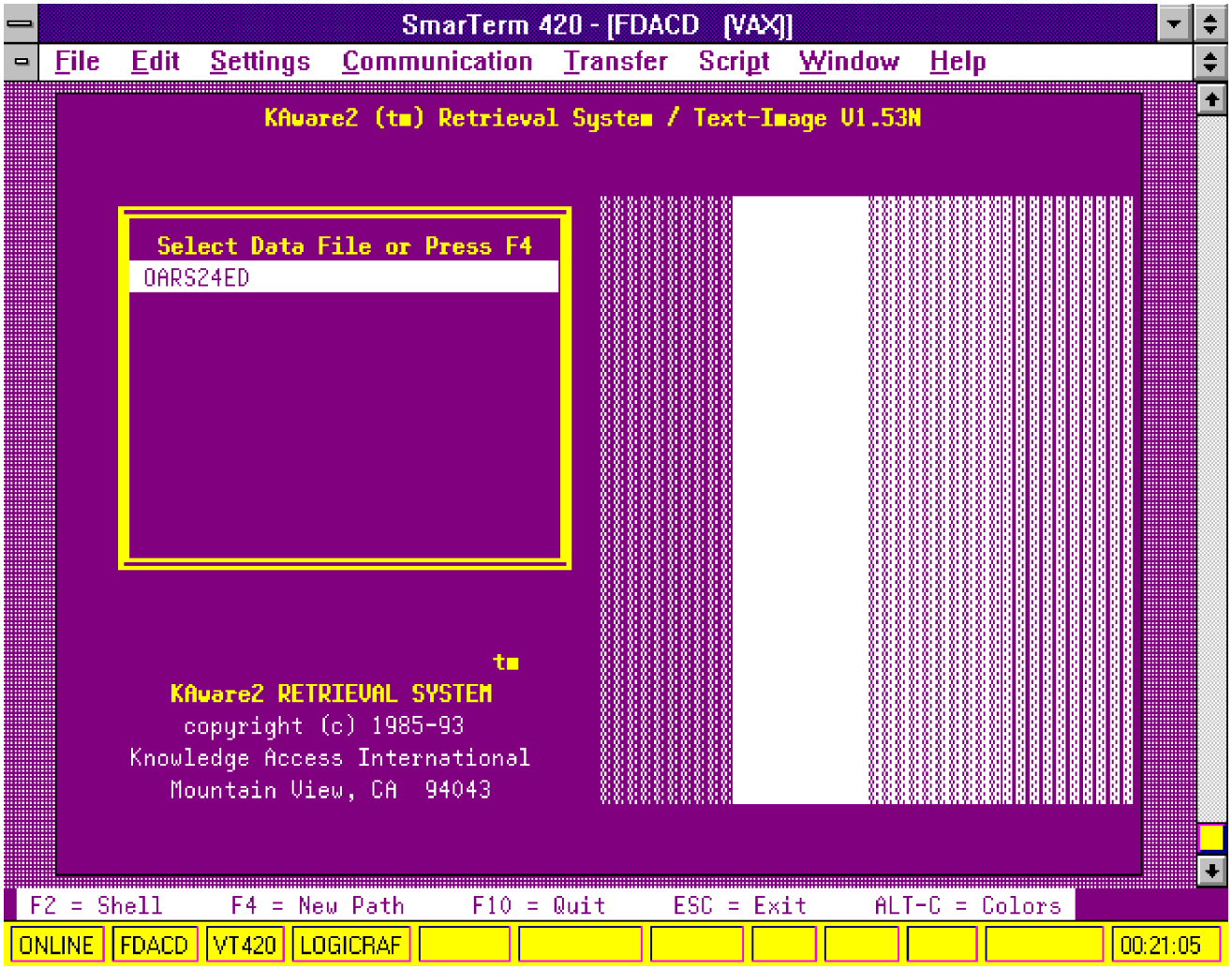
3. Enter “4", for the Legal/Regulatory Information Menu



