CHPA

founded 1881

November 6, 2009

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

Re: Docket No. FDA-2009-N-0247
FDA Transparency Task Force; Public Meeting; Request for Comments, 74 Fed. Reg. 51161 (October 5, 2009)

Dear Sir or Madam:

In the October 5, 2009, *Federal Register*, the Food and Drug Administration invited comments on the above-referenced public meeting, which sought views on considerations and principles the agency should consider with respect to communicating to the public about emerging safety issues concerning FDA-regulated products.

The Consumer Healthcare Products Association (CHPA), founded in 1881, is the national trade association representing manufacturers and distributors of over-the-counter (OTC) medicines and dietary supplements in the United States. As FDA notes in the meeting notice and request for comments, FDA may communicate with the public about ongoing safety reviews of drugs, or may issue an early communication about a dietary supplement. As such, we have an interest in the subject matter discussed in the notice and at the meeting. CHPA took part in the discussion group on emerging safety issues concerning FDA-regulated products on November 3, 2009, and we appreciate the opportunity to reiterate or expand on some of the comments made during the discussion.

1. FDA should apply principles on communicating about emerging safety issues consistently within product categories.

As the agency has discussed in other contexts, such as the Strategic Plan for Risk Communication, the agency should have both processes and criteria to better define when and under what circumstances they will issue statements or otherwise actively disseminate information on emerging safety issues. See http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm183673.htm.

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2. Communicating about emerging issues requires active issues management.

The very act of issuing a statement on an emerging safety question triggers a need for the agency to take part in a continuing communication stream – an ownership interest, if you will, in the on-going conversation which follows. This includes providing the public with an expectation of what steps may follow, and providing further information as the questions at-hand in the early communication are answered or otherwise addressed.

FDA statements on emerging issues need an action step or, stated differently, "news you can use." That is, what is the agency's expectation on what a consumer or patient is supposed to do with the information? If there is no intended action on the part of the message recipient, then the agency should not issue a statement or at least be explicit on what the message does not mean. If a message cannot meet this criterion, it speaks to the need for processes and criteria around communicating on emerging issues in the first instance.

The need for an action step is further illustrated in the case of OTC medicines contrasted with prescription medicines. Unlike the case of prescription medicines, for OTCs, there is no built-in interpreter – ie, the prescriber – for the end user for messages on emerging questions. It is true that, in the case of an OTC medicine, the end user can ask a healthcare professional about questions they may have, but that assumes they have access to a healthcare professional and that the healthcare professional has sufficient context on which to guide them. This is unlike the prescription situation where the prescriber made a treatment decision in the first instance.

Given that the very purpose of issuing statements on emerging issues is to let the public know of the information and to give them advice or information to act on, we believe it is in the agency's interest to leverage such statements or messages through other interested parties. In the case of a drug or dietary supplement, or a class of drugs or supplements, this includes the parties about whom the message is being communicated: The manufacturers or sponsors. We believe it is in the agency's interest to provide manufacturers with advance notice (even if it is only hours) of messages so that the manufacturers can be better prepared to speak to those same issues. This point is recognized in the call within the agency's Strategic Plan for Risk Communication to "optimize policies for engaging with partners to facilitate effective communication about regulated products." Id.

Finally, as part of its communication, FDA should provide an expectation on what the next step is likely to be.

3. Recognize the "law of unintended consequences."

Imbedded within the need to include an action or "news you can use" within a statement on an emerging issue, FDA should recognize that without clear direction on what a consumer should do with the information, confusion and unintended consequences can result. This can include unfounded actions being taken by consumers not only in the U.S., but beyond as well, where there is even less context in which to interpret the information FDA has released. Regulatory authorities outside the U.S. are among those who may react on information provided by FDA on an emerging issue without a full understanding of the context. This again emphasizes the need for clarity in communication.

To conclude, FDA should apply communication principles consistently, engage in on-going communication once a decision has been made to put out a message on an emerging issue, provide the message recipient with an action step, give the party about whom the message is being communicated advance notice, and recognize the risks of unintended consequences.

Thank you for the opportunity to take part in the emerging issues discussion group and to provide these views.

Sincerely,

/s/

David C. Spangler
Senior Vice President, Policy
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