REQUEST FOR RECORDS DISPOSITION AUTHORITY

(See Instructions on reverse)

TO: NATIONAL ARCHIVES and RECORDS ADMINISTRATION (NIR)
WASHINGTON, DC 20408

1. FROM (Agency or establishment)
Department of Health and Human Services

2. MAJOR SUBDIVISION
Food and Drug Administration

3. MINOR SUBDIVISION
Center for Biologics Evaluation and Research (CBER)

4. NAME OF PERSON WITH WHOM TO CONFER: Jules Meisler

5. TELEPHONE: (301) 827-2863

LEAVE BLANK (NARA use only)

JOB NUMBER: N1-088-03-05

DATE RECEIVED: 08/09/2003

NOTIFICATION TO AGENCY

In accordance with the provisions of 44 U.S.C. 3303a the disposition request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10.

DATE: 1-21-05

ARCHIVIST OF THE UNITED STATES: [signature]

6. AGENCY CERTIFICATION

I hereby certify that I am authorized to act for this agency in matters pertaining to the disposition of its records and that the records proposed for disposal on the attached ____ page(s) are not now needed for the business of this agency or will not be needed after the retention periods specified; and that written concurrence from the General Accounting Office, under the provisions of Title 8 of the GAO Manual for Guidance of Federal Agencies,

☑ is not required; ☐ is attached; or ☐ has been requested.

DATE	SIGNATURE OF AGENCY REPRESENTATIVE	TITLE
APR 15 2004	A. P. Barnes [signature]	HHS Records Officer

7. ITEM NO.	8. DESCRIPTION OF ITEM AND PROPOSED DISPOSITION	9. GRS OR SUPERSEDED JOB CITATION	10. ACTION TAKEN (NARA USE ONLY)
1	SEE attached [signature] 4/1/04 Fred Ansell, FDA Office of the Chief Counsel — Date [signature] 3/31/04 Seung Ja Sinatra, FDA Records Officer — Date cc: Agency, NWMD, NWMW, NWCTC	N1-88-96-3	

115-109

NSN 7540-00-634-4604 **STANDARD FORM 115** (REV. 3-91) (CDC Adobe Acrobat 5.0 Electronic Version, 8/2001)
PREVIOUS EDITION NOT USABLE

Prescribed by NARA
36 CFR 1228

Created by Electronic Document Services/USDHHS: (301) 443-2454

EF

NOTE:
This schedule applies to all formats and media in which records are created and maintained including paper, microform, and electronic, unless specifically stated otherwise in a description of the record item.

Most FDA files scheduled on this SF115 are not historically valuable and the disposition instructions set forth herein, should be followed. However, files that document events of historical importance should be brought to the attention of the FDA Records Officer as they may require transfer to the National Archives. Such "events" may include a major scientific discovery, a major health program, or other event, which generates significant media, public, or historic interest.

In the event that records of this type are in electronic format and are scheduled for permanent retention in the National Archives, the records must be will be transferred in a NARA acceptable format according to 36 CFR 1228.270 Electronic Records.

1. **FDA Item B-4 <u>Pending Establishment or Product License Applications and Supplements</u>** (Supersedes N1-088-96-3, Item B-4)

Files consist of applications for licenses and/or license supplements (formerly amendment), license action notification memorandums (Form FDA 2671 or NIH-523) or letters, CBER Review Committee assignments, Correspondence between FDA and the manufacturer including additional submissions to the file, reviews, related memorandums and records of telephone conversations. May also contain sample labels, clinical records, SOP manuals, package insert/circular of information and electronic media (such as disks, CD-ROM, etc.)

Effective July 1, 2000, all Pending Establishment or Product License Applications or Supplements were transferred and became a Pending Biologic License Application (See Item B-30). Information concerning retention and destruction periods ~~are~~ is cited here to maintain a history of record management.

A. <u>Approved or Accepted Applications or Supplements</u>

Applications or supplements for which FDA has issued a license.

1) Record Keeping Copy.
Disposition: **Temporary**. Place documents in Establishment or Product License file jackets at time of approval or acceptance (see Item B-6: Establishment License Applications and Supplements or B-7: Product License Applications and Supplements).

