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



RE: [Docket No. 02N-0131]

Notice: Agency Information Collection Activities; Proposed Collection; Comment Request; Generic FDA Rapid Response Surveys

Merck & Co., Inc. is a leading worldwide, human health product company. Because of Merck's corporate strategy of discovering new medicines through breakthrough research, we spend more than \$2 Billion annually on worldwide research and development (R & D). Through a combination of the best science and state-of-the-art medicine, Merck's R & D pipeline has produced many of today's important pharmaceutical products.

Merck supports regulatory oversight of product development that is based on sound scientific principles and good medical judgment. Regulators must be reasonable, unbiased and efficient when they review the quality, effectiveness and safety of our products. It is in the interest of the public health to see that important therapeutic advances reach patients without unnecessary or unusual delays.

In the course of the life-cycles of our products, we have wide experience in monitoring post-market safety information, obtaining and evaluating follow-up information, and responding appropriately to signals generated from this information to help assure the continued safe use of our products. Therefore we are qualified to comment the April 30, 2002, proposed collection of information cited above.

General Comment:

We commend the Food and Drug Administration for taking a leadership role in risk management related to pharmaceutical products and for seeking new tools to improve the safe use of medical products. We also appreciate the opportunity to comment on the proposed "generic rapid response surveys."

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The April 30, 2002 notice seeking public comment on generic rapid response surveys provides no description of the surveys being proposed, the nature of the information to be sought, the respondents to whom the surveys will be sent, the "triggers" for issuing a survey, or proposed use of the results of these surveys. Therefore, it is impossible to provide comments on the issues identified in the notice, specifically: (1) whether the proposed collection of information is necessary, including whether the information collected will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection, including the validity of the methodology and assumptions; (3) ways to enhance the quality, utility and clarity of the information to be collected; or (4) ways to minimize the burden of the collection. We recommend that the notice be reissued with adequate details about the

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proposed collection of information to enable the public to understand the proposal so that comments can then be made to the Agency based on full knowledge of the proposal.

While we are unable to comment on the issues identified in the notice regarding this proposal without further details, the notice causes us some general concerns which we have summarized below for your consideration.

1. Risk management requires the involvement of all stake holders, including government, industry, health-care professionals, and patients. The role of industry is clearly recognized in the draft goals for the reauthorization of the Prescription Drug User Fee Act (PDUFA 3). On the other hand, based on the limited information in the notice, the role of the sponsor of a medical product identified for a rapid response survey is not clear. As described, however, the sponsor appears to be left out of this process.
2. It is unclear to whom the surveys will be directed. Although the notice identifies general groups ("community based health care professionals, general type medical facilities, specialized medical facilities, other health care professionals, patients, consumers, and risk managers working in medical facilities"), there is no discussion of how members of these groups will be identified to participate in the surveys.
3. The voluntary nature of the surveys risks the collection of potentially confounded, biased and unconfirmed information on which, according to the notice, the agency intends to "take appropriate public health or regulatory action."
4. The notice doesn't address the mechanism by which the surveys will produce "rapid responses" from those surveyed. Whether the surveys will be conducted by mail, facsimile, telephone, or the internet, there is a need to validate the source(s) and medical accuracy of the information provided. One of the hallmarks of responsible risk management is confirmation of the information upon which decisions are based. Decisions should not be based on information gathered in haste if/when the source and validity of the data have not been confirmed.

Conclusion:

In the absence of further details about the proposed generic rapid response surveys, it is impossible for the public to offer reasoned comments in response to this notice. We oppose this information collection until a more complete explanation of the proposal is provided. As currently constituted, the notice seeks a "blank check" for authorization of information collection.

In addition, the implications of the proposal raise concerns that sponsors will not be included in this process, and that information gathered may be biased and impossible to validate. Such information should not be the basis of public health or regulatory actions.

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We welcome the opportunity to comment on this notice and, if appropriate, to meet with you to discuss these issues.

Sincerely,

A handwritten signature in black ink that reads "David W. Blois". The signature is written in a cursive style with a prominent initial "D".

David W. Blois, Ph.D.
Senior Vice President
Global Regulatory Policy