REQUEST FOR RECORDS DISPOSITION AUTHORITY

(See Instructions on reverse)

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

LEAVE BLANK (NARA use only)

JOB NUMBER: N1-88-96-3

DATE RECEIVED: 8-30-96

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request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10.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: 12-16-96

ARCHIVIST OF THE UNITED STATES: John W. Carlin

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

4. NAME OF PERSON WITH WHOM TO CONFER

Calvin Daniels

5. TELEPHONE

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,

[X] is not required; [ ] is attached; or [ ] has been requested.

DATE	SIGNATURE OF AGENCY REPRESENTATIVE	TITLE
8/30/96	Calvin C. Daniels	Records Mgmt. Officer

7. ITEM NO.	8. DESCRIPTION OF ITEM AND PROPOSED DISPOSITION	9. GRS OR SUPERSEDED JOB CITATION	10. ACTION TAKEN (NARA USE ONLY)
	See attached		

JAN 16 1997 MNV Copy to: Agency NWD9, WRRC-Director

Food and Drug Administration (FDA)
Center for Biologics Evaluation and Research (CBER)

~~**Item B-1**~~ **Consumer Complaints** (NC1-88-78-1).

Delete from manual.

~~**Item B-2**~~ **Manufacturers' Correspondence and Data** (NC1-88-78-1).

Delete from manual.

~~**Item B-3**~~ **Correspondence Cross Reference (Salmon)** (NC1-88-78-1).

Delete from manual.

Item B-4 **Pending Establishment or Product License Applications and Supplements** (NC1-88-78-1).

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, CDRom, etc.)

A. Approved or Accepted Applications or Supplements

Applications or supplements for which FDA has issued a license.

Place original documents in Establishment or Product Licence files jackets (see B-6 or B-7).

Destroy duplicate copies 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.

Temporary. Cut off official files upon denial of application. Destroy application and supporting materials 5 years after cut off.

Destroy duplicate copies at the time of denial.

C. Withdrawn Applications or Supplements

Applications or supplements voluntarily withdrawn by the manufacturer.

Temporary. Cut off official files upon withdrawal of an application. Destroy application and supporting materials 5 years after withdrawal.

Destroy duplicate copies 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.

Temporary. Cut off official applications and supporting materials upon inactivation. Destroy 5 years after cut off.

Destroy duplicate 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.

Temporary. Cut off official file upon issuance of refusal to file letter. Retire to WNRC 1 year after cut off. Destroy 5 years after cut off.

Offer to return duplicate 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.

~~**Item B-5**~~ **License Application Notices** (NC1-88-78-1).

Delete from manual.

Item B-6 **Establishment License Applications and Supplements** (NC1-88-83-2).

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, productions 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 section of Product License Applications and Supplements, B-7).

A. Active License Applications

Retain until license is revoked, suspended, or superseded. See B-6 C, for instruction thereafter.

B. Transferred License Applications

Establishment License Application files revoked and transferred (or "roll over") to another company through formal FDA approval will be refiled as Active License Application File (B-6 A).

C. Revoked, Suspended, or Superseded License Applications

Temporary. Cut off files upon their revocation, suspension, or supersession. Retire to WNRC 2 years after cut off. Destroy 10 years after cut off.

Item B-7 **Product License Applications and Supplements** (NC1-88-83-2).

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 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).

~~A.~~ Active License Applications

Retain until license is revoked, ~~suspended~~, or superseded. See 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 will~~ be refiled as Active License Application File (B-7 A).

C. Revoked, Suspended, or Superseded License Applications

Temporary. Cut off files upon their revocation, suspension, or supersession. Retire to WNRC 2 years after cut off. Destroy 10 years

after cut off. Files of significant historical value may be proposed for permanent retention by submitting an SF 115 to the National Archives and Records Administration.

~~Item B-8~~ **Import Permits** (NC1-88-78-1).

Delete from manual.

Item B-9 **Protocol Releases** (NC1-88-78-1).

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).

Temporary. Cut off files upon release, rejection, withdrawal, or other final action. Retire to WNRC 3 years after cut off. Destroy 20 years after cut off.

Item B-10 **Investigational New Drug Applications (INDs) (Biologicals)** (NC1-88-83-2).

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.

Originals

Temporary. Cut off upon withdrawal, cancellation, inactivation, exemption, or termination of an IND. Retire to WNRC 1 year after cut off. Destroy 30 years after cut off.

~~Destroy duplicate~~ when original is retired to WNRC.

Destroy triplicate after review of each submission ~~(original~~ or supplement/amendment) is completed.

Item B-11 **Efficacy Reviews** (NC1-88-83-2).

