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July 20, 2010

Transparency Task Force
U.S. Department of Health and Human Services
Food and Drug Administration
(Submitted via www.regulations.gov to Docket FDA-2009-N-0247))

Dear Sir or Madam,

Enclosed herein are comments on “FDA Transparency Initiative: Draft Proposals for Public Comment Regarding Disclosure Policies of the U.S. Food and Drug Administration”¹. The Consumer Healthcare Products Association (CHPA) is the national trade association representing the leading manufacturers and distributors of over-the-counter (OTC) medicines and dietary supplements in the United States. CHPA and its members support the Transparency Initiative and support FDA’s goal of facilitating transparency that promotes public health and innovation, while maintaining confidentiality of trade secrets and individually identifiable patient information. FDA states that the Task Force “weighed the public interest in disclosure of additional information and the public interest in confidentiality (including potential competitive interests)”. Many of our comments reflect the competitive environment for OTC medicines, where the majority of products are not protected by patents. Confidentiality of information is critical to innovation and the ability to recover the substantial investment in new product development.

Prioritization

FDA requested input on how the Agency should prioritize the proposals. CHPA and its members support prioritizing those proposals most likely to impact the public health, followed by those that disclose information of interest to the public without risk of unintended consequences, such as prematurely damaging a company’s or a product’s reputation. Proposals that offer no benefit to public health or that carry significant risk of disclosing competitively sensitive information, hence, affecting innovation, should be reconsidered for any action.

Specifically, we support and recommend the following proposals have the highest priority for implementation:

¹ **Federal Register**, Vol. 75, No. 98, pp 28622-3, May 21, 2010.

- Proposal 2 (individual consumer comments posted on www.regulations.gov in the same manner as other comments)
- Proposal 4 (disclosure of Agency work plans older than 5 years)
- Proposal 5 (disclosure of the outcome of the filer evaluations for importers or third parties working on behalf of importers)
- Proposal 6 (disclosure of inspection reports)
- Proposal 7 (disclosure of the most common inspectional observations made during inspections of FDA-regulated establishments)
- Proposal 18 (communication of information related to product recalls)
- Proposal 19 (communication of information related to products not affected by recalls)
- Proposal 20 (communication of recall termination)
- Proposal 21 (posting of untitled letters/responses)

Comments on Specific Proposals

We offer the following comments on the individual proposals that likely have little or no public health benefit or are likely to negatively impact a sponsor due to disclosure of sensitive, confidential, or trade secret information.

Proposal 1 – Adverse Event Reports

Providing the public with better tools to summarize data in AERS is not likely to advance the public health. Information about adverse events, alone and in the absence of an analysis of their association to the FDA-regulated product, has the potential to lead to significant unintended consequences when summarized and interpreted by consumers rather than by FDA and the product's manufacturers. The specific product involved in the adverse event is frequently unknown or reported in error and many times more than one drug is involved in the adverse event. The public is not sufficiently educated to interpret these data or sort out a causal relationship, especially when more than one drug is involved. Total adverse events cannot be determined from the AERS database due to lack of mandatory reporting from various sources. Likewise, the rate of adverse events cannot be determined from AERS due to lack of "denominator" data representing the amount of product used over a period of time. Presentation of summary information only without knowing the "denominator" could mistakenly appear to the public that one product is safer than another when this might not be the case. Disclosure of adverse event information, interpretation of data, and discussion of appropriate actions, if any, should be handled between FDA and a product's manufacturer.

Proposals 8-17

The protections set forth in current law represent the correct balance between disclosure of information and maintaining confidentiality. Innovation in the OTC medicine field is highly dependent on confidentiality of information. Patent protection is rarely available for products regulated under the OTC Monograph system. For products regulated under NDAs, such as Rx to OTC switches, confidentiality of information, even about the existence of a

development program, is essential to protecting the significant investment to switch these drugs into the OTC market.

Proposal 8 – Disclosure of Investigational Applications

We disagree with FDA's reasoning that there are important public health benefits to disclosing the existence of investigational applications received by FDA. Truly important public health benefits are realized after the approval, and subsequent marketing, of a product. FDA's contention that disclosure of information pertaining to clinical trials is important is correct, and there are many ways for potential patients to identify opportunities to participate in clinical trials today (e.g. www.ClinicalTrials.gov), without additional disclosures from FDA. Especially for products regulated under the OTC Monograph system, where patent protection is not common, disclosure of information related to investigational applications can provide competitors an advantage by providing access to previously unavailable information about products under development. This would be a disincentive to innovation.