2) All other copies.
Disposition: **Temporary** Destroy at time of approval or acceptance.

B. Denied Applications or Supplements

Applications or supplements for which the FDA has determined do not meet standards established in the Code of Federal Regulations.

See July 25th, 2014 email from Al Minick regarding pen & ink changes. VST 7/29/14

1) Record Keeping Copy.
Disposition: **Temporary.** Cut off at end of year of denial of application. Retire to ~~WNRC~~ Federally certified facility 1 year after cut off. Destroy 5 years after cut off.

2) All other copies.
Disposition: **Temporary.** Destroy at time of denial

C. Withdrawn Applications or Supplements

Applications or supplements voluntarily withdrawn by the manufacturer.

1) Record Keeping Copy.
Disposition: **Temporary.** Cut off at end of year of withdrawal of an application. Retire to ~~WNRC~~ Federally certified facility 1 year after cut off. Destroy 5 years after withdrawal.

2) All other copies.
Disposition: **Temporary**. Destroy at time of withdrawal.

D. Inactivated Applications or Supplements

Applications or supplements for which no action has been taken for an extended period of time and there is no reply to "30 day" request from CBER for status.

1) Record Keeping Copy
Disposition: **Temporary.** Cut off at end of year of inactivation. Destroy 5 years after cut off.

2) All other copies.
Disposition: **Temporary**. Destroy copies at time of inactivation.

E. Refusal-to-file Applications or Supplements

Applications or supplements that have been deemed to be incomplete or inadequate for filing.

1) Record Keeping Copy.

Disposition: **Temporary.** Cut off at end of year of issuance of refusal to file letter. Retire to ~~WNRC~~ Federally certified facility 1 year after cut off. Destroy 5 years after cut off.

2) All other copies.
Disposition: Offer to return copies to submitting manufacturer. Manufacturer may pick up documents at their expense; copies will not be packed for shipping by the Agency. If submitting manufacturer does not wish the return of files, destroy.

2. **FDA Item B-6 <u>Establishment License Applications and Supplements</u>** (Supersedes N1-088-96-3, Item B-6)

License applications and subsequent supplements authorizing production of licensed biologicals. Files include supporting materials consisting of application forms, curricula vitae of responsible officials, changes of officials, production method documents, plant layouts, production procedures, production SOPs and new equipment validation. Also included in the files is correspondence between FDA and the manufacturer/establishment including additional submissions to the file, reviews, memorandums, and records documenting telephone conversations. (Also see Item B-7: Product License Applications and Supplements,)

Effective July 1, 2000, all Establishment License Applications or Supplements were transferred and became a Biologic License Application (See Item B-31). Information concerning retention and destruction periods are cited here to maintain a history of record management.

License files are retained in format, by License Number, as they were created before July 1, 2000.

A. <u>Active License Applications</u>

Record Keeping Copy:
Disposition: **Temporary.** Retain until license is revoked, suspended, or superseded. See Item B-6 C, for instruction thereafter.

B. <u>Transferred License Applications</u>

Establishment License Application files revoked and transferred (or "roll over") to another company through formal FDA approval.

Record Keeping Copy.
Disposition. **Temporary.** File as Item B-6 A. Active License Application.

C. Revoked, Suspended, or Superseded License Applications

Disposition: **Temporary.** Federally certified facility Cut off at end of year of revocation, suspension, or supersession. Retire to ~~WNRC~~ 2 years after cut off. Destroy 10 years after cut off. Upon 90 day notice of destruction from ~~WNRC~~ Federally certified facility, review records for any possible record of firm of ongoing interest.

3. **FDA Item B-7 Product License Applications and Supplements**. (Supersedes N1-088-96-3, Item B-7)

License applications and subsequent supplements authorizing production of specific products and consisting of application requests and changes in production methods and procedures. Also included in the files ~~is~~ are correspondence between FDA and the manufacturer/establishment including additional submissions to the file, reviews, memorandums, and records documenting telephone conversations, as well as product stability data, product labels, and package inserts (Circulars). (Also see section on Establishment License Applications and Supplements, B-6).

Effective July 1, 2000, all Product License Applications or Supplements were transferred and became a Biologic License Application (See Item B-31) Information concerning retention and destruction periods ~~are~~ is cited here to maintain a history of record management.