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

30 yrs. old or when

Permanent. Transfer to the National Archives when no longer needed by Agency for reference purposes, whichever is sooner. per M. Lewandowski 10/3/96

B. Supporting Materials

Temporary. Cut off upon termination of review. Retire to WNRC 2 years after cut off. Destroy 20 years after ~~publication of report or~~ cut off ~~5 years after publication of final order in the Federal Register, whichever comes later~~. per M. Lewandowski 10/3/96

~~**Item B-12** **Efficacy Review Committee Members** (NC1-88-78-1).~~

~~Delete from manual.~~

Item B-13 **Inspection and Investigation Reports** (NC1-88-83-2).

Reports made on inspections and investigations of biological and blood collecting and producing establishments. Includes supporting material, follow-up actions, and related correspondence. Some field Establishment Inspection Reports (EIR) may be included.

Temporary. Cut off after inspection occurs. Retire to WNRC 5 years after cut off for active establishment licenses or 2 years after revocation, suspension, or supersession of establishment license. Destroy 10 years after cut off. Upon 90 day notice of destruction from WNRC, review records for any possible record of firm of ongoing interest.

Item B-14 **Laboratory Test Records** (NC1-88-78-1).

Laboratory notebooks, control test results, evaluations, experimental findings, and related correspondence. Files also include cards containing summaries of test results and receipt of samples.

A. Inspection Sample and Official Complaint Sample Test Result

Original record forwarded to Office of Compliance after completion of

action. Records are to be included as part of Inspection or Investigative Report Files and retained as appropriate (see section on Inspection and Investigation Reports, B-13).

Destroy duplicate copies 5 years after completion of test.

B. Control Test Results

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

Temporary. Destroy 20 years after completion of test.

C. Poliovirus Neurovirus Experiment Findings

~~Not scheduled~~ no change from NC1-88-78-1

D. Individual Animal Study Record Cards

Temporary. Cut off animal cage record cards after completion of test. Destroy 5 years after cut off.

E. Animal Test Cards

Temporary. Cut off after completion of test. Destroy 10 years after cut off.

F. Sterility Records

Temporary. Cut off upon completion of test. Destroy 10 years after cut off.

G. Sample Receipt Records

Temporary. Destroy 5 years after receipt of sample.

Item B-15 **Blood Establishment Registration System** (NC1-88-83-2).

~~Reserved.~~ no change from NC1-88-83-2

Item B-16 **Adverse Experience Reports, Product Defects and Consumer Complaints** (NC1-88-83-2).

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) and reports on product defects and consumer complaints received from the general public and FDA field offices. Reports may be submitted either be 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 records. Key data may be transferred to ADP media.

Temporary. Cut off upon revocation, suspension or supersession. Retire to WNRC 2 years after cut off. Destroy 10 years after cut off.

Item B-17 **Biological Products Lot Releases** (NC1-88-78-1).

~~Delete from manual.~~

~~**Item B-18** **Swine Flu Clinical Trials and Lot Releases** (NC1-88-78-1).~~

Delete from manual.

Item B-19 **Histocompatibility Research** (NC1-88-79-2).

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

Temporary. Retire to WNRC upon approval of this schedule. Destroy January 1, 2006.

Item B-20 **Master Files (MFs)** .

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

Originals

Temporary. Cut off after file is closed or inactivated. Retire to WNRC 1 year after cut off. Destroy 15 years after cut off.

Destroy duplicate upon retirement of originals to WNRC. Destroy triplicate after review of each submission is completed.

Item B-21 **New Drug Applications (NDAs)** .

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. Original application approved by FDA

~~Retain in agency space until application is revoked or withdrawn.~~

~~B. Original application revoked or withdrawn after approval~~ per M. Lewandowski 10/3/96

Temporary. Cut off file upon revocation ~~of~~ or withdrawal of application. Retire to WNRC 2 years after cut off. Destroy 10 years after cut off.

B. ~~C.~~ Original applications disapproved by FDA or withdrawn by applicant before approval.

Temporary. Cut off upon disapproval or withdrawal of application. Destroy 10 years after cut off.

C. ~~D.~~ Duplicate, triplicate, and additional copies of applications.

Temporary. Destroy upon approval, disapproval, or withdrawal of application by applicant.

Item B-22 **Premarket Notification (Device) (510 (k) Submission)**

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).

Temporary. Cut off after completion of final action (determination of substantially equivalent, not substantially equivalent or withdrawn by manufacturer). Retire to WNRC 5 years after cut off. Destroy 20 years after cut off.

Destroy duplicate copies at time of final action.

Item B-23 **Premarket Applications (Device) (BPs)**

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 5 years cut off. Destroy 30 years after cut off.

