SMG 3298.1

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

FOOD AND DRUG ADMINISTRATION

INFORMATION RESOURCES MANAGEMENT - INFORMATION DISSEMINATION

GUIDELINES FOR THE SUBMISSION OF FDA SCIENTIFIC AND TECHNICAL REPORTS TO THE NATIONAL TECHNICAL INFORMATION SERVICE

Transmittal Number 83-38 – Date: 04/01/1983

1. PURPOSE.

This Guide provides instructions and guidelines for implementation of policies regarding the submission of FDA-generated scientific and technical reports to the National Technical Information Service (NTIS).

2. BACKGROUND.

A. NTIS, an agency of the Department of Commerce, is the central point in

the United States for the public sale of Government-funded research and development reports and other analyses prepared by Federal agencies, their contractors, or grantees. NTIS is also the central source for federally-operated machine processable data files and programs. The mission of NTIS is to collect and sell copies of specialized technical information produced by Federal, State, local, and private sources, both foreign and domestic, including data files and computer programs from Federal sources and U.S. Government-owned patent applications, and to promote the use of these products by publishing news bulletins and catalogs, by exhibits and speeches, by mail promotion, and by utilizing other public and private mechanisms, such as marketing agents.

B. NTIS requires a one-time registration fee of $20.00 for each title. This fee will be waived if eleven or more stock copies of a report are provided at time of submission to NTIS. No registration fee will be assessed for magnetic tape units, computer programs, or data files submitted. Registration of a document with NTIS covers the creation of a permanent bibliographic record and a variety of promotional exposures as well as a microfiche master where applicable. The bibliographic record is used to announce the availability of the document to potentially interested users, to operate selective dissemination of information programs, and to prepare published or custom-made bibliographies. The full-text microfiche master of the publication ensures availability of the document on a permanent basis to the source client and the public in both paper copy and microfiche. NTIS assumes all further responsibility for public demand associated with the publication. A separate billing of $1.00 for each document submitted will be made to cover the cost of automatic distribution of a single full-text microfiche (SRIM-Selected Research in Microfiche) to the FDA/NTIS Coordinator, Management Methods Branch (HFA-250) in FDA.

3. POLICY.

A. FDA will use the facilities and services of NTIS to the fullest possible extent. This will result in a wide dissemination of the availability of FDA-generated scientific and technical reports to the general public and the transfer of some clerical and accounting duties involved with answering public requests for FDA reports and analyses from FDA to NTIS.

B. A single microfiche copy of each document submitted to NTIS will be available for public review at the Office of the FDA/NTIS Coordinator, Management Methods Branch, FDA. All persons requesting copies of documents on file at NTIS shall be referred to NTIS Sales Desk.

C. If an FDA office, bureau, or center wishes to transfer a document to NTIS to improve freedom of information servicing, it must send a public review

copy to the Freedom of Information Staff (HFW-35) to satisfy the FDA Freedom of Information Regulation (Section 20.50 of 21 CFR).

4. RESPONSIBILITIES AND PROCEDURES.

A. Each FDA office, bureau, and center will designate an NTIS Liaison Officer whose duties will consist of the following:

1. Assume the responsibility of coordinating all submissions to NTIS with the FDA/NTIS Coordinator.

2. Review all scientific and technical reports generated by the organization for format and content, using criteria provided in this Guide.

3. Assist in the completion and/or the review for completeness of OF 272 (Report Documentation Page) or, in the case of magnetic tape unit, computer program, or data file, Form NTIS 231 (NTIS Computer Products Catalog Data Sheet); SF 277 (Computer Magnetic Tape File Properties); and Form NTIS 79 (Accession Notice).

4. Forward all copies of forms prepared to:

   FDA/NTIS Coordinator
   Management Methods Branch, DMS (HFA-250)

   These forms must be assigned an alphanumeric report number, stamped for approval, and signed by the FDA/NTIS Coordinator prior to submission to NTIS. NTIS will not process FDA reports without approval stamp and signature affixed on them.