License files are retained in format, by License Number, as they were created before July 1, 2000.

A. Active License Applications

Record Keeping Copy.
Disposition. **Temporary.** Retain until license is revoked. suspended, or superseded. See Item B-7 C, for instruction thereafter.

B. Transferred License Applications

Product License Application files revoked and transferred ("or roll over") to another company, through formal FDA approval.

Disposition: **Temporary.** File as Item B-7 A. Active License Application File.

C. Revoked, Suspended. or Superseded License Applications

Disposition: **Temporary.** a Federally certified facility Cut off at end of year of revocation, suspension, or supersession. Retire to ~~WNRC~~ 2 years after cut off. Destroy 10 years after cut off. Files of significant historical value ~~may~~ must be proposed for permanent retention by submitting an SF 115 to the National Archives and Records Administration.

4. **FDA Item B-9** **Protocol Releases** (Supersedes N1-088-96-3, Item B-9)

Files document FDA action taken on individual batches and lots of biologicals submitted for release or surveillance review. File contains copy of manufacturer's protocol showing processing, testing, Release/Rejection/Withdrawal letter, completed computer generated check list, and related correspondence such as cover letters, requests for additional information, and replies concerning the release of a particular batch. Some older files may include NIH or FDA forms (Form NIH 289 or FLH 2558, Forms NIH 837 through 845 and/or acknowledgment letter, Form NIH 30, or FLH 2568).

Disposition. **Temporary.** Cut off at end of year of release, rejection, withdrawal, or other final action. Retire to ~~WNRC~~ Federally certified facility 3 years after cut off. Destroy 20 years after cut off.

5. **FDA Item B-10** **Investigational New Drug Applications (INDs) (Biologicals)** (Supersedes N1-088-96-3, Item B-10)

Applications from sponsors for approval to test new biological products on humans prior to marketing. Also supporting material consisting of supplements/amendments, Form FDA 1571, Investigational New Drug Application (formerly Notice of Claimed Investigational Exemption for a New Drug), formulations, progress and other reports, related correspondence, FDA evaluations, and recommendations. Files may also contain inspection reports, export requests, meeting minutes, memorandums, and records of telephone conversations.

1) Record Keeping Copy
Disposition. **Temporary.** Cut off at end of year of withdrawal, cancellation, inactivation, exemption or termination of IND. Retire to ~~WNRC~~ Federally certified facility 1 year after cut off. Destroy 30 years after cut off.

2) ~~Duplicate Copy.~~ All other copies
Disposition: **Temporary**. Destroy when ~~record keeping copy is retired~~ no longer needed for business. to ~~WNRC.~~

3) ~~All other copies.~~ Duplicate copy Non-record

~~Disposition. **Temporary**. Destroy after review of each submission (original or supplement/amendment) is completed.~~ Non-record

6. **FDA Item B-11** **Efficacy Reviews** (Supersedes N1-088-96-3, Item B-4)

Documentation submitted by manufacturers regarding product efficacy, reviews, and evaluations of material by Agency professionals. An Efficacy Review Committee composed of outside consultants/experts reviews the submitted documentation and Agency evaluation and prepares report.

A. Reports
Disposition: **Permanent.** Transfer to the National Archives when 30 years old or when no longer needed by Agency for reference purposes, whichever is sooner.

B. Supporting Materials
Disposition: **Temporary.** Cut off at end of year of termination of review. Retire to ~~WNRC~~ Federally certified facility 2 years after cut off. Destroy 30 years after cutoff.

7. **FDA Item B-13** **Inspection and Investigation Reports** (Supersedes N1-088-96-3, Item B-13)

Reports made on inspections and investigations of biological and blood collecting and producing establishments. Includes supporting material, follow-up actions, and related correspondence. Establishment Inspection Reports (EIR) may be included. Reports on pre-approval inspections are incorporated into the Biologics License Application.

Disposition: **Temporary.** Cut off at end of year when inspection occurs. Retire to ~~WNRC~~ Federally certified facility 2 years after revocation of biologics license. Destroy 10 years after cut off. Upon 90 day notice of destruction from ~~WNRC,~~ Federally certified facility review records for any possible record of firm of ongoing interest.

