

*Aventis Pasteur*



0948 '02 JUN -3 19:31

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1060  
Rockville, MD 20852

**Re: Docket No. 00D-1542**

Draft Guidance for Industry on Electronic Records; Electronic Signatures, Time Stamps  
[67 FR 12999, March 20, 2002]

31 May 2002

Dear Sir/Madam:

Aventis Pasteur would like to thank you for the opportunity to comment on the above-referenced "Draft Guidance for Industry on Electronic Records; Electronic Signatures, Time Stamps." We offer the following comments for your consideration.

**Section 5. Key Principles and Practices**

**5.1.1 Synchronization**

*page 5*

In the fourth sentence which reads, "The network "master clock" or time server should, itself, be synchronized to a recognized standard computer clock," we recommend that FDA provide examples of what the agency considers to be a "...recognized standard computer clock."

For example, are any of the following clocks considered as a recognized standard?

- NIST-F1 Cesium fountain Atomic Clock
- UTC (Coordinated Universal Time)
- TAI (International Atomic Time)

**5.2 Systems Clock Security**

*page 5*

**00D-1542**

**C1**

Automated equipment and instruments lacking specific system clock security features are commonly in use in the pharmaceutical industry. These systems do not have "standard" operating systems (i.e., Windows, UNIX, etc.) We suggest a reference to such automated equipment/instruments in addition to the example of laptops in section 5.2.

*Aventis Pasteur*



**Section 6. Other Uses of Time Stamps In Electronic Recordkeeping**

*page 9*

We recommend that section 6 should be omitted from the guidance. Although this section contains examples of where time stamp-based controls may be helpful in implementing part 11 compliance, these examples do not represent agency expectations related to system controls, procedures, etc. and are therefore inconsistent with other sections of the draft guidance.

On behalf of Aventis Pasteur Inc., we appreciate the opportunity to comment on the Draft Guidance for Industry on Electronic Records; Electronic Signatures, Time Stamps and thank you for your consideration.

Should you like to discuss any of our comments or concerns, please address them directly to Joseph H. Quinn, Director, Operations & Regulatory Information Management, by telephone at (570) 839-4359, or by facsimile at (570) 839-5529, or by email at [joe.quinn@aventis.com](mailto:joe.quinn@aventis.com).

Sincerely,

A handwritten signature in black ink, appearing to read "Luc Kuykens", with a long horizontal flourish extending to the right.

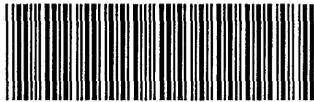
Luc Kuykens, MD, MPH, DTM  
Vice President, Regulatory Affairs, North America  
and Authorized Official

LK/JHQ/kh

PLEASE FOLD THIS SHIPPING DOCUMENT IN HALF AND PLACE IT IN A WAYBILL POUCH AFFIXED TO YOUR SHIPMENT SO THAT THE BAR-CODE PORTION OF THE LABEL CAN BE READ AND SCANNED.  
\*\*\*WARNING: USE ONLY THE PRINTED ORIGINAL LABEL FOR SHIPPING. USING A PHOTOCOPY OF THIS LABEL FOR SHIPPING PURPOSES IS FRAUDULENT AND COULD RESULT IN ADDITIONAL BILLING CHARGES, ALONG WITH THE CANCELLATION OF YOUR FEDEX ACCOUNT NUMBER.

FROM: Marlene Smith (570)839-4789  
Aventis Pasteur Inc.  
Discovery Drive  
Route 611  
Swiftwater, PA 183700187

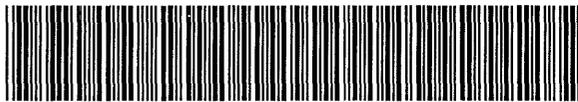
SHIPPER'S FEDEX ACCOUNT NUMBER



TO: Dockets Management Branch (301)827-6210  
FDA (HFA-305)  
5630 Fishers Lane  
Room 1060

SHIP DATE: 31MAY02  
MAN-WGT: 1 LBS

REF: 317588.6248300  
Rockville, MD 20852-



DELIVERY ADDRESS BARCODE (FEDEX-EDR)

CAD # 2735688

**PRIORITY OVERNIGHT**

**MON**

A2



TRK # 7904 3663 4828 FORM 0201

Deliver By:  
IAD 03JUN02

20852-MD-US

**ZM GAIA**