5. Receive from the FDA/NTIS Coordinator the completed documentation and mail Form NTIS 79 (Accession Notice) with the approved OF 272, or Form NTIS 231, and SF 277, and eleven clearly legible copies or computer tape(s) to:

   Information Services Branch
   National Technical Information Service
   U.S. Department of Commerce
   Springfield, Virginia 22161

6. File by title Form NTIS 79 upon its return from NTIS and the FDA/NTIS Coordinator, Management Methods Branch. This form will give NTIS Accession Number with the paper copy and microfiche price codes of each report.

B. The FDA/NTIS Coordinator will be responsible for monitoring all FDA submissions to NTIS and will perform the following duties:

1. Assume the responsibility of coordinating all submissions to NTIS with the FDA/NTIS Coordinator.

2. Review all scientific and technical reports generated by the organization for format and content, using criteria provided in this Guide.

3. Assist in the completion and/or the review for completeness of OF 272 (Report Documentation Page) or, in the case of magnetic tape unit, computer program, or data file, Form NTIS 231 (NTIS Computer Products Catalog Data Sheet); SF 277 (Computer Magnetic Tape File Properties); and Form NTIS 79 (Accession Notice).

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   These forms must be assigned an alphanumeric report number, stamped for approval, and signed by the FDA/NTIS Coordinator prior to submission to NTIS. **NTIS will not process FDA reports without approval stamp and signature affixed on them**.

5. Receive from the FDA/NTIS Coordinator the completed documentation and mail Form NTIS 79 (Accession Notice) with the approved OF 272, or Form NTIS 231, and SF 277, and eleven clearly legible copies or computer tape(s) to:

   Information Services Branch
   National Technical Information Service
   U.S. Department of Commerce
   Springfield, Virginia 22161

6. File by title Form NTIS 79 upon its return from NTIS and the FDA/NTIS Coordinator, Management Methods Branch. This form will give NTIS Accession Number with the paper copy and microfiche price codes of each report.

C. The FDA/NTIS Coordinator will be responsible for monitoring all FDA submissions to NTIS and will perform the following duties:

1. Serve as the primary liaison between FDA and NTIS.

2. Receive all microfiche copies of FDA submissions to NTIS and maintain a file and index of all such reports.

3. Receive OF 272 or Form NTIS 231 and SF 277 from the liaison officers and assign an alphanumeric code for each report in sequential order as they are submitted. (The code format is set forth in Paragraph 5.)

4. Affix approval stamp and sign the OF 272 or Form NTIS 231. A file copy of these forms will be retained by the FDA/NTIS Coordinator.

5. Receive from NTIS a copy of Form NTIS 79, which gives the accession number and the paper copy and microfiche price codes for each report; record this information and forward the form to the originating office.

6. Provide access to microfiche file and report index to interested parties in a public reading area located in the Management methods Branch. Refer public requests for paper copy and microfiche copy of reports to NTIS.

7. Coordinate with NTIS technical consultants to ensure maximum exposure and promotion of FDA scientific and technical reports. Review NTIS advertising and publicizing of FDA reports.

8. Maintain the running total of all reports submitted to NTIS in a fiscal year for review by office/bureau/center liaisons and other FDA personnel.

9. Promote FDA use of NTIS services and benefits through publications, advertising, personal contacts, presentations, and any other available means.

10. Publish annual supplements to the Bibliography of FDA Reports at NTIS. Disseminate quarterly NTIS source client information to component NTIS liaison offices. Encourage use of NTIS services and benefits by field and district office personnel.

5. FORMAT REQUIREMENTS FOR REPORTS AND DOCUMENTS.

A. The following are the format requirements for scientific and technical reports prepared by and for FDA and submitted to NTIS. All documents generated by FDA offices, bureaus and centers are to reviewed by NTIS liaison officers using this criteria before documents are submitted to NTIS.