8. **FDA Item B-14** **Laboratory Test Records** (Supersedes N1-088-96-3, Item B-14)

A. Inspection Sample and Official Complaint Sample Test Result

1) Record Keeping Copy.
Disposition: Original record forwarded to the CBER inspection review staff office after completion of action. Records are to be included as part of Inspection or Investigative Report Files and retained as appropriate (see Item B-13. Inspection and Investigation Reports,).

2) Duplicate copy.
Disposition: **Temporary**. Destroy copies 5 years after completion of test or when no longer needed.

B. Control Test Results

Log books and other records associated with the release of a biological product lot.

Disposition: **Temporary.** Destroy 20 years after completion of test.

C. Poliovirus Neurovirulance Experiment Findings

Disposition: **Temporary.** Retain records in Agency folders

D. Individual Animal Study Record Cards

Disposition: **Temporary.** Cut off at end of year of completion of test. Destroy 5 years after cut off.

E. Animal Test Cards

Disposition: **Temporary.** Cut off at end of year of completion of test. Destroy 10 years after cut off.

9. FDA Item B-15 Blood Establishment Registration Files (Supersedes N1-088-96-3, Item B-4)

Information on registered blood establishments submitted annually on FDA Form 2830. Data consists of name, address, product and other key data associated with the location. Files may include updated information submitted on above form or by letter between annual reporting period.

A. Forms or Letters

Disposition: **Temporary**. Cut off yearly on November 1 when annual reporting registration begins. Retire to ~~WNRC~~ Federally certified facility 1 year after cutoff. Destroy 10 years after cutoff.

B. Blood Establishment Data Base

RESERVED. Item will be submitted on a separate SF-115.

10. **FDA Item B-16** **Adverse Experience Reports, Product Defects and Consumer Complaints** (Supersedes N1-088-96-3, Item B-16)

Information on adverse experiences associated with the use of biological products submitted by manufacturers and health professionals on various Drug and Biological Report forms (FDA Form 3500, FDA Form 3500A, Form FDA-1639, VAERS Form VAERS-1 or other forms) and reports on product defects and consumer complaints received from the general public and FDA field offices. Reports may be submitted either by a mandatory requirement or voluntarily to the agency through the Medical Products Reporting Program (MedWatch), or the Vaccine Adverse Expert Reporting System (VAERS). These systems are used for adverse experience report preparation and other regulatory actions. Correspondence with firms concerning complaints and corrective action taken as well as memorandums for the record regarding the complaint are also retained in files. Key data may be transferred to a computer database.

A. Forms Submitted

Disposition: **Temporary**. Cut off at end of calendar year submitted. Retire to ~~WNRC~~ Federally certified facility 2 years after cutoff. Destroy 10 years after cutoff.

B. Adverse Experience Report Database

RESERVED. Item will be submitted on a separate SF-115.

11. **FDA Item B-19** **Histocompatibility Research** (Supersedes N1-088-96-3, Item B-19)

Names, blood types, and Human Leukocyte Antigens (HLA) lab results of tested patients used for research analysis.

Disposition: **Temporary.** Destroy 20 years after analysis is completed. Analysis competed December 1985.
Records previously transferred to WNRC. Destroy January 1, 2006.

12. **FDA Item B-20** **Master Files (MFs)** (Supersedes N1-088-96-3, Item B-20)

Privileged information concerning and provided by drug producers on personnel involved, facilities, production methods, and formulations involving the development of products.

1) Record Keeping Copy
Disposition: **Temporary.** Cut off at end of year file is closed. Retire to Federally certified facility ~~WNRC~~ 1 year after cut off. Destroy 30 years after cut off. Upon 90 day notice of destruction from WNRC, review for any possible record of firm

Federally certified facility

of ongoing interest or if firm/product might be referenced in another active application.

2) ~~Duplicate Copy:~~ All other copies
Disposition: **Temporary.** Destroy when ~~Record Keeping Copy is retired to WNRC.~~ no longer needed for business.

