

**sanofi aventis**

Because health matters

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July 22, 2005

Via fax and UPS

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

Re: Docket No. 2005D-0169***Draft Guidance on Useful Written Consumer Medication Information***

Dear Sir/Madam:

Sanofi-Synthelabo Inc. and Aventis Pharmaceuticals, members of the sanofi-aventis Group, appreciate the opportunity to comment on the FDA *Draft Guidance on Useful Written Consumer Medication Information*. The guidance provides useful information concerning the continuing effort to reach the 2006 goal to provide helpful information to 95% of consumers.

We are proposing the following comments regarding the guidance for your consideration.

SPECIFIC COMMENTS:**Section III.A General Considerations**

Lines 144-147: CMI that adheres to the Action Plan criteria for a specific prescription drug will be considered useful when (1) the most recent FDA-approved professional labeling or package insert (PI) serves as the source document for the information contained in CMI...

Often, in the case of important safety changes to the professional labeling, revised labeling is implemented prior to FDA approval. In these cases the labeling is submitted to FDA as changes being effected according to 21CFR 314.70 (c)(2) and is considered as current labeling by the sponsor. Consideration should be given to using the current labeling in use by the sponsor rather than the most recently approved labeling. This will result in the most up-to-date safety information being available for the consumer.

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Section B. Specific Recommendations for Each Action Plan Criteria, Criterion 1

Lines 185-187: *All FDA-approved indications listed in the PI for the medication. Information on unapproved indications should only be included in CMI customized for individual patients.*

Inclusion of unapproved indications or indications not listed in the PI for the medication should be discouraged and not be included in CMI. Addition of unapproved indications could lead to confusion on the part of the consumer, and may not provide the proper dosage instructions and important safety information related to unapproved uses.

Section B. Specific Recommendations for Each Action Plan Criteria, Criterion 3

Lines 235-237: *If specified in the PI, include information on how to use the medication, such as whether to take it with or without food or water, time of day to take the medication, and any other instructions...*

In the case of complicated dosage or administration instructions, consideration could be given to provide a statement such as "Follow your doctor's instructions" rather than trying to explain complicated dosage steps, such as dosage titration.

Section B. Specific Recommendations for Each Action Plan Criteria, Criterion 8

Line 387: *Use short paragraphs and bullets where possible.*

Consideration should be given to revising to "Use short directive paragraphs and bullets where possible" (e.g., Take your medicine. Call your doctor.).

On behalf of Sanofi-Synthelabo Inc. and Aventis Pharmaceuticals, members of the sanofi-aventis Group, we appreciate the opportunity to comment on the *Draft Guidance on Useful Written Consumer Medication Information* and are much obliged for your consideration.

Sincerely,



Steve Caffé, M.D.
Vice President, US Deputy Head
Regulatory Development