Destroy duplicate copies at time of final action.

Item B-24 **Advertisements and Promotional Labeling**

Copies of nonviolative advertisements and promotional labels for products under jurisdiction of the Center including biologics, drugs and devices. Material includes traditional advertisements, promotional labeling, reminder advertisements, material on video tape or other high technology materials. Material is submitted accompanied by transmittal form FDA-2567 or any similar transmittal form(s) such as, Form FDA 2253 or revision there of.

A. Non-violative material

Temporary. Cut off files upon completion of review. Destroy ~~2~~ 3 years per M. Lewandowski 10/7/96 after cut off.

~~B.~~ Violative material

~~Material identified as violative within the 2 year period prior to destruction will be maintained in agency space under the appropriate product correspondence file in license, 510 (k), PMA or NDA file. Material will be transferred to WNRC and/or destroyed according to the appropriate disposition instruction for that file.~~

Item B-25 **Non-Licensed Correspondence (General Correspondence)**

Files consist of incoming and outgoing correspondence addressed to or answered by CBER staff, but no relating to a specific manufacturer or product; registered establishment; or device manufacturer or IND sponsor. These files are arranged alphabetically by unlicensed company, trade group or organization. Files also contain Correspondence and other information relating to pre-PLA or pre-ELA from an unlicensed manufacturer.

Temporary. Cut off annually. Retire to WNRC 10 years after cut off. Destroy 20 years after cut off.

Item B-26 **Biological Advisory Committee Members**

Documents relating to members of standing committees. Files include information of member's financial interests, conflict of interest matter, waivers and participation, as well as appointments and travel.

A. ~~Current members~~

Retain by Scientific Advisors and ~~Consultants~~ Staff until members leaves committee.

B. Former members

Temporary. Cut off upon departure of committee member. Destroy 6 years after cut off, unless needed for ongoing investigation.

Item B-27 **Advisory Committee Records**

Records of Public Advisory Committees. Committees are established to provide the FDA Commissioner with specific advice and recommendations on scientific and regulatory matters regarding blood products; vaccines and related biological products; allergenic products; biological response modifiers; and other topics.

Files include:

A. Committee files:
Rosters of committee members, charters, and committee recommendations.

B. Reports:
Reports required by FACA and related reports.

C. Official Minutes and typed transcripts

~~D.~~ Verbatim Transcripts:
~~Word-for-word~~ recordings of Advisory Committee meetings, including:
(1) Steno tapes, ~~tape~~ recordings, and other audio recordings.
(2) Typed copies from recordings.
(3) Verbatim records never officially transcribed.

Permanent. Cut off upon issuance of final report or the committees final meeting. Transfer to the National Archives 20 years after cut off, or when no longer needed, whichever is sooner.

(Recordings may be destroyed when typed verbatim transcripts have been prepared.)

per M. Lewandowski 10/3/96

D. All other Advisory Committee Records
(1) Records containing substantive information not duplicated in items B-27A-C.
Contact FDA records officer for preparation of SF 115.
(2) Non Substantive Records
Destroy upon termination of committee

Item B-28 **Recall Files.**

Reserve.

Item B-29 **Error and Accident Reports**

Reports received by establishments concerning errors or accidents in currently approved manufacturer's products that may affect the safety, purity, or potency of a product. Associated correspondence concerning individual reports may also be included.

Temporary. Cut off annually. Retire to WNRC 2 years after cut off. Destroy 10 years after cut off.

the permanent retention of those Committee records usually approved for transfer by NARA, the identification of potentially permanent records and their submission on a SF 115, and the destruction of non-archival records. Although the retention period prior to transfer seems excessive, it is in accordance with many other FDA retentions. I recommend approval of this item as revised.

Item B-29, Error and Accident Reports, consists of approximately 100 cubic feet of records, accumulating at the rate of 10 to 20 cubic feet annually, containing reports concerning preventable errors or unpreventable accidents that may have affected the safety, purity, or potency of a biologic product. Reports and subsequent correspondence are received and maintained by CBER's Office of Compliance. The agency has recommended these records for disposal after 10 years, at which point they are no longer of value to FDA. I recommend approval of this instruction. The reports kept in these files are simple, one page forms completed by manufacturers after minor errors or accidents have occurred and contain a minimal amount of information. Major accidents or errors that require substantial action on the part of manufacturers are documented in FDA's Recall Files, scheduled for disposal 15 years after recall action is effected (NC1-88-83-5). I agree there is no need to keep this information beyond its primary value to FDA.

Susan Y. Elter

SUSAN Y. ELTER
Records Appraisal
and Disposition Division