ELECTRONIC SUBMISSION INSTRUCTIONS FOR BIOLOGICAL LOT DISTRIBUTION DATA (eLDD) in ASCII file format

Please submit comments and questions concerning these instructions to
mailto:LDDDISTRIBUTION@FDA.HHS.GOV

U.S. Department of Health and Human Services
Food and Drug Administration Center for Biologics Evaluation and Research

TECHNICAL REQUIREMENTS

Lot distribution data submissions include required information defined in 21 CFR 600.81 and portions of the suggested format provided in the guidance for industry entitled *Post marketing Safety Reporting for Human Drug and Biological Products Including Vaccines (March 2001)*.
Two files should be sent to FDA for Lot Distribution Data:
1. Lot Distribution Report (provides data for each final container lot)
2. National Distribution Code (NDC) data for all submitted products (provides details of each NDC code)

Each pair of submitted electronic files must contain records for distributed product under a single license. If a firm distributes products under three licenses, for example, it would submit three different files.

A. Data Elements for Lot Distribution Report

Field Name	Field Description	Business Rules/Comments
Manufacturer License	FDA-assigned US license number for the manufacturer of the product being reported in this row.	• Required 4 digit valid license number
Folder ID (STN First Level)	FDA assigns a Submission Tracking Number for each licensed product. This STN is also known as a "Folder ID."	• Required 6 digit valid Folder ID number
Product Name	Provides product name stored in manufacturer database.	• Required data field • Data field length restricted to 200 characters
National Drug Code (NDC)	FDA National Drug Code (NDC) used in product marketing and distribution to describe product presentation and formulation.	• Required 10-digit, 3-segment number separated by hyphens field that identifies the labeler, product, and trade package size • NDC format can be in one of the following configurations: 4-4-2, 5-3-2, or 5-4-1
Bulk Lot ID	The identification code associated with the largest manufacturing quantity	• Manufacturer-specific character field • If a particular product is manufactured directly into final containers, use a space as a place-holding character. • Provision of bulk and fill lots are required per CFR § 600.81 • Data field length restricted to 15 characters

Field Name	Field Description	Business Rules/Comments
Fill Lot ID	The identification code associated with an intermediate size manufacturing unit	• Manufacturer-specific character field • If a particular product is manufactured directly into final containers, use a space as a place-holding character. • Provision of bulk and fill lots are required per CFR § 600.81 • Data field length restricted to 15 characters
Label Lot (=Final Container Lot) ID	The identification code associated with the smallest manufacturing quantity	• Manufacturer-specific character field • Data field length restricted to 15 characters
Final Containers Distributed	This field corresponds to the total number of final product containers (e.g., vials, syringes, etc.) distributed during the reporting period. If products are distributed in cartons or other packages, then the final containers total should be pre-calculated. For instance, if products are packaged in a 5-dose carton pack of single vials, the final containers total should be presented as number of cartons * 5	• Data element must present a whole number. *"Distributed" refers to shipment from a manufacturer to an independent consignee who assumes control over the product, typically a wholesaler or retailer or health care facility or physician or patient. Product retained by a manufacturer, available for distribution but not yet shipped from the firm's own facilities, should not be included in "distributed" amounts.*
Final Containers Returned	This field corresponds to the total number of final product containers/units (e.g., vials, syringes, etc.) returned during the reporting period	• Data element must present a whole number.
Doses per Container	Doses per final container in which product is distributed.	• Data element must present a whole number. • Numeric, e.g., 1 for single dose vials or bags • FDA will use this data for reporting purposes to calculate total number of doses per final container lot by using this algorithm: Total Doses Distributed = (doses per container) * (number of final containers distributed) Net Doses Distributed = (Total Doses Distributed) – (Total Doses Returned)