3) ~~All other copies~~: Duplicate copies: Non-record
~~Disposition: **Temporary.** Destroy after review of each submission is completed~~. Non-record

13. FDA Item B-21 **New Drug Applications (NDAs)** (Supersedes N1-088-96-3, Item B-21)

Applications for FDA approval to market new drugs in interstate commerce. Files include case reports (clinical data); test results; labeling, manufacturing, chemistry, progress and other reports; and adverse reactions. Also included are notices of termination/withdrawal/approval, FDA evaluations, recommendations supporting these notices, and related records.

A. Approved Application or Supplement.

1) Record Keeping Copy
Disposition. **Temporary.** Retain until application is revoked or withdrawn. See Item B-21 C for instructions thereafter.

2) All other copies
Disposition. **Temporary.** Destroy at time of approval.

B. Applications disapproved by FDA or withdrawn by applicant before approval

1) Record Keeping Copy.
Disposition: **Temporary.** Cut off at end of year of disapproval or withdrawal of application. Retire to ~~WNRC~~ Federally certified facility 1 year after cutoff. Destroy 10 years after cut off.

2) All other copies.
Disposition. **Temporary.** Destroy at time of disapproval or withdrawal.

C. Revoked or withdrawn application.

Disposition: **Temporary.** Cut off at end of year of revocation or withdrawal of application. Retire to ~~WNRC~~ Federally certified facility 2 years after cut off. Destroy 10 years after cut off.

14. **FDA Item B-22** **Premarket Notification (Device) (510 (k) Submission)** (Supersedes N1-088-96-3, Item B-22)

Applications from manufacturers seeking to introduce a medical device on the market that is substantially equivalent to an already approved device. Also FDA evaluations and approved decisions made under Section 510 (k).

A. Application determined to be substantially equivalent

1) Record Keeping Copy.
Disposition. **Temporary.** Retain until application is revoked or withdrawn. See Item B-22 C for instructions thereafter.

2) All other copies.
Disposition. **Temporary.** Destroy at time of determination of equivalency.

B. Application determined to be not substantially equivalent or withdrawn by manufacturer.

1) Record Keeping Copy
Disposition: **Temporary.** Cut off at end of year of final determination of non-equivalency or withdrawal. Retire to ~~WNRC~~ Federally certified facility 1 year after cut-off. Destroy 20 years after cut-off

2). All other copies.
Disposition. **Temporary.** Destroy at time of determination of non-equivalency or withdrawal.

C. Application revoked or withdrawn.

Disposition: **Temporary.** Cut off file at end of year of revocation or withdrawal. Retire to ~~WNRC~~ Federally certified facility 5 years after cut off. Destroy 20 years after cut off.
Upon 90 day notice of destruction from ~~WNRC~~ Federally certified facility, review records for any possible record of firm of ongoing interest.

15. **FDA Item B-23** **Premarket Applications (Device) (BPs)** (Supersedes N1-088-96-3, Item B-23)

Applications for approval to market Class III medical device products. File may also contain clinical data, test results; amendments; supplements; labeling; promotional material; progress reports; adverse reports; adverse reactions; FDA evaluations; and related correspondence and other material. The information in this files is used to determine the safety and effectiveness of medical devices.

Temporary. Cut off after final action (approval, disapproval or withdrawal). Transfer to ~~WNRC~~ Federally certified facility 5 years after cut off. Destroy 30 years after cut off.
Destroy duplicate copies at time of final action.

A. Application Approved.

1) Record Keeping Copy.
Disposition. **Temporary.** Retain until application is revoked or withdrawn. See Item B-23 C for instructions thereafter.

2) All other copies.
Disposition. **Temporary.** Destroy upon approval.

B. Application disapproved or withdrawn by manufacturer

1) Record Keeping Copy.
Disposition: **Temporary**. Cut off at end of year of disapproval or withdrawal. Retire to ~~WNRC~~ Federally certified facility 1 year after cut-off. Destroy 30 years after cut-off

2) All other copies.
Disposition: **Temporary.** Destroy upon disapproval or withdrawal.

C. Application revoked or withdrawn.

Disposition: **Temporary.** Cut off at end of year of revocation or withdrawal. Retire to ~~WNRC~~ Federally Certified facility 5 years after cut off. Destroy 30 years after cut off. Upon 90 day notice of destruction from ~~WNRC,~~ Federally certified facility review records for any possible record of firm of ongoing interest.

