

ZLB



2026 '00 JAN 24 A9:09

**Zentrallaboratorium
Laboratoire central
Laboratorio centrale**

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Dockets Management Branch
HFA 305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

United States

Bern, January 20, 2000/mpm

*Rotkreuzstiftung
Zentrallaboratorium
Blutspendedienst SRK*

*Fondation Croix-Rouge
Laboratoire central
Service de transfusion
sanguine CRS*

*Fondazione Croce Rossa
Laboratorio centrale
Servizio trasfusione
di sangue CRS*

Docket No. 99D-4577

Comments regarding the Draft Guidance on the Application of Current Statutory Authority to Nucleic Acid Testing of Pooled Plasma (published: 11/26/99)

Dear Sir or Madam,

please find below our comments on the Draft Guidance for Industry on the Application of Current Statutory Authority to Nucleic Acid Testing of Pooled Plasma.

ZLB, Central Laboratory, Blood Transfusion Service SRC (Lic.647) as one of the largest manufacturers of plasma derivatives from US- Recovered Plasma agrees with the principle that the additional donor screening by a nucleic acid test method should be considered as donor screening and that therefore requirements regarding donor deferral and donor notification etc. are applicable. However we respectfully disagree with the assumption that any nucleic acid tests performed on plasmapools have to be considered as donor screening. Therefore we would like to suggest the addition of a clarification concerning the requirements for the NAT testing of plasmapools which consist of already tested plasma units or subpools (=minipools).

Under individual Short Supply agreements ZLB purchases recovered plasma from many licensed US blood banks. Since mid 1999 this plasma is „screened“ in minipools by HCV NAT. This NAT-testing is performed under an IND under the responsibility of the different centers.

At ZLB, plasma units from different centers are pooled to one large production plasmapool. Only plasma units, which have been certified to be tested negative at the collection center for the viral markers required by our specifications are pooled. As it is not feasible for a fractionator to retest each single plasma unit, we must rely on the



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certification of the collection centers, which are also audited on behalf of ZLB. As an additional safety measure ZLB performs an additional NAT test for HCV, HIV and HBV as an in-process control. If a plasmapool is found to be positive with these tests a deviation report is issued and the plasmapool will be discarded.

It will not be possible to trace and identify the original positive donation from these plasmapools, as the pool consists of approximately 12'000 donations from up to 30 different plasma collection centers. For this same reason the Draft Guidance states that „FDA does not consider final product testing of products made from pooled plasma to be donor screening, because it may be extremely difficult to ascertain the identity of individual donors.“ At the ZLB, this problem is not only applicable to the final product but also to the production plasmapool; we would not be able to meet the proposed requirements for donor deferral, donor notification etc. In this case we would be forced to stop testing our production pools for US products by NAT as an in-process control, which is neither the intent of the draft guidance nor within the scope of current Good Manufacturing Practices.

Therefore we would ask you to reconsider your position and to amend the Draft Guidance for Industry with a clarification stating that this Guidance is not applicable to production plasmapools and that an IND is only required for the first testing of a donation by a NAT method, when this test is performed with the intention of donor screening. Therefore all subsequent testing should be considered as in-process tests, which do not require an IND, and which in the case of a positive result do not require identification of the positive donor.

We highly appreciated the opportunity to submit our comments to this Guidance.

Sincerely yours

ZLB Central Laboratory
Blood Transfusion Service SRC


Dr. Andreas Gardi
Executive Vice President


Dr. Markus-Peter Müller
Head Compliance

FedEx International Air Waybill

0/100 11674673

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Address WANKDORF STRASSE 10 EE

BERN CH Postal Code 3014

2 Your Internal Billing Reference 1460

3 To

Recipient's Name _____ Phone _____

Company Food and Drug Administration

Address Dockets Management Branch HPA 305

5630 Fishers Lane, Room 1061

City Rockville State MD

Country USA ZIP Postal Code 20852

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Total Declared Value for Carriage	Specify Currency	Total Value for Customs	