4. Enter “406", for the ORA Gold Disk



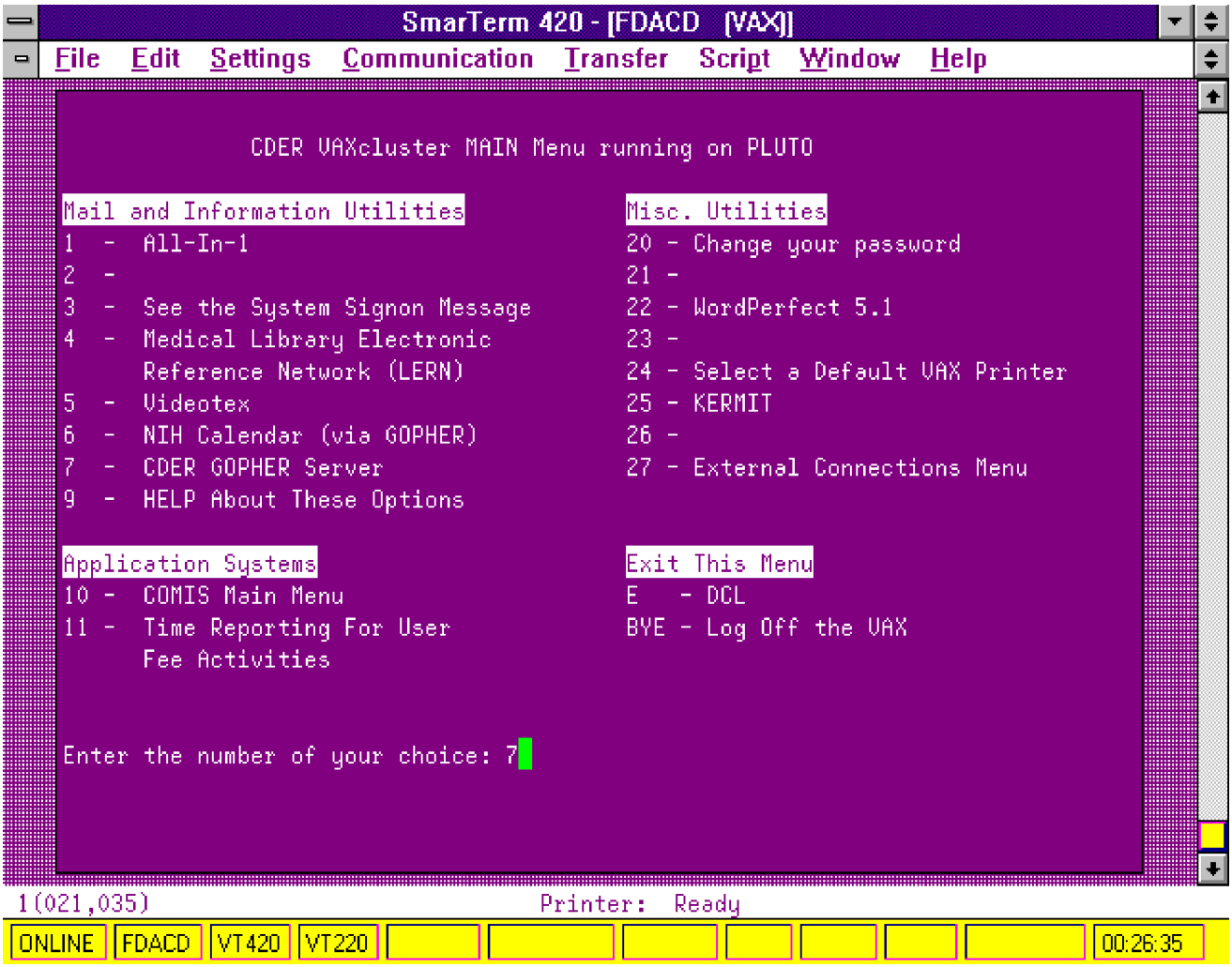
5. Enter “ORAGOLD”