16. FDA Item B-24 Advertisements and Promotional Labeling (Supersedes N1-088-96-3, Item B-24)

Copies of nonviolative advertisements and promotional labeling for products under jurisdiction of the Center including biologics, drugs and devices. Material includes traditional advertisements, promotional labeling, reminder advertising, material on video tape or other multi-media materials. Material is submitted

accompanied by transmittal form FDA-2567 or FDA 2253 or any similar transmittal form or revision there of.

A. Non-violative material

Disposition: **Temporary.** Cut off at end of year of completion of review. Destroy 2 years after cut off.

B. Violative material

Disposition: **Temporary.** Material deemed possibly violative will have been removed prior to destruction date for follow-up action and new cut off date established.

17. **FDA Item B-25 General Correspondence** (Supersedes N1-088-96-3, Item B-25)

Files consist of incoming and outgoing correspondence addressed to or answered by CBER staff, but not relating to a sponsor or manufacturer holding a license for an approved or pending marketable biologic product, to an approved or pending biologic device or to a biologic IND. These files are arranged alphabetically.

Disposition: **Temporary.** Cut off at end of year of closure. Retire to ~~WNRC~~ Federally certified facility 5 years after cut off. Destroy 20 years after cut off.

18. **FDA Item B-26 Advisory Committee Members and Consultants** (Supersedes N1-088-96-3, Item B-26)

Documents relating to members and consultants of standing committees. Files include information relating to financial interests, conflict of interest matters, waivers and participation, as well as appointment and travel documents.

Disposition: **Temporary.** Cut off at end of year of departure of committee member or consultant. Destroy 6 years after cut off unless needed for ongoing investigation.

19. **FDA Item B-27 Advisory Committee Records**

This Item is scheduled under the FDA Records Control Schedule as Item S-2 under Systems and Policy Heading (NARA Job number NC1-88-78-1). The files are to be transferred to ~~WNRC~~ Federally certified facility 5 years after cutoff date and then ~~offered~~ transferred to National Archives 20 years after cutoff date.

20. FDA Item B-28 Recall Files (Supersedes N1-088-96-3, Item B-28)

Documents relating to a firm's removal or correction of a marketed product that is considered to be in violation of law, and against which a legal action may otherwise be initiated. A recall may be initiated by FDA or the manufacturer. Material consists of recommendation to initiate recall, approvals, notification of classification, inspection reports, labels, samples and photographs of recalled products, summaries of the extent and effectiveness of the recall, and related correspondence and documentation.

1) Record Keeping Copy.
Disposition: **Temporary.** Cut off at end of fiscal year of closure of file. Retire to ~~WNRC~~ Federally certified facility 2 years after cut off. Destroy 20 years after cut off. Upon 90 day notice of destruction from ~~WNRC~~ Federally certified facility, review records for any possible record of firm of ongoing interest.

2) Duplicate copy
Disposition: **Temporary.** Destroy at time of final action.

21. FDA Item B-29 Biological Product Deviation Reports (Supersedes N1-088-96-3, Item B-29)

These reports were formerly known as "error and accident reports". Reports received from establishments concerning deviations in manufacturing (formerly error and accidents) of licensed products or unlicensed blood products that may affect the safety, purity, or potency of a product. Associated correspondence concerning individual reports may also be included.

Disposition: **Temporary.** Cut off at end of fiscal year of closure of file. Retire to ~~WNRC~~ Federally certified facility 2 years after cut off. Destroy 10 years after cut off.

22. FDA Item B-30 Pending Biologic License Applications and Supplements

Files consist of applications for licenses and/or license supplements, CBER Review Committee assignments, correspondence between FDA and the manufacturer including additional submissions to the file, reviews, related memoranda and records of telephone conversations. May also contain sample labels, clinical records, SOP manuals, package insert/circular of information and electronic media (such as disks, CDRom, etc.). The Biologic License Application (BLA) replaced the Product License Application and Establishment License Application in July 2000. (See Item B-4)

A. Approved or Accepted Applications or Supplements

Applications or supplements for which FDA has issued a license.