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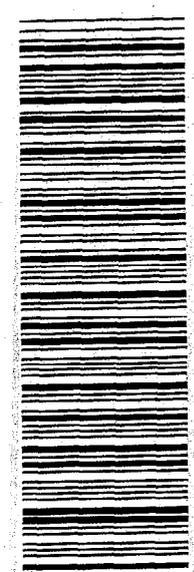
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Received At: <input checked="" type="checkbox"/> Reg. Stop <input type="checkbox"/> On-Call Stop <input type="checkbox"/> Drop Box <input type="checkbox"/> World Service Center <input type="checkbox"/> Station			Total Volume (cm) Forms Attached: <input type="checkbox"/> Ct <input type="checkbox"/> SED <input type="checkbox"/> CO
Base Charges <u>58564</u>	Declared Val. Chrg. Audit Emp. # _____	Other ODA/OPA Date <u>1/21</u> Time _____	Credit Card Auth. Del. Courier Emp. # _____ Date _____ Time _____

FedEx International Air Waybill

1 From
 Date 012100 Sender's FedEx Account Number 1860-8608-2

Sender's Name _____ Phone _____

Company ZENTRALLABORATORIUM SRK

Address _____

WANKDORF STRASSE 10 _____

BERN _____ Postal Code 3014

2 Your Internal Billing Reference
1460

3 To
 Recipient's Name _____ Phone _____

Company Food and Drug Administration

Address Dockets Management Branch WPA 305

5630 Fishers Lane, Room 1061

City Rockville State MD

Country USA ZIP Postal Code 20852

Recipient's Tax I.D. number for Customs purposes
 e.g., IN/VAT/EIN, or as locally required

4 Shipment Information ALL shipments can be subject to Customs charges.¹
 Total Packages 1 Total Weight 0.1 kg DIM L / W / H cm
Shipper's Load and Count/SLAC

Commodity Description	Harmonised Code	Country of Manufacture	Value for Customs
Documents			
Total Declared Value for Carriage		Specify Currency	Total Value for Customs

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Packages up to 68 kg
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 PW FedEx 10kg Box PX FedEx 25kg Box
These unique brown boxes with special pricing are provided by FedEx for FedEx Intl. Priority only.

7 Special Handling
 HOLD at FedEx Location SATURDAY Delivery
Available to select locations

Shipper must tick:
 This shipment does not contain Dangerous Goods.
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8a Payment Bill transportation charges to:
 Sender Acct. No. in Section 1 will be billed. Recipient Third Party Credit Card Cash Cheque
Enter FedEx Acct. No. or Credit Card No. below.

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8b Payment Bill duties and taxes to: *FedEx cannot estimate Customs charges.
 Sender Acct. No. in Section 1 will be billed. Recipient Third Party Cash Cheque
Enter FedEx Acct. No. below.

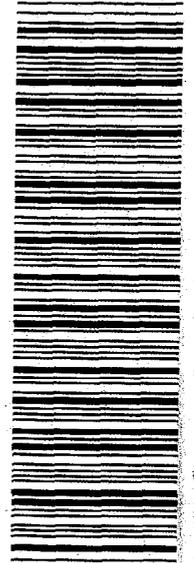
9 Required Signature
 Use of this Air Waybill constitutes your agreement to the Conditions of Contract on the back of this Air Waybill. Certain international treaties, including the Warsaw Convention, may apply to this shipment and limit our liability for damage, loss, or delay, as described in the Conditions of Contract.

Sender's Signature: F. Finkbein Date Executed 2/1/00
This is not authorisation to deliver this shipment without a recipient signature.

Received above shipment in good order and condition. We agree to pay all charges including Customs duties and taxes as applicable and to the Conditions of Contract as stated on the reverse side of the Recipient's Copy.
 Recipient's Signature: _____

FedEx Tracking Number 8155 6470 2402 Form I.D. No. 0405

Origin Station I.D. <u>BRN</u>	Destination Station I.D. <u>EDGA</u>	URSA Routing <u>XV EDGA</u>	Handling Units
Received At: <input checked="" type="checkbox"/> Reg. Stop <input type="checkbox"/> On-Call Stop <input type="checkbox"/> Drop Box <input type="checkbox"/> World Service Center <input type="checkbox"/> Station			Total Volume (cm)
Base Charges Val. Chrg. Declared Vol. Chrg. Audit Emp. #			Forms Attached: <input type="checkbox"/> CI <input type="checkbox"/> SED <input type="checkbox"/> CO
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