Field Name	Field Description	Business Rules/Comments
Initial Distribution Date	Represents the initial distribution date for each final container lot	• Required data element field must be formatted as MM/DD/YYYY.
Expiration Date	Represents expiration date for each final container lot distributed	• Required data element field must be formatted as MM/DD/YYYY.
Reporting Start Date	Beginning of the reporting interval	• Required data element field must be formatted as MM/DD/YYYY.
Reporting End Date	End of the reporting interval	• Data element must be formatted as MM/DD/YYYY.
Package Lot ID (If applicable)	Unique package lot identification for two separately licensed products, which are packaged together and distributed with a package lot identification code.	• Manufacturer-specific character field • Data element must have a value if two separately licensed products are packaged together and distributed with a package lot identification code; otherwise this field should use a space holding character. • Data field length restricted to 15 characters • Data element must have a space holding character for multivalent products, e.g., DTAP/HIB, distributed under one US license. • Two separate records (rows) must be used to present data for a two product package, one for each product. *Although diluent vials for reconstitution of some biological products bear separate label lot codes from those of the primary vaccine or other product, diluent lot data should not be submitted for lot distribution reports.*
Foreign/Domestic Distributions Flag	Represents domestic or international product distributions. Do not include country codes.	• Data element must be present • Data element must have one character value D - Domestic (USA) *FDA requires lot distribution reports only for domestic distribution within the U.S. or to U.S. military bases abroad. This field is retained for consistency with a previously required file format.*
Distribution Type	Represents the kind of data reported for this final container lot	• Data element must be present • Data element must have one character value I – Interval, C – Cumulative, A – Anticipated total for final container lot

B. Data Elements for National Drug Code

Field Name	Description	Business Rules/Comments
Folder ID	FDA assigns a Submission Tracking Number for each licensed product. This STN is also known as a "Folder ID."	• Required 6 digit valid Folder ID number
Product Name	Provides product name stored in manufacturer database.	• Required data field • Data field length restricted to 200 characters
Trade Name	Provides product trade name stored in manufacturer database. This data will be used for verification of consistency between STN and identified product	• Required character field • Field length is restricted to 200 characters
National Drug Code (NDC)	FDA National Drug Code (NDC) used in product marketing and distribution to describe product presentation and formulation.	• Required 10-digit, 3-segment number separated by hyphens field that identifies the labeler, product, and trade package size • NDC format can be in one of the following configurations: 4-4-2, 5-3-2, or 5-4-1
Doses per Container	Doses per final container in which product is distributed.	• Data element must present a whole number. • Numeric, e.g., 1 for single dose vials or bags • FDA will use this data for reporting purposes to calculate total number of doses per final container lot by using this algorithm: Total Doses Distributed = (doses per container) * (number of final containers distributed) Net Doses Distributed = (Total Doses Distributed) – (Total Doses Returned)
Final Container Type	Type of the final container in which product was distributed (vials, syringes)	• Required character field • Field length restricted to 20 characters
Final Container Product Amount	Amount of product in the final distribution container in which product was distributed, i.e., - the volume of drug filled in the final container (see below for examples)	• Required numeric field
Final Container Product Amount	Measurement units of the final container product volume;	• Required character field

Field Name	Description	Business Rules/Comments
Measure	Example 1: A "10 ml vial" would have: Final Container Product Amount = 10 Final Container Product Amount Measure = ml Example 2: A "5 mL glass vial filled with 2 mL of drug" would have: Final Container Type: vial Final Container Product Amount: 2 Final Container Product Amount Measure: mL	• Field length restricted to 20 characters
Product Dosage	Amount of medication in one dose. Product Dosage refers to reconstituted product ready for administration	• Required numeric field • Field can contain “>”, “<”, “≤”, or ”≥” symbols if product dosage varies
Dosage Measure	Dosage measurement unit, e.g., mg, grams, IU, etc.	• Required character field • Field length restricted to 20 characters
Presentation	Text Description of final container (examples: >312 IU/mL single dose vial 400 mg/vial single dose vial	• Required character field • Field length restricted to 400 characters
Formulation	Specific product subtype (e.g., dialysis vs. pediatric vs. adult formulations for hepatitis B vaccine); use a place-holding comma or space for products with only one formulation.	• Required character field • Field length restricted to 400 character
Label URL	Web link (if available) to professional package insert (“label”)	• Manufacturer specific data • If information can not be provided leave this data field as a space holding character • Field length restricted to 400 characters
Packaged NDC	This field needs to be used for NDC numbers located on the outside carton which contains the single components for the packaged products. Packaged NDC will be used for linking each individual component for the packaged products; otherwise this field should use a space holding character.	• 3-segment number separated by hyphens field that identifies the labeler, product, and trade package size • NDC format can be in one of the following configurations: 4-4-2, 5-3-2, or 5-4-1

C. File Format

To ensure that the FDA can process data electronically both files should conform to the following general rules:

1. The file should be produced in ASCII format, regardless of the operating system that will be used to generate the file.