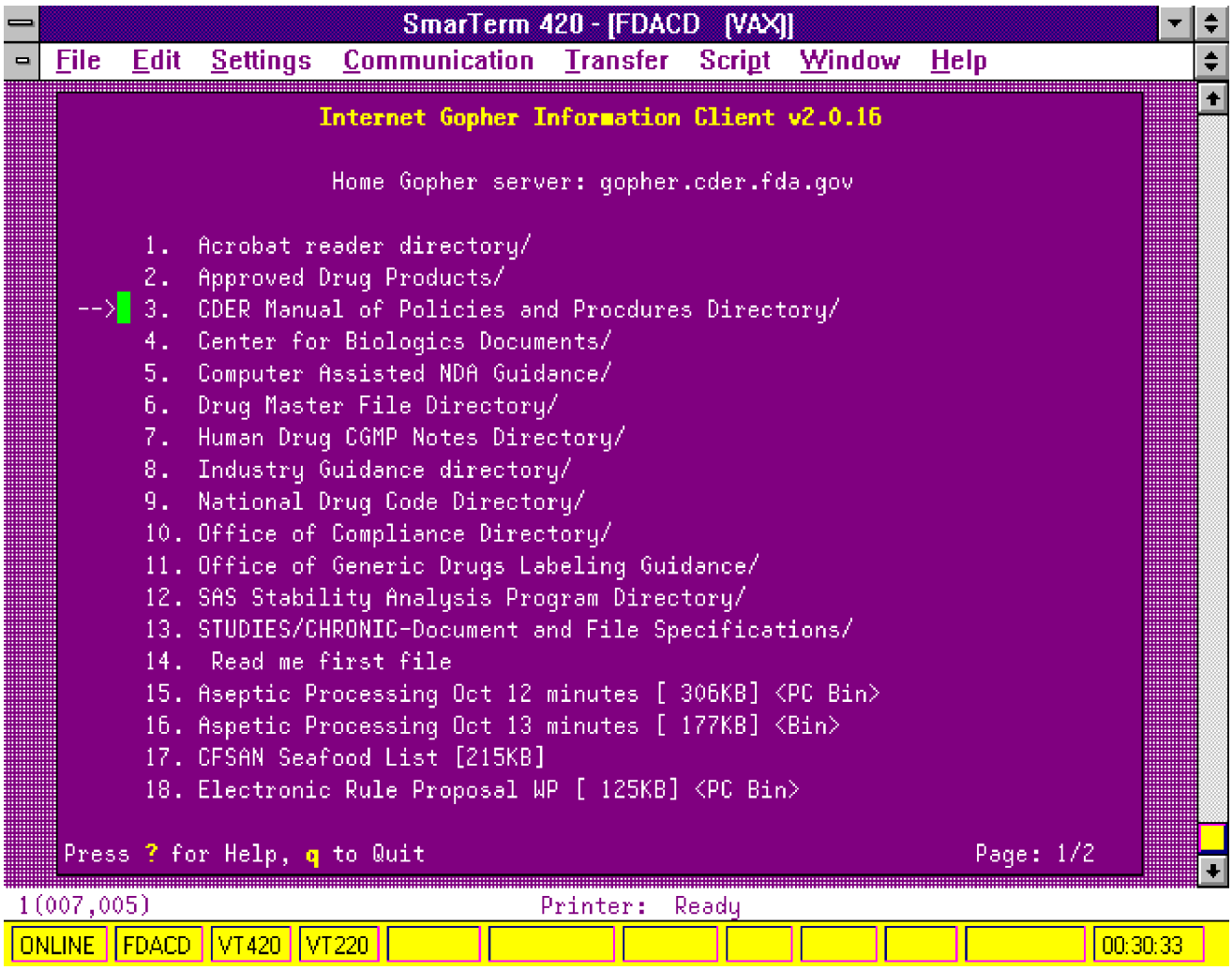
6. You are now in the ORA Gold Disk. Follow the ORA Gold Disk Menus