1) Record Keeping Copy
Disposition: **Temporary.** Place documents in Biologic License files jackets (see Item B-31).

2) Duplicate and Triplicate Copies
Disposition: **Temporary**. Destroy at time of approval or acceptance.

3) All other copies
Disposition: **Temporary.** Destroy at completion of individual review.

B. Denied Applications or Supplements

Applications or supplements for which the FDA has determined do not meet standards established in the Code of Federal Regulations.

1) Record Keeping Copy.
Disposition: **Temporary.** Cut off at end of year of denial of application or supplement. Retire to ~~WNRC~~ Federally certified facility 1 year after cut off. Destroy 5 years after cut off.

2) Duplicate and Triplicate Copies
Disposition: **Temporary**. Destroy at time of denial.

3) All other copies
Disposition: **Temporary.** Destroy at completion of individual review.

C. Withdrawn Applications or Supplements

Applications or supplements voluntarily withdrawn by the manufacturer.

1) Record Keeping Copy
Disposition **Temporary.** Cut off at end of year of withdrawal of application or supplement. Retire to ~~WNRC~~ Federally certified facility 1 year after cut off. Destroy 5 years after cut off

2) Duplicate and Triplicate Copies.
Disposition. **Temporary.** Destroy at time of withdrawal.

3) All other copies
Disposition. **Temporary.** Destroy at completion of individual review.

D. Inactivated Applications or Supplements

Applications or supplements for which no action has been taken for an extended period of time.

1) Record Keeping Copy.
Disposition: **Temporary.** Cut off at end of year of inactivation. Retire to ~~WNRC~~ Federally certified facility 1 year after cut off. Destroy 5 years after cut off.

2) Duplicate and Triplicate Copies.
Disposition: **Temporary.** Destroy at time of inactivation

3) All other copies
Disposition: **Temporary.** Destroy at completion of individual review.

E. Refusal-to-file Applications or Supplements

Applications or supplements that have been deemed to be incomplete or inadequate for filing.

1) Record Keeping Copy.
Disposition: **Temporary.** Cut off at end of year of issuance of refusal to file letter. Retire to ~~WNRC~~ Federally certified facility 1 year after cut off. Destroy 5 years after cut off.

2) All other copies.
Disposition: Offer to return copies to submitting manufacturer. At time of Refusal to File Notice. Manufacturer may pick up documents at their expense; copies will not be packed for shipping by the Agency. If submitting manufacturer does not wish the return of files, destroy.

23. FDA Item B-31 Biologic License Applications and Supplements

License applications and subsequent supplements authorizing production of licensed biologicals. Files include supporting materials consisting of application requests, production procedures, SOPs and new equipment validation methods, plant layouts, product stability data, product labels, and package inserts (Circulars). Also included in the files is correspondence between FDA and the sponsor/establishment including additional submissions to the file, reviews, memorandums, and records documenting telephone conversations.

A. Active License Applications and Supplements

Record Keeping Copy.
Disposition. **Temporary.** Retain until license is revoked, suspended, or superseded. See B-31 B, for instruction thereafter.

B. Revoked Suspended or Superseded License Applications

Disposition: **Temporary.** Cut off at end of year of revocation. Retire to ~~WNRC~~ Federally certified facility 2 years after cut off. Destroy 10 years after cut off. Upon 90 day notice of destruction from WNRC Federally certified facility, review records of any possible record of firm of ongoing interest

24. FDA Item B-32 Market Withdrawal Files

Documents relating to a firm's removal or correction of a distributed product. A market withdrawal is initiated by the manufacturer when a minor violation occurs that would not ordinarily be subject to legal action, or when there is no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc. Material may consist of recommendation to recall action, notification of reclassification to market withdrawal, inspection reports, labels, samples and/or photographs of products, and related correspondence and documentation.

1) Record Keeping Copy.
Disposition: **Temporary.** Cut off at end of fiscal year of closure of action. Retire to ~~WNRC~~ Federally certified facility 2 years after cut off. Destroy 20 years after cut off.

2) Duplicate Copy.
Disposition: **Temporary.** Destroy at cut off.

