# 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 (FDA)

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

| 4. NAME OF PERSON WITH WHOM TO CONFER | 5. TELEPHONE |
|---|---|
| Jules Meisler | (301) 827-2863 |

**LEAVE BLANK (NARA use only)**

JOB NUMBER N1-088-09-9

DATE RECEIVED 8/17/09

**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request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10.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 | ARCHIVIST OF THE UNITED STATES |
|---|---|
| 11-12-09 | Adrienne C. Thomas |

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 5 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 |
|---|---|---|
| 8/12/09 | Yvonne K. Wilson | 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 GRS OR SUPERSEDED JOB CITATION | 10.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) |
|---|---|---|---|
| | Unless specifically stated otherwise in the description or the retention, all items are media-neutral and apply to paper, electronic, microform, or other media in which records may exist.<br><br>SEE attached sheet: CBER Information Systems Records<br><br>Seung Ja Sinatra - FDA Records Officer — Date 9/8/06<br><br>Ann Wion - FDA Office of the Chief Counsel — Date 8/6/09 | | |

**Information System Records for CBER Programs**

**File Code: Prefix = CBER**

| Item No. | Records Description and Authorized Disposition | NARA Approved Citation |
|---|---|---|
| 1 | **Regulatory Management System - Biologics License Applications (RMS-BLA) Database.**<br>Authority Supports managed review process for the review and approval of Biologic License Applications (BLA) for biological derived drugs, blood products and In Vitro Diagnostic (IVD) Test Kits. Interfaces with other CBER information systems including Document Accountability Tracking System (DATS), Biologics Investigational Related Applications Management System (BIRAMS), Blood Establishment Registration (BER) database, Lot Release System (LRS) and Electronic Document Room.<br><br>Certain records contain trade secret and confidential commercial information that may not be publicly released; disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations. | **New**<br>Related authority item B-31. |
| 1.1 | **RMS-BLA Database -- Data Files.**<br>Provides a summary record of licensed biologic products. Data may be used to prepare ad-hoc reports and to respond to questions concerning the regulation of biologic products, as well as the approval, withdrawal and revocation of BLAs.<br><br>Includes submission tracking number (STN), product name, company name, application status (approved, withdrawn, revoked, Refused to File, etc.) and application status date.<br><br>**Disposition: TEMPORARY**<br>Cut off at the end of the calendar year after final action. Delete/destroy 10 years after cutoff, or when no longer needed for business or reference use, whichever is later. | |
| ~~1.2~~ | ~~**RMS-BLA Database -- Outputs.**~~<br>~~Includes reports/queries listing content or portions of the content from RMS-BLA database. These reports/queries are used throughout the review and post-marketing process and provide general application information for information requests.~~<br><br>~~**Disposition: TEMPORARY**~~<br>~~Delete/destroy when no longer needed for administrative or reference purposes, whichever is later.~~ | **GRS 20 Items 12 and 16** |

~~1.3~~ ~~**RMS-BLA Database -- System Documentation.**~~ **GRS 20**
~~Includes system operation and user manuals, as well as other system related materials.~~ **Item 11a2**

~~**Disposition: PERMANENT**~~
~~Transfer to the National Archives with the permanent electronic records to which the documentation relates.~~

2 **Lot Release System (LRS) Database.** **New**
Supports FDA's lot release program for biologic products. Provides information on sample lots for product approval and on the routine release of lots to market. Related Authority Item B-9

Certain records contain trade secret and confidential commercial information that may not be publicly released; disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations.

2.1 **LRS Database -- Data Files.**
System data provides a record of tests performed on product lots that were released or rejected. Data may be used to prepare ad-hoc reports and to respond to questions concerning the regulation, approval, withdrawal and rejection of product lots.

Includes submission tracking number (STN), license number, product name, establishment name, type code, lot number, date sample received, date protocol received, final designation code, and final designation date.

**Disposition: TEMPORARY**
Cut off at the end of the calendar year after final action. Delete/destroy 20 years after cutoff, or when no longer needed for business or reference use, whichever is later.

~~2.2~~ ~~**LRS Database - Outputs.**~~ **GRS 20**
~~Includes reports/queries listing content or portions of the content from LRS database. These reports/queries are used throughout the lot release process and provide general information for information requests.~~ **Items 12 and16**

~~**Disposition: TEMPORARY**~~
~~Delete/destroy when no longer needed for administrative or reference purposes, whichever is later.~~

~~2.3~~ ~~**LRS Database - System Documentation.**~~ **GRS 20**
~~Includes system operation and user manuals, as well as other system related materials.~~ **Item 11a1**

~~**Disposition: TEMPORARY**~~
~~Delete/destroy when superseded or obsolete, or upon authorized deletion of the system, whichever is later.~~

3 **Lot Distribution Database (LDD).** **New**
Includes distribution data supplied by the manufacturer on all non-whole blood or tissue biologic products released through distribution channels. Related Authority Items B-30 & B-31

Data is used to quantify the proportion of adverse events received for individual CBER-regulated products, to detect "problem lots," and to track the national supply of products during recalls.