TO ACCESS MAPPS ON INTERNET VIA THE GOPHER SERVER

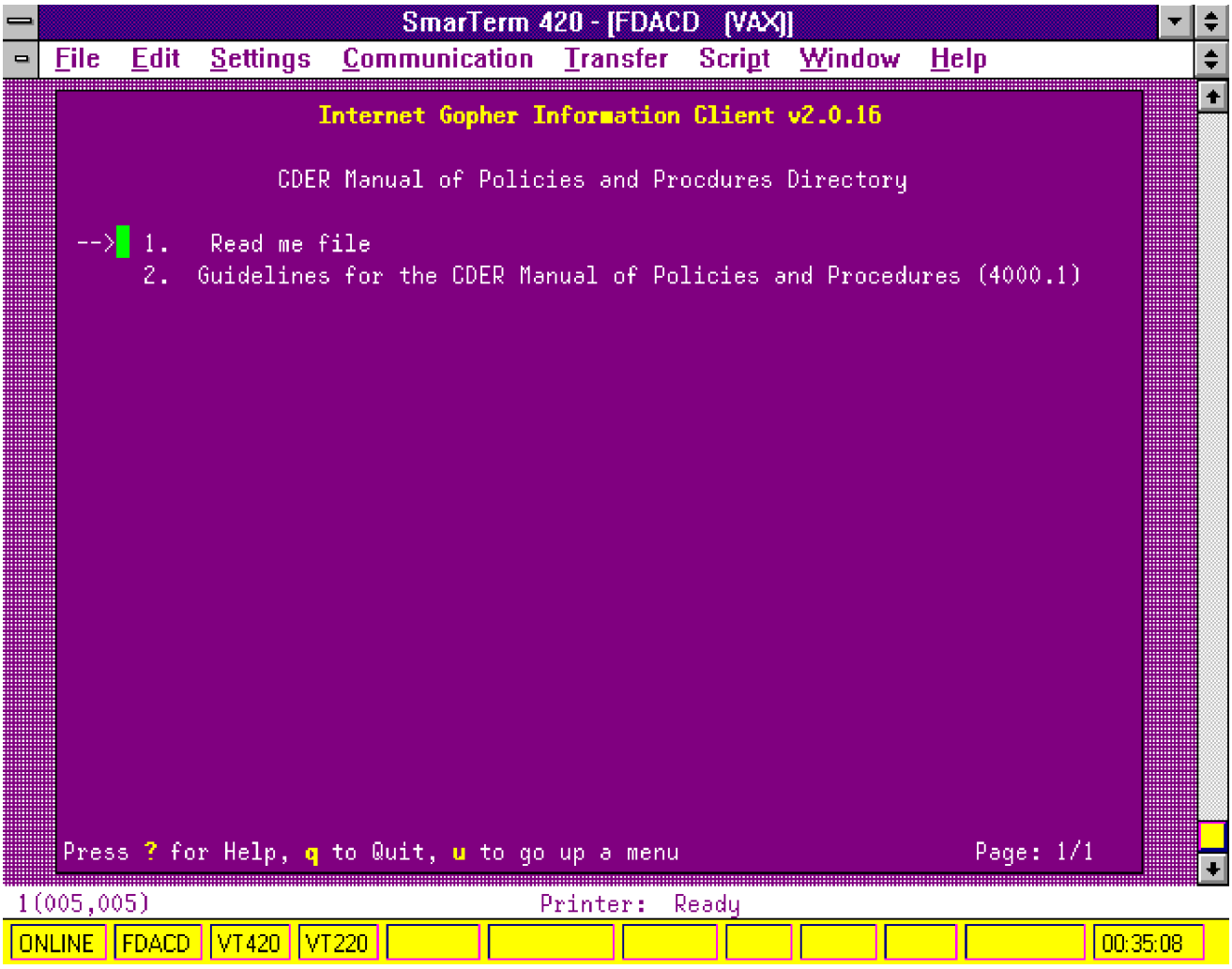
1. Log on to the CDER VAX
2. Enter “7" from the Main Menu