25. FDA Item B-33 Export Files

Requests or notification received from a sponsor, manufacturer or foreign government requesting authorization to export investigational or unapproved biologic products or biologic devices for investigational or commercial use. Requests may be made under provisions of 21 CFR 312.110 or selected subsections of Sections 801 or 802 of the FD & C Act. Exported Biologic Product (EBP) or Partially Processed Biological (PPB) Product requests may be submitted under provisions of the 1986 Export Amendments.

Disposition: **Temporary**. Cut off at end of fiscal year of closure of action. Retire to ~~WNRC~~ Federally certified facility 1 year after cut off. Destroy 10 years after cut off.

26. FDA Item B-34 Post Marketing Products Safety Reviews and Adverse Event Summaries

Reports prepared by Agency personnel that evaluate and analyze adverse events associated with a licensed biological product. Reports provide analysis and

recommendations related to the types of adverse events associated with a product, safety concerns, and whether or not further investigation or analysis is required by other Center Offices.

Disposition: **Temporary**. Cut off at end of year of report preparation. Retire to WNRC 3 years after cut off. Destroy 20 years after cut off.

27. **FDA Item B-35** **<u>Post-Marketing Surveillance Lot Analysis Reports</u>**

Reports prepared by Agency personnel that evaluate and analyze adverse events associated with certain batches or lots of biological products. Reports provide analysis and recommendations related to the types of adverse events associated with a batch or lot and whether or not further investigation or analysis is required other Center Offices.

Disposition: **Temporary**. Cut off at end of year of report preparation. Retire to ~~WNRC~~ 3 years after cut off. Destroy 20 years after cut off.
Federally certified facility

28. **FDA Item B-36** **<u>Collection and Transfusion Related Fatality Report Files.</u>**

Reports submitted to the Center following a fatality confirmed to be the result of complication of blood collection or transfusion. This report is prepared by the collecting facility or the performing the compatibility tests in a transfusion reaction. This is a requirement of 21 CFR 606.170(b).

Disposition: **Temporary**. Cut off at end of fiscal year of submission. Retire to ~~WNRC~~ 1 year after cut off. Destroy 10 years after cut off.
Federally certified facility

29. **FDA Item B-37** **<u>Compliance Files</u>**

Pen and Ink Change
Richard L. Green
3/17/2021

Files are associated with Compliance activities: Material may consist of recommendation memoranda, inspection reports, exhibits, labels, samples, photographs of products, practices, processes, or other activities, and related correspondence (such as complaints), and documentation.

Types of files include the following:

- Advisory Action Files (action taken advising an individual or firm that FDA considers one or more products, practices, processes, or other activities to be in violation of the law)
- Judicial Action Files (adjudication, follow-up, seizures, injunctions, inspection warrants, search warrants, prosecutions or other judicial actions)

- Administrative Action Files (license suspensions, license revocations, and/or section 305 meetings)
- Consent Decree Files (a consent decree action between FDA and a manufacturer/sponsor of a biologic product)

1) Record Keeping Copy.
Disposition: **Temporary**. Cut off at end of fiscal year of closure of file. Retire to ~~WNRC~~ Federally certified facility 3 years after cut off. Destroy 20 years after cut off. Upon 90 day notice of destruction from ~~WNRC~~ Federally certified facility, review records for any possible record of firm of ongoing interest.

2) Duplicate Copy
Disposition. **Temporary.** Destroy copies when record keeping copy is retired to ~~WNRC~~ Federally certified facility of final action.

30. E-mail and Word Processing System Copies

Includes electronic copies of records that are created on electronic mail and word processing systems and used solely to generate a recordkeeping copy of the records covered by the other items in this schedule. Also includes electronic copies of records created on electronic mail and word processing systems that are maintained for updating, revision, or dissemination.

A. Copies that have no further administrative value after the recordkeeping copy is made. Includes copies maintained by individuals in personal files, personal electronic mail directories, or other personal directories that are used only to produce the record-keeping copy.

Disposition: **Temporary**. Destroy/delete within 180 days after the recordkeeping copy has been produced or when it has no further archival value.

B. Copies used for dissemination, revision, or updating that are maintained in addition to the recordkeeping copy.

Disposition: **Temporary**. Destroy/delete when dissemination, revision, or updating is completed.