B. **Order of Elements**. When some or all of the following elements are appropriate for a report, the standards order will be as follows:

1. Front cover
2. Inside front cover
3. Front matter, including:
    a. Report Documentation Page (OF 272) (this form must include the FDA/NTIS Coordinator's approval)
    b. Preface
    c. Table of contents
    d. List of illustrations
    e. List of tables
    f. List of abbreviations and symbols
4. Body of report, including:
    a. Introduction
    b. Main text
    c. Conclusions
    d. Recommendations
5. Reference material, including:
    a. Appendices
    b. Glossary of terms
    c. References
    d. Bibliography
    e. Index
6. Back cover

C. **Front Cover**. Either self covers (of the same paper as the text) or separate covers (of different paper than the text) are required for all

reports. The cover must include the information shown in Attachment A, Sample Report Cover. Each cover will include the following information:

1. **Report number**. Specify the unique alphanumeric designation of report. The alphanumeric system, which will be used for FDA documents submitted to NTIS, is as follows:

   a. Acronym of originating office - fiscal year of report/sequential number of report. For example, a technical report generated by the Bureau of Foods which was the 252nd FDA report to be submitted to NTIS in FY 82 would be coded: FDA/BF-82/252.

   b. A list of appropriate acronyms follows:

Office of Regulatory Affairs	- ORA
Office of Management & Operations	- OMO
Office of Planning & Evaluation	- OPE
Office of Legislation & Information	- OLI
Office of Consumer Affairs	- OCA
Office of Science Coordination	- OSC
National Center for Devices and Radiological Health	- NCDRH
National Center for Toxicological Research	- NCTR
Bureau of Foods	- BF
Bureau of Veterinary Medicine	- BVM
Executive Director for Regional Operations	- EDRO

2. **Title and Subtitle**. Display the title prominently and make it indicate clearly and briefly the subject coverage of the report. Set subtitle, if used, in smaller type or otherwise subordinate it to the main title. When a report is prepared in more than one volume, repeat the primary title and have subtitle identify that specific volume (e.g., Volume 1, Volume 2., etc.)

3. **Performing Organization Name and Address**. Give name, street, city, state, and zip code. List no more than two levels of an organizational hierarchy.

4. **Date**. Specify date of report. The sponsoring agency may specify the basis for dating. If it does not, the author will provide a date and indicate the basis on which it was selected (e.g., date of issue, date of approval, date of preparation, etc.).

5. **Type of Report and Period Covered**. Indicate whether report is interim, final, etc., and, if applicable, dates covered.

6. **Sponsoring Agency's Name and Address**. Include sponsoring agency's name and complete address including zip code.

D. **Inside Front Cover**. Special notices may be included on the inside front cover as required by the sponsoring agency. These notices pertain to such matters as reproduction limitations, legal and supersedure information, sponsor's disclaimers, statements of compliance with special regulations, and disposition instructions.

E. **Front Matter**. The following elements should be included in the front matter of a report to fulfill the requirements prescribed below:

1. **OF 272, Report Documentation Page**. Show approval stamp and signature of FDA/NTIS Coordinator. These must accompany each report submitted to NTIS. In addition, one copy of this form will remain with the FDA/NTIS Coordinator when the document is submitted to NTIS (see Paragraph 4.b.(4) of this Guide).

2. **Preface**. Prefaces are used to show the relation of the work reported to associated efforts, to give credit for the use of copyrighted material, and to acknowledge significant assistance received. When copyrighted material is contained in a report, the copyright holder must state in a letter that NTIS is authorized to reproduce and sell. This letter will be forwarded to NTIS for their retention. If the Government by contract has the right to reproduce and sell the material regardless of a copyright, the issuing office will so state in a letter to NTIS which must accompany the document.

3. **Table of Contents**. In the table of contents (not suggested for a report of less than 10 pages) list principal headings as they appear in the report together with the page numbers on which the headings occur. Items included in the front matter should not be listed. The table of contents should be started on a new page.