3. Enter “3" for the MAPP Directory

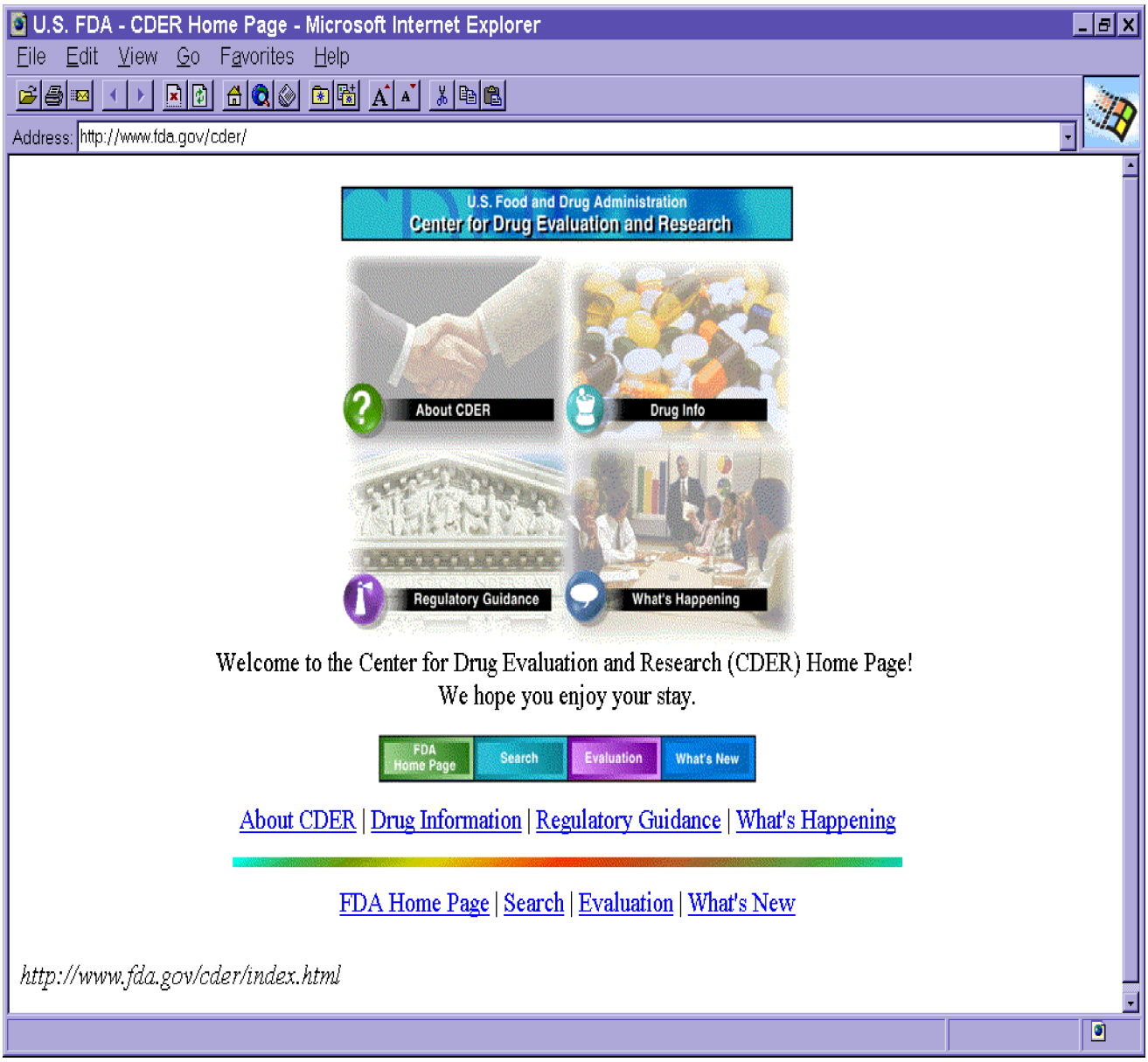


4. Enter the appropriate number

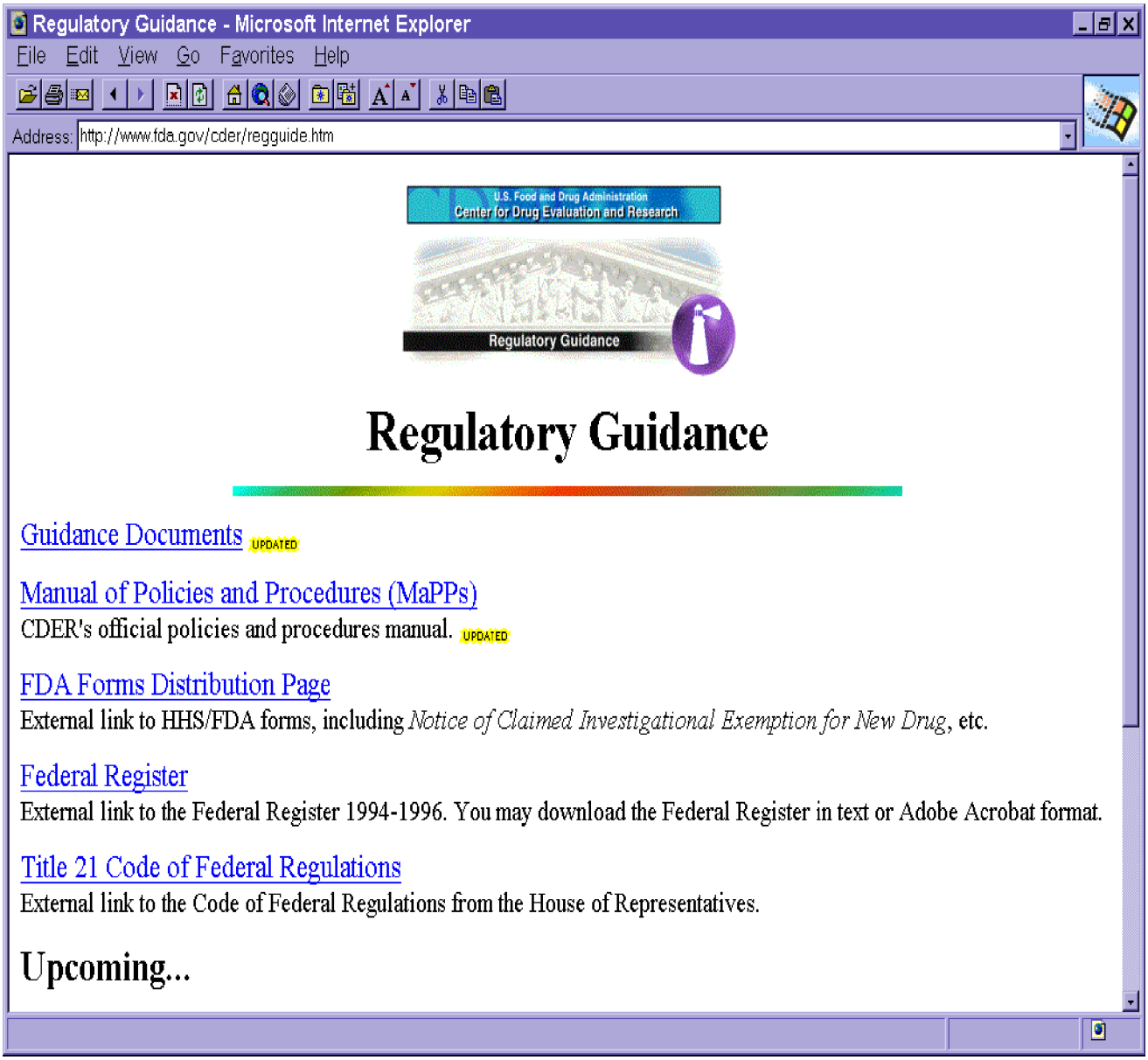


TO ACCESS MAPPS ON THE INTERNET VIA THE WWW

