

Aventis Pasteur



6118 '02 AUG -2 19:14

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

Re: Docket No. 00N-1652

Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format [67 FR 22367, May 3, 2002]

01 August 2002

Dear Sir/Madam:

Aventis Pasteur Inc. is located in Swiftwater, PA, and is a subsidiary of Aventis Pasteur SA. Aventis Pasteur Inc. provides the broadest range of human vaccines and biologicals commercially available from any single U.S. vaccine company. It is a leading supplier of vaccines to protect against influenza, diphtheria, tetanus, pertussis, polio, Japanese encephalitis, yellow fever, *Haemophilus influenzae* type b disease, meningitis, rabies, and typhoid fever.

We would like to thank you for the opportunity to comment on the above-referenced proposed rule entitled "Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format." We offer the following comments for your consideration.

1. We are requesting clarification or confirmation that reference to the word "labeling" throughout the proposed rule refers only to the package insert or circular and that all other labeling components are excluded.
2. Under Section VI. Paperwork Reduction Act of 1995, through the request to comment on: "(4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology," we have the following comments:

As noted in the proposed rule, it was determined that less than 15 minutes of time will be needed to prepare content of labeling in electronic format for submission to the FDA. However, through our extensive experience and recent work on package inserts in Word format followed by conversion to PDF, we believe this is a considerable under-estimation of the time required to prepare the content of these labeling components.

00N-1652

Cb

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Quality assurance checks throughout the conversion process from Word documents to PDF file format must be completed as part of Aventis Pasteur internal policy. The process for completing these quality checks for consistency and accuracy is being further developed; however, we want to bring to your attention the fact that the process will be more time-consuming than presently understood, and in turn, more burdensome.

The initial conversion of the package insert (labeling) from Word to PDF file (Master PDF file) will require proofreading steps to ensure accuracy of copy content and text after completion of the PDF file conversion. This proofreading process takes from four to five hours to complete, dependant upon the length of the package insert. Once a Master PDF file is obtained, future PDF files for the same product package insert can be verified for accuracy based on that Master through electronic means, such as optical recognition. However, in the event that extensive modifications are incorporated to the labeling at any point, the proofreading quality assurance process will have to be repeated. Therefore, the hours and costs involved will be much greater than originally estimated within this proposed rule.

On behalf of Aventis Pasteur Inc., we appreciate the opportunity to comment on this proposed rule regarding the submission of labeling in electronic format and thank you for your consideration of these comments. Should you like to discuss any of our comments or concerns further, please address inquiries directly to Kenneth P. Guito, Director, Regulatory Policy and Intelligence, by telephone at (570) 839-4212, or by facsimile at (570) 839-5529, or by email at ken.guito@aventis.com.

Sincerely,

A handwritten signature in cursive script that reads "Kenneth P. Guito".

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

LK/KPG/kh

From: KIM HENDERSON (570)839-4637
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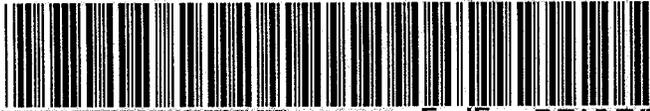
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