Electronic Submissions of Biological Product Lot Distribution Data

ELECTRONIC SUBMISSION INSTRUCTIONS FOR LOT DISTRIBUTION DATA (eLDD)

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

Providing Post marketing Lot Distribution Reports in Electronic Format

GENERAL INFORMATION AND LOT DATA SUBMISSION INSTRUCTIONS

1. INTRODUCTION

This procedure is intended to assist manufacturers of vaccines and other biological products to electronically submit post marketing lot distribution data to CBER's Lot Distribution Database (LDD). In the past, these data primarily came to CBER under 21 CFR 600.81 as paper reports. Conversion to uniform electronic submissions will improve accuracy, efficiency, and timeliness. We outline below the necessary file format, physical media, and submission procedures for the lot distribution reports.

2. 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)*.

Although FDA recognizes that the content and structure of each company database can and will differ, there are high-level steps that every organization needs to follow in preparing compliant files. Companies must map their output data to the specifications for the file and data layout. Instructions for mapping have not been included, since this is highly dependent on the structure and content of individual databases. Where feasible, values for each field should be drawn from FDA electronic data standards (http://www.fda.gov/oc/datacouncil/splncicodes.html). If no appropriate value appears to meet the needs for a particular product, requests for additional values should be submitted via: http://www.fda.gov/cder/dsm/Vocabulary_Change_Request_Form.pdf,

FDA accepts submission reports in two formats:

ASCII file format
This file format will be accepted from the manufacturers who previously submitted LDD reports in the ASCII format. FDA encourages manufactures to participate in the pilot program to convert the existing ASCII file submissions into the XML Format as the old ASCII format will be discontinued in the nearest future.

XML file Format
This is a new format and FDA encourages manufactures to participate in the pilot program to convert the existing ASCII file submissions into the XML Format

3. REPORTING REQUIREMENTS

Lot Distribution Data must be reported by the company that manufactures the product. In situations where a licensed manufacturer sells a product to a second manufacturer, if the second one conducts further manufacturing steps under its own license, such as packaging with a diluent or another primary product or modifying the package labeling, then the second manufacturer has the reporting obligation. Alternatively, if the second simply distributes the unchanged product to wholesalers, retailers, doctors' offices, and other parties, then the second is a distributor, and the first retains the reporting obligation. By understanding this difference, we can avoid receiving duplicate reports for the same product. CBER may grant waivers to allow alternative reporting arrangements on a case by case basis.
Distribution Type: The kind of distribution data reported may be Interval, Cumulative, or Anticipated Total. Interval refers to product distribution between the identified start and end dates. Cumulative would refer to reporting of all product distributed thus far (as of the end date provided), including amounts previously reported. Anticipated Total would describe an entire lot’s size, not all of which would necessarily have been distributed during a given reporting interval. For consistency with previous data submissions, LDD retains the distinction between these three types of distribution. However, CBER currently prefers that routine submissions employ the Interval format.

Please send any questions or comments you have concerning implementation to mailto:ldddistribution@fda.hhs.gov