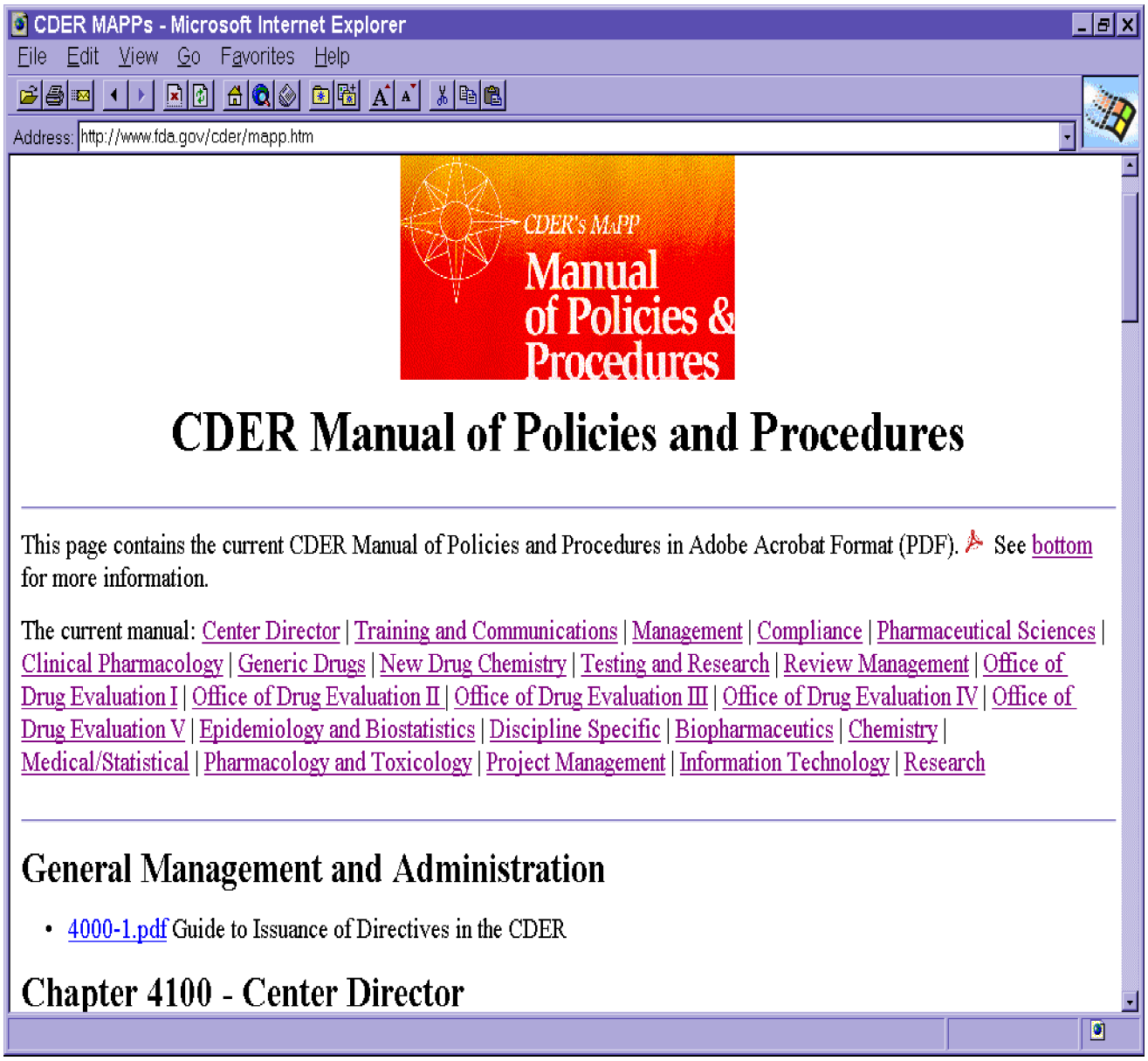
1. Type in the following url address: http:\\www.fda.gov/cder
2. Double click on the “Regulatory Guidance” section.



