

Aventis Pharmaceuticals



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September 15, 2000

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

Re: Docket No. 00D-1306
Draft Guidance for Industry on the Content and Format of the Adverse Reactions Section of Labeling for Human Prescription Drugs and Biologics

Dear Sir/Madam:

Aventis Pharmaceuticals is submitting this set of comments on the "Draft Guidance for Industry on the Content and Format of the Adverse Reactions Section of Labeling for Human Prescription Drugs and Biologics" in response to the Federal Register notice of June 21, 2000.

General Comments

Although we appreciate that a clear distinction between adverse reactions and adverse events is aimed for, we have the impression that this system is not carried through in the draft. We should propose first to define how adverse reactions are identified and then base the recommendations on how to present the data on those defined adverse reactions only.

I. Introduction

In principle, Aventis Pharmaceuticals fully endorses the purpose of this initiative as stated in the Introduction – with emphasis on presenting what is important to prescribers in a clear and accessible form.

II. Adverse Reactions Section – Content and Format

The approach of presenting an overview supported by a subsequent more detailed analysis, and the discussion of how to go about it, also appears both realistic and helpful. Furthermore, this approach resembles the principles of the European approach on the respective issues which is valuable in the light of international harmonization.

II.B.2 Description of Data Source

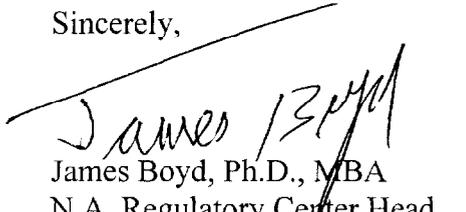
Concerning frequency of adverse reactions, we do not agree that all events should be the basis for frequency estimation (despite the given clear definition requiring at least possible relationship to drug use). This approach contradicts the concept of labelling only adverse reactions.

II.B.4 When Additional Tables may be Needed

Regarding the advice on tabular presentation, we accept the value of tables and advocate use of this format, however, we have some reservations concerning additional tables for e.g. dose response data, different populations, indications, formulations and/or for listing of less common adverse reactions. The potential exists that by endeavouring to include everything, the original concept of "conveying the important information clearly" will be lost - or at least diluted in an unduly lengthy section comprising both narrative text and multiple tables. Instead we would recommend specifying information for different patient groups in the narrative text if necessary.

On behalf of Aventis Pharmaceuticals, we appreciate the opportunity to comment on Draft Guidance for Industry on Content and Format of the Adverse Reactions Section of Labeling for Human Prescription Drugs and Biologics and thank you for your consideration.

Sincerely,



James Boyd, Ph.D., MBA
N.A. Regulatory Center Head
Global Drug Regulatory Affairs

Aventis Pharma AG, the pharmaceutical company of Aventis S.A., (NYSE: AVE), is dedicated to treating and preventing human disease through the discovery, development, manufacture, and sale of innovative pharmaceutical products aimed at satisfying unmet medical needs. Aventis Pharma focuses on important therapeutic areas such as cardiology, oncology, infectious diseases, arthritis, allergies and respiratory disorders, diabetes, and central nervous system disorders. The corporate headquarters of Aventis Pharma is in Frankfurt, Germany. In North America, Aventis Pharmaceuticals conducts the business of Aventis Pharma AG.