Proposal 9 – Clinical Trial Holds, Withdrawals and Terminations

The status of clinical trials can be communicated via government databases (e.g. www.ClinicalTrials.gov), rather than via separate communication about the status of an investigational application. Efforts should be focused on ensuring that all appropriate clinical trials are disclosed to the public, rather than creating new disclosure systems for investigational applications. Disclaimer statements about the limits of the information may not be understood by the general public.

Proposal 10 – Existence or Non-Existence of Marketing Applications

FDA should not deviate from its current disclosure policy. The existence of a marketing application for a drug should not be disclosed by FDA unless the application has been previously publicly disclosed or acknowledged by the sponsor. Early disclosure about the status of a particular product in development could give competitors an advantage by providing access to previously unavailable insights (e.g. proposed product name) into a sponsor's development pipeline. Disclosing whether an application has been submitted for a specific use in no way provides helpful information to potential future users of the new product, or to healthcare providers, since the product can only be made available following FDA approval. Since many factors can contribute to the review, approval and availability of a product, existence of an application does not correspond to product availability. Industry appreciates that members of the public are curious about products in development; however, it should be the sponsor's, not FDA's, decision regarding what information about new products is disclosed and when.

Proposal 11 – Withdrawn or Abandoned Unapproved Applications

FDA should not deviate from its current disclosure policy. Withdrawn or abandoned applications contain information that remains of value to the sponsor and could be used in a future application. In contrast, there is no public health benefit to such disclosures. In the

case of a safety issue, sponsors or investigators associated with patient exposure will ensure appropriate follow-up. The general public would be protected from future sponsors' attempting to investigate a similar product as the sponsors meet with FDA to attempt to begin trials. Citing EMA's disclosure policy does not provide grounds for action in the U.S. As FDA likely knows, without a Freedom of Information Act or similar law in the EU, far more information about FDA-regulated products is available in the U.S. today than in the EU.

Proposal 13 – Letters Issued When FDA Does Not Accept a Marketing Application or Approve or Clear a Marketing Application

There is no public health benefit from disclosing information about letters FDA issues when the Agency does not accept a marketing application. Patients do not have access to unapproved medicines. Competitors may gain access to sensitive information regarding future development plans by such disclosures. Citing EMA's disclosure policy does not provide grounds for action in the U.S.

Proposal 16 – Safety and Effectiveness Data

Safety and effectiveness information from an investigational application, or from a pending marketing application, even in summary form, should not be disclosed in advance of FDA approval. If such information were to be subsequently presented before an FDA Advisory Committee, then premature disclosure of such information may significantly bias the results of the proceedings by allowing panelists to make conclusions before hearing the perspectives of both FDA and industry. Sponsors and developers of safety and effectiveness data have an interest in recouping the significant investment of resources that was required to develop the data, and it should not be made available to competitors prematurely. Disclosure of data from clinical trials or from pending applications may negatively affect product development. Especially in the OTC medicines market, new products are often unprotected by patents and may not be protected by exclusivity periods. If FDA concludes it is necessary to correct misleading information about a product, in the interest of public health, this should be done in cooperation with the sponsor.

Proposal 17 – Possible Uses of Non-Summary Safety and Effectiveness Data

CHPA would welcome the opportunity to participate in a meeting of internal and external stakeholders to discuss the possible uses of non-summary safety and effectiveness data from product applications. At this time, it is difficult to conceive of circumstances under which disclosing such data would be helpful to the public.

Proposals 18 and 20 – Recalls

Proposal 18 (public disclosure of recall information) assumes a system is already established and a requirement is already in effect for firms to inform FDA about voluntary recall/recovery information. If a decision is made to move in this direction, then FDA should

work closely with industry stakeholders to develop and implement a process that best assures aligned and clear communication.

Proposal 20 (communication of recall termination) is supported as a priority; however, communicating the status of a recall in layman's terms, such as "completed" should be adequate. It seems unnecessary and potentially confusing to publicly disclose the actual "written notification sent to a recalling firm notifying the firm that FDA considers the recall terminated", since there is likely to be other extraneous information contained in the communication that is not relevant to the public at large.

Proposal 21 – Posting of Untitled Letters

CHPA requests FDA engage with sponsors at least 48-72 hours in advance of communicating such letters, particularly if they relate to emerging safety information or results of manufacturing site inspections. Companies need to be prepared to respond to inquiries from media, international health authorities, advocacy groups, and consumers that will be triggered by FDA public announcements.

Trade Secrets

In FDA's document (page 13), FDA attempts to distinguish between trade secret and confidential commercial information and states that trade secrets should remain confidential, while there may be more value to the public in the disclosure of some confidential commercial information. CHPA believes that confidential commercial information deserves the same protection as trade secrets.

We appreciate the opportunity to submit comments to the Transparency Task Force. Please contact me if additional information is required.

Sincerely,



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Vice President, Regulatory Affairs
Consumer Healthcare Products Association