2. Each record or row of information should be on a separate line. A carriage return or line feed combination (e.g., decimal 13 and 10, hexadecimal 0D and 0A, ASCII symbolic CR and LF) should be used for line termination.

3. All date fields should be formatted as described in the above tables.

4. Columns should be tab delimited or separated by a double-quote (if any of data fields contains double-quote it needs be replaced with space or single quote).

5. Transmitter Record (a.k.a. Trailer Record) should be the last record in the file with the following information: mailto:sender-email-address. This field will be used to notify manufacturer that the FDA has accepted or rejected the submission data.

6. Column headers should not be included in the file layout.

7. File Naming Convention. Electronic file names should follow the designated naming convention.

Lot Distribution Report: prefix "LDD", company name, reporting interval covered in the submission.
Example:
LDD DOECOM Oct-1-2006 through Oct-31-2006.TXT
LDD DOECOM 4Q2006.TXT

National Drug Code (NDC): prefix "LDD", company name, "NDC" label, and submission date.
Example:
LDD DOECOM NDC Oct-11-2006.TXT

8. Completed file submissions should be stored on CD-ROM. A paper cover letter should accompany the electronic media to describe the report type, i.e., Lot Distribution report, and include the reporting interval covered in the submission.

D. Technical Problems or Questions

If you have any questions or technical comments related to submission of lot distribution reports, please contact us via email at mailto:ldddistribution@cber.fda.gov

APPENDIX 1 – FILE LAYOUT SAMPLE FOR LOT DISTRIBUTION REPORT

The figures below provide examples of the final file layout for a variety of product distribution reports received by FDA. Examples provided with header columns for better readability, headers should not be included into the file layout.

EXAMPLE ONE: Sample File Layout for products distributed with one (1) final container Bulk, Fill and Label ID

Manufacturer License	Folder ID	Product	NDC	Bulk Lot ID	Fill Lot ID	Label Lot ID	Final Containers Distributed	Final Containers Returned	Doses Per Container	Initial Distribution Date	Expiration Date	Reporting Start Date	Reporting End Date	Package Lot ID	Distribution Flag	Distribution Type
1	111111	Product 1	1111-2222-33	B1	F1	L1	200	0	1	03/02/2006	05/02/2007	04/01/2006	04/30/2006		D	I
1	111111	Product 1	1111-2222-33	B2	F2	L2	300	0	1	03/01/2006	05/05/2007	04/01/2006	04/30/2006		D	I
1	11111	Product 1	1111-2222-33	B3	F3	L3	400	20	1	03/06/2006	05/06/2007	04/01/2006	04/30/2006		D	I
1	11111	Product 1	1111-2222-33	B4	F4	L4	500	0	1	03/09/2006	05/09/2007	04/01/2006	04/30/2006		D	I
1	11111	Product 1	1111-2222-33	B5	F5	L5	600	0	1	03/02/2006	05/02/2007	04/01/2006	04/30/2006		D	I
1	222222	Product 2	1111-2222-44	B6	F6	L7	500	0	5	03/02/2006	07/02/2007	04/01/2006	04/30/2006		D	I
1	222222	Product 2	1111-2222-55	B7	F7	L8	600	100	5	03/02/2006	07/02/2007	04/01/2006	04/30/2006		D	I
1	333333	Product 3	2222-2222-22			X1	100	0	1	03/01/2006	06/30/2007	04/01/2006	04/30/2006		D	I

EXAMPLE TWO: Sample File layout for products distributed with multiple Bulk and Fill lot IDs