3. Double-click on the “Manual for Policies and Procedures”



4. Double-click on the MAPP you would like to view. MAPPs are available in pdf format.



ATTACHMENT F

HFD	Organization	MAPP Point of Contact	Location	Telephone #
1	Office of the Center Director	Khyati Roberts	WOC II, 6th floor	4-6740
10	Office of Management	Paula Bourkland	WOC II, 6007	4-6741
101	Office of Drug Evaluation I	Linda Carter/Joy Bennett	WOC II, 6th floor	4-6758
102	Office of Drug Evaluation II	Lee Ripper	Pkln 13B28	3-2544
103	Office of Drug Evaluation III	Apryl Winters	Pkln 13B45	7-3144
104	Office of Drug Evaluation IV	Toni Nearing	Corp N413	7-2335
105	Office of Drug Evaluation V	Mary Jane Walling	Corp S219	7-2268
110	Division of Cardio-Renal Drug Products	Natalia Morgenstern	WOC II, 5th floor	4-5300
120	Division of Neuropharmacologic Drug Products	Jack Purvis	WOC II, 4th floor	4-2850
150	Division of Oncologic Drug Products	Ellen Cutler and Cynthia Cowthran	WOC II, 2nd floor	4-5717
160	Division of Medical Imaging, & Radiopharm. Drug Products	Jim Cheever and Ann Leonard	Pkln 18B09	3-3500
170	Division of Anesth., Critical Care & Addiction Drug Products	Bonita Moore	Pkln 9B45	3-7341
180	Division of Gastrointestinal & Coagulation Drug Products	Raya McCree	Pkln 6B45	7-1050
20	Office of Review Management	Patricia Desantis	WOC II, 6th floor	4-5465
200	Office of Training and Communications	Linda Brophy	Pkln 11B04	7-1651
205	Freedom of Information Staff	Shirley Johnson	Chap 322	3-8491
21	Advisors and Consultants	Kimberly Topper	Chap 200	3-5455
210	Division of Communications Management	Pam Winborne	MPN I	4-1012
22	Program Management Team	Zulema Miguele	WOCII	4-5482
220	Division of Training and Development	June Cory	Pkln 9B04	3-2200
23	Reports Data Management Team	Brenda Harmon	WOCII	4-1993
230	Medical Library - WOC II	Karen Kapust	WOC II, 3rd floor	3-1539

HFD	Organization	MAPP Point of Contact	Location	Telephone #
230	Medical Library - Corp Blvd	David Graham	Pkln 11B40	3-1539
230	Division of Medical Library	Karen Kapust	Pkln 11B40	3-1539
300	Office of Compliance	Anita Harrell	MPN I	4-1058
310	Division of Labeling and Nonprescription Drug Compliance	Candace Hamilton	MPN I	4-0063
320	Division of Manufacturing and Product Quality	Nancy Hallman	MPN I	4-0093
330	Division of Prescription Drug Compliance and Surveillance	Patricia Johnson	MPN I	4-0101
340	Division of Scientific Investigations	Carolyn Hommel	MPN I	4-0020
350	Office of Pharmaceutical Sciences	Rita Hassall	MPN II	4-0340
354	Chemistry Policy Staff	Yana Mille	MPN I	4-0104
355	Formulations Research Staff	Lloyd Tilman	MPN II	4-0340
356	Formulations Research Laboratory	Gerry Shiu	MODI (FB8)	202-205-4295
358	Operations Staff	Rich Vengazo	WOC II, 6th floor	
40	Division of Drug, Marketing, Advertising and Communications	Melissa Moncavage	Pkln, 17B17	4-6814
50	Division of Management and Budget	Charlene Cherry	Pkln 12A55	7-0517
510	Division of Metabolic and Endocrine Drug Products	Mary Middleton	Pkln 14B04	3-3510
520	Division of Anti-Infective Drug Products	Rita Hecker	Corp S348	7-2149
530	Division of Anti-Viral Drug Products	Toni Nearing	Corp N413	7-2335
540	Division of Dermatologic & Ophthalmic Drug Products	Jonathan Wilkin	Corp N214	7-2021
550	Division of Anti-Inflammatory, Analgesic & Dental Drug Products	Dennis Bashaw	Corp N316	7-2534
560	Division of Over-the-Counter Drug Products	Mel Lessing	Corp S208	7-2242
570	Division of Pulmonary Drug Products	Cathie Schumaker	Pkln 10B45	7-1050
580	Division of Reproductive and Urologic Drug Products	Cathy Curtis	Pkln, 17B45	7-4260
6	Executive Operations Staff	Angelique Williams	WOC II, 6th floor	4-6467
6	Executive Secretariat Staff	Terri Martin	WOC II, 6th floor	4-6740

