

ABBOTT

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Division of Dockets Management (HFA-305)
Food and Drug Administration
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Rockville, MD 20852

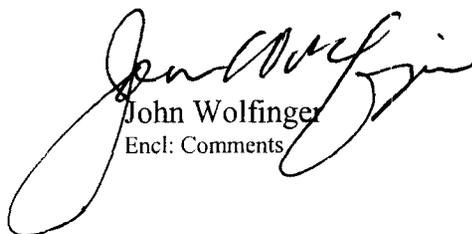
Ref: Docket No 2005D-0385 Draft Guidance for Industry on Using Electronic Means to Distribute Certain Product Information

To Whom it May Concern:

Abbott is very pleased to have the opportunity to provide comments on the Draft Guidance for Industry on Using Electronic Means to Distribute Certain Product Information published on September 30, 2005 in the Federal Register.

We thank the Food and Drug Administration for your consideration of our comments. Should you have any questions, please contact Kathy Wessberg (tel: 847-938-1264, e-mail: kathy.wessberg@abbott.com).

Sincerely,


John Wolfinger
Encl: Comments

2005D-0385

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ABBOTT COMMENTS TO FDA ON

Docket No. 2005D-0385

COMMENTS

General Comments:

Abbott agrees there are many positive aspects to being able to handle the communication of recalls or urgent safety information electronically as mentioned in the draft guidance, such as reducing time and costs. These are beneficial for both the firms and the customers. However, with the cost barrier lowered, the potential is increased for the entry of false or incorrect communications to be made to customers and possibly the public at large.

Currently there are laws protecting firms and the public against fraudulent activity using current means of communication, such as the US Postal Service. Abbott is concerned that such protections do not exist to discourage the dissemination of fraudulent information electronically, such that nefarious parties could disseminate false information that could potentially harm the public. For example, anyone can type "URGENT RECALL" in a subject line and proceed to collect recipients' information or provide false information. To this point, FDA should encourage firms to build in safeguards to assure that a customer can verify the legitimacy of the firm's own electronic communication. We recommend FDA address this concern in the guidance. An additional system may be needed to confirm an electronic notification.

Specific Comments:

II. Background

Last sentence of the second paragraph:

"If receipt is never acknowledged, the sender can resort to more traditional methods of notification."

Proposed change:

The phrase "never acknowledged" is ambiguous.

Reword to: "If receipt is not acknowledged within the company's expectations, the sender can resort to more traditional methods of notification."



ABBOTT COMMENTS TO FDA ON

Docket No. 2005D-0385

III. Agency Position on Use of Electronic Communications

The last paragraph references a few sources (21 CFR 7.49(b) and 21 CFR 200.5) to obtain formatting and specifications that should be used to “the extent possible”. Since these sources refer to letters and envelopes, they are generally inapplicable to electronic communications.

For the same reasons stated above in our General Comments, and the fact that Healthcare Professionals are frequently spammed with numerous e-mails regarding pharmaceutical products, a standard format is beneficial to ensure attention is given to these important notifications and they can be easily distinguished from other electronic communications. Consistency among firms would also aid the customers in easily identifying important recall and product safety notifications. We recommend format information be specific to electronic notification of recalls and urgent safety information.