Manufacturer License	Folder ID	Product	NDC	Bulk Lot ID	Fill Lot ID	Label Lot ID	Final Containers Distributed	Final Containers Returned	Doses Per Container	Initial Distribution Date	Expiration Date	Reporting Start Date	Reporting End Date	Package Lot ID	Distribution Flag	Distribution Type
1	444444	Product 4	1111-2222-66	**B**	FA	L10	400	0	1	03/06/2006	05/06/2007	04/01/2006	04/30/2006		D	I
1	444444	Product 4	1111-2222-66	**B**	FA	L10	400	0	1	03/06/2006	05/06/2007	04/01/2006	04/30/2006		D	I
1	555555	Product 5	1111-2222-66	**B**	FC	L11	600	20	1	03/02/2006	05/02/2007	04/01/2006	04/30/2006		D	I
1	555555	Product 5	1111-2222-77	**B**	FC	L11	600	20	1	03/02/2006	05/02/2007	04/01/2006	04/30/2006		D	I
1	666666	Product 6	1111-2222-88	**B**	FC	L11	600	20	1	03/02/2006	05/02/2007	04/01/2006	04/30/2006		D	I

* For this scenario only first Lot ID record presents actual totals distributed and returned. CBER load module will ignore totals after the first line that presents Lot ID.

EXAMPLE THREE: Sample File Layout for combined products distributed with a unique package ID. In this scenario, there are two separately licensed products with separately labeled containers (bulk, fill and label). These products are packaged and distributed under one distinct package identifier:

Manufacturer License	Folder ID	Product	NDC	Bulk Lot ID	Fill Lot ID	Label Lot ID	Final Containers Distributed	Final Containers Returned	Doses Per Container	Initial Distribution Date	Expiration Date	Reporting Start Date	Reporting End Date	Package Lot ID	Distribution Flag	Distribution Flag
1	333333	Product 3	1111-2222-33	B1	F1	L1	**50**	**5**	**1**	05/02/2006	05/02/2008	07/01/2007	09/30/2007	**P1**	D	I
1	444444	Product 4	1111-2222-33	B2	F2	L2	50	5	1	05/02/2006	05/02/2008	07/01/2007	09/30/2007	**P1**	D	I
1	333333	Product 3	1111-2222-33	B3	F3	L3	**40**	**0**	**1**	05/06/2006	05/06/2008	07/01/2007	09/30/2007	**P2**	D	I
1	444444	Product 4	1111-2222-33	B4	F4	L4	40	0	1	05/06/2006	05/06/2008	07/01/2007	09/30/2007	**P2**	D	I
1	333333	Product 3	1111-2222-44	B5	F5	L5	**50**	**5**	**5**	05/02/2006	05/02/2008	07/01/2007	09/30/2007	**P3**	D	I
1	444444	Product 4	1111-2222-44	B6	F6	L6	50	5	5	05/02/2006	05/02/2008	07/01/2007	09/30/2007	**P3**	D	I
1	333333	Product 3	1111-2222-44	B7	F7	L7	**40**	**0**	**5**	05/06/2006	05/06/2008	07/01/2007	09/30/2007	**P4**	D	I
1	444444	Product 4	1111-2222-44	B8	F8	L8	40	0	5	05/06/2006	05/06/2008	07/01/2007	09/30/2007	**P4**	D	I
1	555555	Product 5	5555-5555-55	B9	F9	L8	90	0	1	05/06/2006	05/06/2008	07/01/2007	09/30/2007		D	I
1	666666	Product 6	6666-6666-66	B0	F0	L0	80	8	1	05/06/2006	05/06/2008	07/01/2007	09/30/2007		D	I

APPENDIX 2 – FILE LAYOUT SAMPLE FOR NATIONAL DRUG CODE (NDC)

Folder ID	Product	Trade Name	NDC Code	Doses Per Container	Final Container Type	Final Container Product Amount	Final Container Product Amount Measure	Product Dosage	Dosage Measure	Presentation	Formulation	Label URL
123456	Product Name1	Trade Name1	0085-1279-01	1	Vial	0.5	mL	150	mcg	150 mcg/0.5 mL Single Dose Vial	dialysis	www.weblink.com
121212	Product Name2	Trade Name2	1234-0678-13	1	Syringe	1	mL	20	mcg	20 mcg/mL Single Dose Syringe	adult	www.weblink.com
454545	Product Name3	Trade Name3	1234-0678-17	5	Vial	5	mL	50	mcg	250 mcg/5 mL Multidose Vial	pediatric	www.weblink.com