Certain records contain trade secret and confidential commercial information that may not be publicly released; disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations.

3.1 **LDD -- Data Files**
Provides a summary record of product lots reviewed. Data may be used to prepare ad-hoc reports and to respond to questions concerning the regulation, approval, withdrawal and revocation of biologic products.

Includes Document Accountability Tracking System (DATS) log number, product name, submission tracking number (STN), manufacturer name, date of distribution, quantity distributed, quantity returned, expiration date, bulk identification, fill identification, and label lot identification.

**Disposition: TEMPORARY**
Cutoff at the end of the calendar year the related license is revoked or withdrawn. Delete/destroy 10 years after cutoff, or when no longer needed for business or reference use, whichever is later.

~~3.2~~ ~~**LDD -- Outputs.**~~ **GRS 20**
~~Includes reports/queries listing content or portions of the content from LDD database. These reports/queries are used throughout the lot distribution tracking process and provide general information for information requests.~~ **Items 12 and 16**

~~**Disposition: TEMPORARY**~~
~~Delete/destroy when no longer needed for administrative or reference purposes, whichever is later.~~

~~3.3~~ ~~**LDD -- System Documentation.**~~ **GRS 20**
~~Includes system operation and user manuals, as well as other system related materials.~~ **Item 11a1**

~~**Disposition:** TEMPORARY~~
~~Delete/destroy when superseded or obsolete, or upon authorized deletion of the system, whichever is later.~~

4 **Biologics Investigational Related Applications Management System (BIRAMS).** Related Authoirty Items B-10 & B-20

Used to manage the receipt and review processes for CBER's Investigational Related Applications (IRA) including Investigational New Drug Applications (IND), Investigational Device Exemptions (IDE) and Master Files (MF).

Certain records contain trade secret and confidential commercial information that may not be publicly released; disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations.

4.1 **BIRAMS -- Data Files.**

Data may be used to prepare ad-hoc reports and to respond to questions concerning the review of biologic products and master files.

Includes IRA number, sponsor name, IRA title, date submission received, and final action date.

**Disposition:** TEMPORARY
Cut off at the end of the calendar year after final action. Delete/destroy 30 years after cutoff, or when no longer needed for business or reference use, whichever is later.

~~4.2~~ ~~**BIRAMS -- Outputs.**~~ **GRS 20 Items 12 and 16**

~~Includes reports/queries listing content or portions of the content from BIRAMS database. These reports/queries are used throughout the review and management of the investigational related application and provide general application information for information requests.~~

~~**Disposition:** TEMPORARY~~
~~Delete/destroy when no longer needed for administrative or reference purposes, whichever is later.~~

~~4.3~~ ~~**BIRAMS -- System Documentation.**~~ **GRS 20 Item 11a1**

~~Includes system operation and user manuals, as well as other system related materials.~~

~~**Disposition:** TEMPORARY~~
~~Delete/destroy when superseded or obsolete, or upon authorized deletion of the system, whichever is later.~~

5 **Blood Logging and Tracking (BLT) Database.** — **New**

Used to maintain data related to the status and review of applications for devices and products related to blood screening and transfusion, as well as other analogous products. Includes application information for 510(k)s, Pre-Market Applications (PMA), modular PMA supplements (PMS), New Drug Applications (NDA), and Abbreviated New Drug Applications (ANDA), as well as related submission correspondence. — Related Authority Items B-21, B-22 & B-23

Certain records contain trade secret and confidential commercial information that may not be publicly released; disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations.

5.1 **BLT Database -- Data Files.**

Provides a summary record of biologic device and drug files. Data may be used to prepare ad-hoc reports and to respond to questions concerning the regulation and review of biologic device and drug products, as well as their status (approved, substantially equivalent, closed, revoked, etc.).

Includes product name, establishment location, final status date, and application status (approved, withdrawal, revoked, substantially equivalent, etc.).

**Disposition: TEMPORARY**

Cut off at the end of the calendar year after final action. Delete/destroy 30 years after cutoff, or when no longer needed for business or reference use, whichever is later.

~~5.2~~ ~~**BLT Database -- Output Documents.**~~ — **GRS 20 Items 12 or 16**

~~Includes reports/queries listing content or portions of the content from BLT database. These reports/queries are used throughout the review and post-marketing process and provide general application information for information requests.~~

~~**Disposition: TEMPORARY**~~

~~Delete/destroy when no longer needed for administrative or reference purposes, whichever is later.~~

~~5.3~~ ~~**BLT Database -- System Documentation.**~~ — **GRS 20 Item 11a1**

~~Includes system operation and user manuals, as well as other system related materials.~~

~~**Disposition: TEMPORARY**~~

~~Delete/destroy when superseded or obsolete, or upon authorized deletion of the system, whichever is later.~~