4. **List of Illustrations**. Furnish list of illustrations only if it is considered essential. The figure number, legend, and page number of each illustration should be listed. Lengthy legends should be abbreviated.

5. **List of Tables**. Furnish list of tables only if it is considered essential. List table number, caption, and page number of each table. Abbreviate lengthy captions.

6. **List of Abbreviations and Symbols**. Provide separate lists of definitions only for numerous symbols and abbreviations. Define symbols and abbreviations where they are first introduced in the text only if they are few in number.

F. **Body of Report**. The body of the report should contain the following:

1. **Contents and Organization**. In general, the contents and organization of the body of a report shall be determined by the nature of the work. Each section should begin a new page. The first section usually provides background information and work objectives. Succeeding sections describe work procedures, apparatus involved, tests performed, results achieved, and related matters, as appropriate. The last sections usually present conclusions and recommendations.

2. **Headings**. Headings should stand out from the text. The degree of subordination must be apparent. Number headings and paragraphs only when the numbers are needed for clarity.

3. **Authorization Statement**. The statement, "NTIS is authorized to reproduce and sell this material," must be affixed above or below the copyright symbol on copyrighted material.

G. **Reference Material**. Elements of reference material should follow the criteria presented below:

1. **Appendices**. When more than one appendix is used, designate them Appendix A, Appendix B, etc. Each should be titled. When only one appendix is used, omit the letter designation. Start the first appendix on a new page.

2. **Glossary of Terms**. When many unusual technical terms are used, list them in alphabetical order with definitions in a glossary. When only a few such terms appear, define them the first time they are used in the text.

3. **References and Bibliography**. List documents cited in the text under "References." Arrange bibliographic entries not cited in the text but furnished as supplementary information under "Bibliography." Present entries in the reference list and bibliography in a uniform style which includes authors, titles, sources, identifying numbers, and dates.

H. **Illustrations**. Treat illustrations consistently throughout a report and prepare them so that details and callouts (labels) will be clearly legible after final reproduction. Crop or mask photographs to eliminate insignificant detail. Do not add border frames to outline illustrations or use background tones in line drawings unless they contribute substantially to clarity. For reproducible copy, only screened tone or line art and screened photography should be submitted. It should not be inferred that this prevents use of half-tone prints in composite reproducible copy to avoid the necessity of composite negatives. The procedures should be adhered to as appropriate.

1. **Placement**. Illustrations should be located near the first text reference made to them except in special situations (i.e. when a report contains only a few text pages and many illustrations. In such cases, illustrations should be in numerical sequence in the back of the report.) Avoid placing illustrat ions which need to be viewed by turning the page sideways. If an illustration has to be located sideways on a page, orient it so that the page is turned to the right for normal viewing.

2. **Callouts**. Place callouts (labels), if possible, near the item called out and in a horizontal and unboxed manner. Callouts should be consistent in size and typeface through-out a report. The lettering should be of at least 8 point or l/12-inch high in the final reproduced size in order to strive for high contrast and readability.

3. **Color**. Do not use colors unless specifically authorized by the originating office and cleared with NTIS. Substitute different techniques such as screens, crosshatching, reverses, dots, or similar techniques which can be used as effectively as color.

4. **Fold-outs**. Avoid the use of oversize illustrations that must be folded, wherever possible. Divide large illustrations to appear on facing pages. Make fold-ins or gate folds begin on a right-hand page and run the reverse of the sheet blank.

5. **Numbering**. Number illustrations to which reference is made in the text consecutively in Arabic numerals, preceded by the word "Figure" (e.g. Figure 1, Figure 2, or Figure 1-1, Figure 1-2, Figure 2-1, etc.).

6. **Legends**. Accompany each illustration, except for selfexplanatory sketches, by a descriptive legend. Place the legends under the illustration and follow with the figure number.

