

November 29, 2005



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

**RE: 2005D-0385 Draft Guidance for Industry on Using Electronic Means to Distribute Certain Product Information; Availability**

Merck & Co., Inc. (Merck) is a leading worldwide, human health products company. Through a combination of the best science and state-of-the-art medicine, Merck's Research and Development (R&D) pipeline has produced many important pharmaceutical products available today. These products have saved the lives of or improved the quality of life for millions of people globally.

Merck Research Laboratories (MRL), Merck's research division, is one of the leading biomedical research organizations in the world. We have extensive experience in the development, licensure, and marketing of medical products. We also have experience in providing product information to patients, medical professionals, and regulatory health agencies and have used that experience to author the comments below.

The above-referenced draft guidance states that FDA's interpretation of 21 CFR §§ 7.49 and 200.5 provides for "the use of email and other electronic communication methods, such as fax or text messaging, to accomplish any recall notification or distribution of important safety information." Merck recognizes the importance of notifying the public of voluntary recalls in a timely manner. Although this can be completed through electronic delivery, there are risks that should be considered when utilizing electronic delivery mechanisms. Below, we have identified several areas that we believe the Food and Drug Administration (FDA) should consider before finalizing this draft guidance.

One of the highest risks associated with electronic delivery mechanisms includes, but is not limited to, "spoofing." "Spoofing" includes illegitimately claiming to be an entity or authority, e.g., illegitimately claiming to be the originator of a medical product-related action. The act of "spoofing" is particularly problematic in that a "spoofed" recall notice may be distributed giving the appearance that it is genuine and from the product registration holder, when, in reality, it is merely a forged or fake recall notice. The risk that a mal-intentioned person or entity could take part in distributing a false recall notice is high. Without appropriate regulation, misinformation may be disseminated causing, at

**RE: 2005D-0385 Draft Guidance for Industry on Using Electronic Means to Distribute Certain Product Information; Availability- page 2**

a minimum, confusion to the marketplace and even potentially undue harm to patients caused by potential product shortages resulting from an unwarranted recall.

To mitigate this risk, proper validation of the authenticity of a recall communication prior to dissemination should be required. Merck recommends that FDA take appropriate steps in providing a validated secure communication process for product recall communications. To that end, FDA currently provides a website that allows health care professionals and healthcare providers to register for and receive recall communications via an electronic list (E-list). By using this website, the originator of a product recall message is validated by the FDA prior to posting, which minimizes the risk of falsification of the originator. A common process for validating electronic recall notices, provided by FDA, could be leveraged by pharmaceutical companies by using a digital signature and a trusted Certification Authority. Another option for the Agency to consider to minimize the risk of spoofing may be the development of a secure web service for officially validating and posting product recalls, similar to the clinical trials website ([www.clinicaltrials.gov](http://www.clinicaltrials.gov)). This could be set up as a restricted site (i.e., “read-only” access) to physicians or a broadly accessed site for the population at large, but would at a minimum provide current validated status of product recall information.

Another potential risk that should be considered is related to the “gatekeeper” concept introduced by FDA in the above-referenced draft guidance. The draft guidance states that paper-based communications do not consistently reach their intended recipients. The draft document addresses the probability that “gatekeepers” (e.g., mailroom clerks, administrative associates, secretaries, receptionists, etc.) discard important product communications as “junk mail”. This consideration is also true for electronic communications, possibly even more so with the rise of Unsolicited Bulk Electronic-mail (UBE) (a.k.a. SPAM). The public is becoming more aggressive in deleting unwanted and unsolicited electronic communications, often by automating this task through the use of email settings available on most email services. Although more conventional forms of product recall information (e.g., letters) may be susceptible of being discarded as “junk mail”, electronic communications may be even more susceptible to automated deletion. Consumers are more likely, however, to read electronic communications that they have opted to receive, such as the e-list already managed by the FDA. Therefore, we recommend that FDA include in the final guidance instructions to find and sign-up for its E-list site. This will ensure that healthcare professionals and healthcare providers are advised of medical product actions by authenticated sources of information.

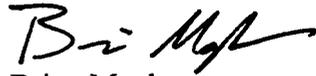
While Merck agrees with the intent of the draft guidance, we believe the above-identified issues should be resolved before FDA moves forward with the draft guidance’s recommendations. Due to the risks previously identified for electronic dissemination of such information, Merck intends to continue product recall notifications pursuant to 21 CFR § 7.49. Merck would like FDA to consider requiring or making available a validated electronic communications system which includes risk mitigation technologies, such as a digital signature which requires verification and authentication of the sender, before the

**RE: 2005D-0385 Draft Guidance for Industry on Using Electronic Means to Distribute Certain Product Information; Availability- page 3**

industry is encouraged to use e-mail as a means of electronic dissemination of product recall information.

We appreciate the opportunity to work with the Agency on this important initiative. Please feel free to contact me if you should encounter any questions regarding our comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Brian Mayhew". The signature is fluid and cursive, with a prominent initial "B" and a long, sweeping tail.

Brian Mayhew  
U.S. Regulatory Policy