



CLINSOFT CORP. 10 MAGUIRE ROAD, SUITE 110 LEXINGTON, MA 02421
TEL 781.778.3700 • FAX 781.778.3800 • WEB WWW.CLINSOFT.NET

9910 01 JUL -3 10:47

Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Robbert P. van Manen, M.Sc.
Worldwide Technical Director
Clinsoft Corporation
10 Maguire Road, Suite 110
Lexington, MA 02421

RE: Docket No. 01D-0185, CDER 200151

June 28, 2001

To Whom It May Concern:

The purpose of this letter is to submit comments regarding the 'Guidance for Industry: Providing Regulatory Submissions in Electronic Format – Postmarketing Expedited Safety Reports.'

After reviewing this draft guidance, there are several items that I would like to raise to your attention:

Section II.A:

"The FDA will implement E2BM in the near future."

- Has a date been determined when the FDA will require submissions to follow the E2BM format?

Section III.A.1 & Section III.A.1.a:

"Currently, the FDA is accepting E2B data elements with the M2 Specification version 2.24, DTD version 2.0 electronic transport format."

"Section B.2 of E2B is designated for reaction / event terms. For these fields, the FDA prefers that applicants use the Medical Dictionary for Regulatory Activities (MedDRA). For the E2B field, B.2.i.1, you should insert the lowest level term (LLT) in MedDRA that most closely corresponds to the term reported by the primary source. For the E2B field, B.2.i.2, you should insert the preferred term (PT) in MedDRA that corresponds to the LLT used in B.2.i.1."

- According to the ICH ICSR DTD Version 2.0, referenced in Section III.A.1 of this Draft guidance, the appropriate usage of these two E2B fields are as follows:

Data Element	Title
B.2.i.1	Reaction / Event as reported by the primary source
B.2.i.2	Reaction / Event term

01D-0185

C3



CLINSOFT CORP. 10 MAGUIRE ROAD, SUITE 110 LEXINGTON, MA 02421
TEL 781.778.3700 • FAX 781.778.3800 • WEB WWW.CLINSOFT.NET

The interpretation of these data elements has been to supply the verbatim term as reported by the reporter in B.2.i.1 and the MedDRA Preferred Term in B.2.i.2. This interpretation of Version 2.0 of the DTD contradicts the statements in the Draft guidance. Version 2.1 of the DTD in fact utilizes these Data Elements in the manner in which you describe, but the previous statement and earlier statements throughout the Draft guidance reference acceptance of Version 2.0 of the DTD.

Section III.A.1.b

“E2B field A.1.10.2 should be filled in by a company if:”

- There is no format provided for the information filled in by the company. What is required in this section? What comprises the sender identification? Should this be only the DUNS number?

“E2B field A.1.11.2 should be filled by the company if: (1) it receives an ICSR from another company AND (2) the report is subsequently sent to one or more entities.”

“The A.1.11.2 field should be used by all companies that receive an ICSR from another company (i.e. this field may contain multiple identification numbers.)”

- These two statements appear contradictory. The first statement places two conditions on filling in this field while the second only places one condition.
- How should multiple companies populate the one field? Is the DUNS number appropriate?

General

The endorsement of a process or testing tool used when checking syntactical correctness and file content would be helpful for companies when implementing this guidance.

I hope that the information contained in this letter is helpful. Should you have any questions or concerns, please do not hesitate to contact me at +1(781) 778-3908.

Regards,

Robbert P. van Manen, M.Sc.
Worldwide Technical Director
Clinsoft Corporation

200

FedEx USA Airbill
Express

FedEx
Tracking
Number

826329156656

Form
10.02

0215

Recipient's Copy

RECIPIENT: PEEL HERE

1 From This portion can be removed for Recipient's records.

Date 07/02/01 FedEx Tracking Number 826329156656

Sender's Name ROBBERT P. VAN MANEN Phone 781 778-3908

Company CLINSOFT

Address 10 MAGUIRE RD STE 110

City LXINGTON State MA ZIP 02421

2 Your Internal Billing Reference

3 To Recipient's Name Doc. MGT. BRANCH (HFA-305) Phone

Company FOOD AND DRUG ADMINISTRATION

Address 5630 FISHERS LANE, RM. 1061

To "HOLD" at FedEx location, print FedEx address. We cannot deliver to P.O. boxes or P.O. ZIP codes.

City Rockville State MD ZIP 20852



0173391022

4a Express Package Service

FedEx Priority Overnight Next business morning
 FedEx Standard Overnight Next business afternoon
 FedEx First Overnight Earliest next business morning delivery to select locations
 FedEx 2Day* Second business day
 FedEx Express Saver* Third business day
* FedEx Envelope/Letter Rate not available Minimum charge: One-pound rate

4b Express Freight Service

FedEx 1Day Freight* Next business day
 FedEx 2Day Freight Second business day
 FedEx 3Day Freight Third business day
* Call for Confirmation

5 Packaging

FedEx Envelope/Letter*
 FedEx Pak*
 Other Pkg. Includes FedEx Box, FedEx Tube, and customer Pkg.
* Declared value limit: \$500

6 Special Handling

SATURDAY Delivery Available only for FedEx Priority Overnight and FedEx 2Day to select ZIP codes
 SUNDAY Delivery Available only for FedEx Priority Overnight to select ZIP codes
 HOLD Weekday at FedEx Location Not available with FedEx First Overnight
 HOLD Saturday at FedEx Location Available only for FedEx Priority Overnight and FedEx 2Day to select locations
Include FedEx address in Section 3.

Does this shipment contain dangerous goods?

No Yes As per attached Shipper's Declaration
 Yes Shipper's Declaration not required
 Dry Ice Dry Ice, UN 1845
Dangerous Goods cannot be shipped in FedEx packaging. Cargo Aircraft Only

7 Payment Bill to:

Enter FedEx Acct. No. or Credit Card No. below.
 Sender Acct. No. in Section 1 will be billed.
 Recipient Third Party Credit Card Cash/Check Obtain Recip. Acct. No.

Total Packages

Total Weight

Total Charges

*Our liability is limited to \$100 unless you declare a higher value. See the FedEx Service Guide for details.

8 Release Signature

[Signature]

By signing you authorize us to deliver this shipment without obtaining a signature and agree to indemnify and hold us harmless from any resulting claims.

Questions? Visit our Web site at www.fedex.com

or call 1-800-Go-FedEx (800)463-3339.

Rev. Date: 7/01-Part #1659123 © 1994-2000 FedEx PRINTED IN U.S.A. GBFE 12/00

402