ELECTRONIC SUBMISSION INSTRUCTIONS FOR BIOLOGICAL LOT DISTRIBUTION DATA (eLDD) in XML 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

Instructions for Pilot Lot Distribution Data Electronic Submission
Revised on 3/12/2008

TECHNICAL REQUIREMENTS

The purpose of this document is to provide manufactures validation and conformance rules for the submission of Lot Distribution Data (LDD) in the XML file format via FDA ESG. The concept of 'validation' is well-defined in XML to mean the successful parsing of an instance against the LDD Schema. In addition, an LDD report must also conform to the business rules outlined in this document.

LDD DATA VALIDATION

LDD validation includes three tiers. The detailed business rules for the first two tiers are presented in the following sub-sections of this document. The third tier involves a manual review of data elements by the FDA reviewers.

First Tier Validation

The first tier validation includes xml file validation, header and data element validation against LDD Schema for the submission files. **Failure of first tier validation prevents LDD from loading into the FDA database**.

File Validation Business Rules for Incoming LDD Submissions lists the rules used to check the LDD submission files. LDD will fail to load into the FDA database if any of the rules are violated.

File Validation Business Rules for Incoming LDD e-submissions.

No.	Business Rule
1	LDD submission files must be accessible (opened and copied) from the electronic submission media (e.g., CD-ROM) .
2	LDD submission files must have valid extension (XML) .
3	The LDD document must be validated against the LDD Schema
4	LDD submission file must be well-formed by the definitions of the XML 1.0 specification.

Note: LDD uses the Oracle Parser utility to parse and validate the LDD against schema. FDA recommends validation of xml file against the LDD schema prior submitting via FDA SEG.

Following link can be used for this task:

http://www.w3schools.com/dom/dom_validate.asp

Second Tier Validations

Second tier validation defined for the data elements validation business rules for incoming LDD e-submissions. LDD data will fail to load into the FDA database if any of the rules are violated.

The following LDD XML Schema should be used for Lot Distribution Data validation prior its' submission to the FDA.

FDA Provides the following Style Sheets for data viewing:

1. summary
2. detail

Lot Distribution Data Elements for XML file structure

Field Name	Field Description	Business Rules/Comments
Email	Email address for sending report confirmation to the submitter	• Required field • Field restricted to 300 characters
Manufacturer License	FDA-assigned US license number for the manufacturer of the product being reported in this row.	• Required 4 digit valid license number
Manufacturer Name	Applicant name registered with FDA	• Required data field • Data field length restricted to 200 characters
Reporting Start Date	Beginning of the reporting interval	• Required data element field must be formatted as YYYY-MM-DD.
Reporting End Date	End of the reporting interval	• Data element must be formatted as YYYY-MM-DD.
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 non-proprietary product name registered with FDA. This data will be used for verification of consistency between STN and identified product.	• 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 be presented as 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) If Doses per Container can't be presented use the value "0" (zero, without quotation marks) for the amount of dosage. We will use this value as

Field Name	Field Description	Business Rules/Comments
		an indicator to skip calculation for the number of doses distributed, and we'll count, instead, only the number of final containers.
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	Measurement amount of the final container product volume; 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	• Required character field • Field length restricted to 20 characters
Final Container Product Amount Measure	Measurement units of the final container product volume; 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	• Required character field • 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-	• Required character field • Field length restricted to 400 character

Field Name	Field Description	Business Rules/Comments
	holding comma or space for products with only one formulation.	
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
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.*
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
Bulk Lot Ingredient	Name of antigen or other ingredient in bulk lot. If multiple bulk lots contribute to each final container lot, as in a multivalent vaccine, then please submit a single row for each distinct combination of bulk and final container lots.	• Manufacturer specific character field • Data field length restricted to 15 characters • If each final container lot derives from only one bulk lot, the non-proprietary product name may be repeated here.
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

Field Name	Field Description	Business Rules/Comments
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 be presented as 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 be presented as a whole number.
Initial Distribution Date	Represents the initial distribution date for each final container lot	• Required data element field must be formatted as YYYY-MM-DD.
Expiration Date	Represents expiration date for each final container lot distributed	• Required data element field must be formatted as YYYY-MM-DD.
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) I = International? *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

The NDC data describe *finished products.* For example, although a combination vaccine like MMR has multiple components, the Product Dosage would be 0.5 mL (or other volume), without specification of the amounts of component antigens in each dose.

FILE FORMAT REQUIREMENTS

To ensure that the FDA can process data electronically, each submitted file should conform to the following general rules:

1. XML files should comply with XML standards as published by the World Wide Consortium (W3C).

2. Test your XML file. You must validate the file syntax against the LDD XML Schema posted on FDA's web site

3. Develop software and procedures to validate that the data you extract from your company database meets the individual field validation specifications in this document. Use the appropriate software to validate each XML document before submitting it to FDA.

4. For data viewing use the following XML style sheets
   - summary
   - detail.

5. File Naming Convention: Electronic file names should follow this format:

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

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