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Because health matters

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February 24, 2006

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. 2005N-0354

Consumer-Directed Promotion of Regulated Medical Products; Public Hearing

Dear Madam or Sir:

Sanofi-aventis U.S. Inc, a member of the sanofi-aventis Group, submits these comments in response to the above-referenced notice of public hearing on direct-to-consumer (DTC) promotion of regulated medical products.

1. ***Does current DTC promotion present the benefits and risks of using medical products in an accurate, non-misleading, balanced, and understandable way?***

i. *Can indications of a drug product or device be effectively communicated to a layperson?*

Yes. We believe that the indication should be presented at a level that is comprehensible to the general public and consumers. One way this can be accomplished is by presenting the indication in language that can be understood at a sixth grade reading level.

ii. *Does providing more information about the disease help consumers understand the use of the drug/device better?*

Yes. Providing additional information about a particular disease state can raise consumer awareness of signs and symptoms and, therefore, assist the consumer in better understanding the correct and appropriate use of a pharmaceutical product/medical device. We believe that this exchange of information should be part of a comprehensive program that includes subject matter available in various media, such as websites, print material, television advertisements, video news releases, etc.

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iii. Why consumers and healthcare providers may believe that the risk information is not being communicated as clearly as benefit information, even though that information is present?

Generally, we believe consumers want to understand their personal risks when considering a medical product as opposed to all possible risks. It is critical that the health care provider discuss the individual risks with his/her patients. Perhaps Major reasons risks may not be as clearly understood as the benefits is due to the way risks are communicated and the amount of risk information given in any particular consumer directed promotion. At a minimum, risk information should be communicated in language clearly understood by the consumer. One way to accomplish this is to apply a standard that would apply to all risk information (i.e. all risk information should be presented at a sixth grade reading level). In addition, the amount of risk information currently presented in consumer directed communication is overwhelming. Consumers are bombarded with multiple warnings, precautions, side effects, etc. that together, tend to diminish the most important risk information. One proposal would be to limit the amount of risk information presented, focusing on the most significant or important.

Some of the review groups within DDMAC already utilize a preference of conveying the risk information throughout the print or television advertisement instead of at just one location. This risk information should be conveyed with limited distraction from overlying text, voice over or any other distracting graphical representations.

iv. Do advertising techniques mislead consumers about risk information?

We object to the term mislead. Mislead is defined by Webster's II New College Dictionary as "to lead into error or wrongdoing: Deceive." We do not believe that advertising techniques are intentionally designed to misinform consumers. This needs to be assessed on a case-by-case basis. Nonetheless, there needs to be a more effective means of communicating the risk information to the consumers. The presentation of the risk information should not compete with other messages on the advertisement and should be clearly presented to ensure readability and understanding of the risk information presented. This information should encourage and facilitate a discussion between the physician and the patient.

v. *Can scientific information comparing two products be conveyed in a way that is informative to consumers without an advanced education, and how well are companies currently doing this?*

In accordance with FDA regulations, comparative information needs to be based on (generally) adequate and well-controlled trials. Although we believe that consumers do understand some comparative claims, we believe that they might not appreciate the benefits of comparative claims based on these types of trials. Usually, consumer directed promotional materials that contain comparative claims present these in a succinct manner as one or two lines of copy announcing the competitive advantage. This should always be conveyed at and appropriate age level. Rarely do these types of promotions include the particulars of the data that support the comparative claim. We believe that there is a concern presenting complex scientific information about data used to support a comparative claim to the public.

It is important to note that comparisons do not always imply superiority, but provide consumers and physicians the ability to understand important differences between products and empower the physician to make a more informed decision for their patients. Therefore we would favor the presentation of comparative information that is rooted in scientific investigations defined by the agency as adequate in a non-scientific manner to consumers.

vi. *What is the potential role of reminder ads?*

The role of reminder ads is to inform consumers about a product that they may want to discuss with their healthcare provider. The purpose, in many cases, is to reinforce name recognition for a product.

2. ***Could changes in certain required prescription drug disclosures--the package insert for print "promotional" labeling and the brief summary for print advertisements--improve the usefulness of this information for consumers?***

The prescribing information and brief summary of some products, such as allergy medications, are more easily understood by consumers. However the FDA should consider allowing the industry to have the option of utilizing a consumer friendly brief summary or the professional brief summary depending on the product information. This could facilitate the patients' understanding of the risk information more clearly. Reformatting the brief summary to focus on the most common and most severe information by replacing technical and scientific terms into consumer-friendly language would improve the usefulness of this information to the consumer. At a minimum, the following sections would need to be translated into consumer-friendly language: Boxed Warnings, Contraindications, Warnings/Precautions and the most common Adverse Events.

3. ***Could changes in the requirements for disclosure of certain information in broadcast advertising improve the usefulness of this information for consumers?***

   We believe the current provisions designed to provide prescribing information for consumer directed advertisements and promotion are adequate, however as discussed in 1. iii. above, creating a standard for presentation of risks and limiting this information to that which would be most significant for the consumer would help make this type of information more useful.

4. ***Is there a way to make information in DTC promotion of medical devices more useful to consumers?***

   DTC promotions for medical devices should contain a consumer friendly statement on the device's intended use while presenting risk information in a balanced manner. If the promotion's target is the consumer, a statement articulating the device's most important warnings, precautions, side effects and contraindications should be presented in a manner that is easily understood by the consumer.

5. ***As new communication technologies emerge, they create opportunities for novel approaches to DTC promotion. What issues should the agency consider with regard to the effect of these technologies on DTC promotion?***

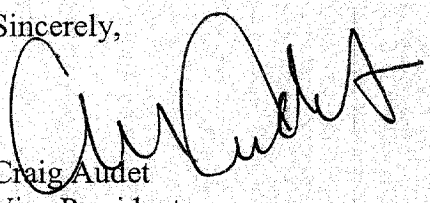
   This must be addressed on a case-by-case basis as new technology is developed. However the agency needs to minimize regulatory uncertainty by providing timely guidances on the use of new technologies such as the Internet, PDA, e-detailing methods and all future new technological advancements. The agency needs to focus on how the adequate provisions will be met as well as the DTC promotion meeting all other regulatory requirements. This will help to ensure that the industry is on par with the current way of thinking at the agency and make certain that patient safety and concerns are not compromised.

6. ***What action should FDA take when companies disseminate violative promotional material to consumers?***

   The agency has adequate enforcement tools available to address potential violative consumer directed advertising and promotional materials. We believe FDA should utilize these tools in regulating violative promotional materials. We also believe however that the agency should encourage closer cooperation with advertisers through agency mediated working groups and information sessions. For example, in the past, FDA's DDMAC used to host an industry forum where issues could be discussed and FDA's positions presented. In addition, there should be a collaborative effort with the FDA and the industry to increase the interaction with one another prior to the issuance of the first letter. This can only lead to enhanced consumer protection and safety.

Sanofi-aventis appreciates the opportunity to comment in response to the notice of public hearing on direct-to-consumer (DTC) promotion of regulated medical products.

Sincerely,



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