HFD	Organization	MAPP Point of Contact	Location	Telephone #
60	Division of Management Services	Janie Saunders	MPNI	4-0584
600	Office of Generic Drugs	Ted Sherwood	MPN II	4-0340
610	Division of Labeling and Program Support	Jerry Phillips	MPN II	4-0340
620	Division of Chemistry I	Genie Patrick	MPN II	4-0375
640	Division of Chemistry II	Florence Fang and Pat Hennigan	MPN II	4-0324
650	Division of Bioequivalence	Linda Johnson	MPN II	4-2290
7	Regulatory Policy Staff	Janet Burroughs	MPN I	4-1038
70	Division of Information Systems Design	Anna Rubino	Pkln 8B45	3-9728
700	Office of Epidemiology & Biostatistics	Angela Davis	Pkln 15B31	7-3081
710	Division of Biometrics I	Philip Orticke (PKLN 18B45)	WOCII 5050	3-4594
715	Division of Biometrics II	Jack Pevenstein	Pkln 18B45	7-3081
720	Division of Biometrics III	Jack Pevenstein	Pkln 18B45	7-3081
725	Division of Biometrics IV	Sandy Shores	Corp S128	7-2551
733	Division of Pharmacovigilance & Epidemiology	Daneene Johnson	Pkln 15B31	7-3219
8	EEO Staff	Noreen Gomez	WOC II, 6th floor	4-6645
80	Division of Drug Information Resources	Lisa Wilder	Chap 218	3-0500
800	Office of New Drug Chemistry	Tammy Mueller	PKLN 12B05	7-3455
810	Division of Chemistry I	Chuck Hoiberg	WOC II, 2061	4-2473
820	Division of Chemistry II	Yuan-Yuan Chiu	PKLN 14B04	3-3510
830	Division of Chemistry III	Eric Sheinin	CORP N112	7-2001
850	Office of Clinical Pharmacology and Biopharmaceutics	Cathy Curtis and Becky Miller	Pkln 13B17	3-2544
860	Division of Pharmacetuical Evaluation I	Carol Noory	Pkln 13B17	3-8098
870	Division of Pharmaceutical Evaluation II	Mei Ling Chen	Pkln 13B17	3-1640
880	Division of Pharmaceutical Evaluation III	Kathy Abel	Corp N107	7-2007
900	Office of Testing and Research	Pam Wellens	Pkln, 13B16	3-4750
900	Office of Testing and Research	Roberta Light	MOD 1, 2023	4-0510
910	Division of Research and Testing	Rose Smith	MODI	4-0510

HFD	Organization	MAPP Point of Contact	Location	Telephone #
920	Division of Drug Analysis	Loretta Saey	1114 Market St. Rm 1002, St. Louis, MO	3-4119
930	Division of Clinical Pharmacology Research	Jerry Collins	GNTB	427-1065
GCF-1	Office of the Chief Counsel	Lori Pepple	Pkln 6-89	7-1143
HF-12	Office of Aids and Special Health	Kimberly Thornton	Pkln, 9-49	3-0104
HF-32	FDA OCOD	Anita O'Connor	Pkln 17-35	7-3312
HFC-230	ORA Gold Disk	Howard Kawazoe	TW 517	7-0414
HFM-478	CBER, OD, ADP	Bob Yetter	WOCI, 400N	7-0381