I. **Tables**. Design tables as simple as possible so that the reader can easily grasp the meaning of the data. Use letters and numbers in tables that will

be at least 6 point or 1/12-inch high in the final reproduced report. Prepare printout sheets from which electronically tabulated data are directly reproduced so that letters and numbers are sharp and unbroken. The following procedures should be followed when preparing tables:

1. **Placement.** Locate tables near the first text reference to them, except in special situations, such as when a report contains only a few text pages and many tables. In such cases, place the tables in numerical sequence in the back of the report. Avoid placing tables so they have to be viewed by turning the page sideways. Orientate (sideway-placed) tables so the page is turned to the right for normal viewing.

2. **Headings and Columns**. Give applicable units of measure or degree in the column headings of tables. Do not repeat in the columns. For multi-page tables, note the continuation and repeat the column headings and rules on each page.

3. **Numbering**. Number tables to which reference is made in the text consecutively in Arabic numerals, preceded by the word "Table" (e.g., Table 1, Table 2, or Table 1-1, Table 1-2, Table 2-1, etc.).

4. **Captions**. Give each table, except short ones included in the text, a descriptive caption following the table number. Place caption above the table.

J. **Equations**. Prepare mathematical matter with extreme care. Use machine or transfer-type composition when available. Identify symbols after first use or in a separate list. Make opening and closing parentheses, brackets, and braces the same height as the tallest expression they enclose. Separate the numerator from the denominator with a line as long as the longer of the two. Center both numerator and denominator on the line. The following should be observed:

1. **Placement**. Indent or center displayed equation in the line immediately following the first text reference made to it. Break equations before an equal, plus, or multiplication sign. Aline a group of separate but related equations by the equal signs and indent or center the group as a whole. Place short equations, which are not part of a series, in the text rather than display them.

2. **Numbering**. Number equations which are part of a series or which are referred to in the text consecutively in Arabic numerals (e.g., 1, 2, or 1-1, 1-2, 2-1, etc.). Enclose each number in parentheses at the right margin on the last line of the equation to which it refers. Aline the equation numbers.

K. **Production**. The following procedures should be observed when preparing reports for submission to NTIS:

1. **Composition**.

   a. **Type Size**. Use type size for the main text of the reproduced report of at least 8 point or equivalent. (Use black ribbon to type reproducible copy.)

   b. **Line Spacing**. Use single or 1 1/2 spacing for reports prepared by typewriter for reproduction, except when extra spacing between lines is necessary, to assure clarity of run-in equations, symbols, etc.

   c. **Margins**. Use margins of at least 1 inch on all sides of text pages.

   d. **Columns**. Prepare text pages with a single column, not justified on the right margin, unless the sponsoring agency authorizes justification or use of more than one column.

   e. **Page Numbering**. Number all pages, wherever possible, throughout a report consecutively at the bottom with Arabic numerals. Number by sections or chapters only in special cases (1-1, 1-2, 2-1, etc.).

2. **Workmanship**. Do not accept filled-in or broken letters, illegible text or illustrations (including lettering), and other imperfections which would make the report non-reproducible on microfilm.

3. **Cover Size, Stock, and Ink**. Reproduced reports may have separate covers or self covers cut to page size. Use 110-pound index (Government Specification JCP K10); 50-pound antique (JCP L20); 44-pound white ledger (JCP J10); or similar commercial weight paper for separate covers. Ink color is optional for separate covers. Use black ink for self covers. Do not use covers with windows.

4. **Page Size, Stock and Ink**. Reproduced reports shall be approximately 8 X 10 1/2 inches or 8 1/2 by 11 inches in size. Use black ink on opaque white paper. Use both sides of the sheet to the maximum extent practicable.

5. **Decorative Features and Advertising**. Simple organization symbols or logos are permissible on covers. Do not use advertising display.

6. FORMAT REQUIREMENTS FOR DATA FILES AND MACHINE-PROCESSABLE DATA.

The following are the format requirements for all FDA-generated data files and machine-processable data submitted to NTIS.

