

Aventis Pasteur



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

Re: Docket No. 01D-0435

International Conference on Harmonisation; Draft Guidance on Electronic Common Technical Document Specification [66 FR 59431, November 28, 2001]

25 February 2002

Dear Sir/Madam:

Aventis Pasteur Inc. would like to thank you for the opportunity to comment on the above-referenced draft guidance entitled "International Conference on Harmonisation; Draft Guidance on Electronic Common Technical Document Specification." The document defines the means for industry-to-agency transfer of regulatory information that will facilitate the creation review, life cycle management, and archiving of the electronic submission. We offer the following comments/clarification for your consideration.

Page 2-1: Directory Structure

Paragraph 1

Consider providing an example of what would be a "reasonable number" of entries (directories or files) per directory.

Paragraph 2

Consider noting that the maximum length of a directory name or a file name is 256 characters, as described on Page 2-6.

Page 2-2: Backbone

Paragraph 1

Recommend defining checksum (or MD5 checksum) in the Appendix 15 Glossary.

01D-0435

C1

3646 '02 FEB 28 PM 12:58

Aventis Pasteur



Page 5-1: Folder and File Naming Conventions for Module 2

Paragraph 1

This paragraph states that "the folder hierarchy for module 2 is presented in the screenshot in Figure 1." The correct reference is Figure 5-1.

Page 9-2: Table 9-3

Recommend including information on "example size of submission" for DVD format and stating which (if any) regulatory authorities are prepared to accept submissions in DVD format.

On behalf of Aventis Pasteur Inc., we appreciate the opportunity to comment on the draft guidance for industry on Electronic Common Technical Document Specification, and thank you for your consideration.

Sincerely,

for *Maurice W. Harman, Ph.D., etc*

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

LK/MWH/kh

FedEx®
FedEx®
FedEx®

FROM: KIM HENDERSON (570)839-4637
AVENTIS PASTEUR
DISCOVERY DRIVE, RT. 611
MB-1, 129 L
SWIFTWATER, PA 183700187

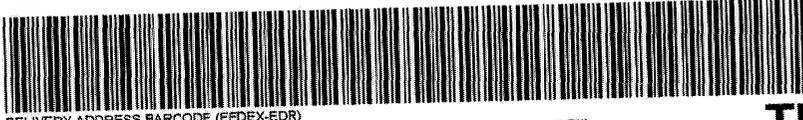
SHIPPER'S FEDEX ACCOUNT NUMBER



TO: Dockets Mgt Branch (HFA-305) (301)827-6210
Food and Drug Administration
5630 Fishers Lane, Rm 1061

SHIP DATE: 25FEB02
MAN-WGT: 1 LBS

REF: Rockville, MD 20852-
317588.6248300



DELIVERY ADDRESS BARCODE (FEDEX-EDR)

CAD # 2902850

PRIORITY OVERNIGHT

TUE
A2

TRK # 7903 2108 9970 FORM 0201

IAD

Deliver By:
26FEB02

20852-MD-US

ZM GAIA