A. **Requirements for Tapes and Cards**.

1. Attach a completed NTIS Computer Products Catalog Data Sheet and Computer Magnetic Tape File Properties Form, available from NTIS as Form NTIS 231 and SF 277. These forms must show the approval stamp and signature of the FDA/NTIS Coordinator prior to submission to NTIS.

2. Attach a completed Form NTIS 79 (Accession Notice).

3. Attach record layouts, which must be complete and reproducible by xerography, with backup explanations of character sets, special codes, format conventions, blocking factors, etc. Label records and other sentinel information (tape marks, record marks, end-of-file) must be defined.

4. If the computer file is updated, make the updates available to NTIS as they occur so that the file may be sold on a continuing subscription basis. If available, include the update schedule with the original submissions.

B. **Magnetic Tape Physical Structure Specifications**.

1. Tape must be contained in an IBM-compatible tape reel in either 2400-foot or 600-foot size.

2. Recording may be either 7-track, 556 bits per inch (BPI), odd or even parity or 9-track, 800 or 1600 BPI, odd parity only. A reflective spot must precede the first record, and end-of-file sentinel must follow the last record. A 2400-foot reel must contain not more than 2200-feet of recorded data and a 600-foot reel must contain not more than 500 feet of recorded data.

3. External labels must be affixed to tape reel containers, bearing the following information:

   a. The FDA alphanumeric report number. See Paragraph 5.c.(1) of this Guide for this procedure.

   b. The date of the file.

c. The density of the file, e.g. 556.(BPI and/or 800 or 1600 BPI).

d. Whether the file is 7 or 9 track.

e. The character code of the file.

f. Whether the file is odd or even parity.

g. The data set name and data control block information.

h. The reel number, e.g., 1 of 1, or 1 of 4, etc.

i. The title or the abbreviated title of the file.

j. Specific instructions as to whether the tape reel should or should not be returned to the source client.

7. AVAILABILITY OF FORMS.

Supplies of necessary NTIS forms mentioned in this Guide may be obtained from the designated office, bureau or center NTIS liaison officer, or from the FDA/NTIS Coordinator. OF 272 (Report Documentation Page) is available from GSA Federal Supply Stores.

8. OBTAINING NTIS PUBLICATIONS.

FDA offices, bureaus, and centers who desire to purchase NTIS publications should use normal channels to procure these publications.

If an office, bureau, and center desires to repurchase a report at the time of submission, contact the FDA/NTIS Coordinator for instructions. NTIS offers a discount for this one time repurchase to its source clients.

FDA 2470.3 Attachment A

SAMPLE REPORT COVER

Report number -	Report FDA/HFX-75/6
Title & subtitle (if any) -	BIOLOGICAL BASES FOR AND OTHER ASPECTS OF A PERFORMANCE STANDARD FOR LASER PRODUCTS
Performing organization -	Federation of American Societies for Biology 25 State Street Bethesda, Maryland 20745
Date -	July 1974
Type of report & period covered -	Interim Report for Period January – June 1974
Sponsoring agency -	Prepared for: Food and Drug Administration National Center for Devices and Radiological Health 5600 Fishers Lane Rockville, Maryland 20857

Staff Manual Guide 3298.1, Attachment F

LISTING OF FDA/NTIS LIAISON OFFICERS

Organizational Component

Office/Center/Bureau	Mailing Symbol
Office of Regulatory Affairs	HFC-10
Office of Science Coordination	HF-8
Office of Planning and Evaluation	HFP-2
Office of Management and Operations	HFA-250
Office of Legislation and Information	HFW-1
Office of Consumer Affairs	HFE-88
National Center for Drugs and Biologics	HFN-5
National Center for Devices and Radiological Health	HFZ-25
National Center for Toxicological Research	HFT-3
Bureau of Foods	HFF-326
Bureau of Veterinary Medicine	HFV-5
Executive Director of Regional Operations	HFO-12