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September 9, 2008

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

Re: Draft Guidance for Industry: Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Drug Listing; 73 Fed. Reg. 134 (July 11, 2008); Docket No. FDA-2005-N-0464 (Formerly Docket No. 2005N-0403)

Dear Sir or Madam:

The Structured Product Labeling (SPL) Over-the-Counter (OTC) sub-team (the sub-team), under the coordination of Consumer Healthcare Products Association (CHPA)¹ staff, appreciates the opportunity to comment on the July 2008 Draft Guidance for Industry: Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Drug Listing (the “Draft Guidance”). The SPL OTC sub-team, comprised of manufacturers, consultants, and vendors, was formed in May 2008 to address issues resulting from the new requirement that drug establishment registration and drug listing information be submitted electronically as noted in the Food and Drug Administration Amendments Act of 2007 (Public Law 110-85). More specifically, the sub-team seeks to address the concerns and needs of manufacturers and distributors affected by this change. We respectfully submit the following comments and requests for clarification associated with the Draft Guidance.

I. Voluntary Pilot Program and Transition

The Draft Guidance communicates that a voluntary Pilot Program has been established that will enable industry to voluntarily submit establishment registrations and drug listing in electronic format prior to the June 1, 2009, implementation date. The SPL OTC sub-team believes that the use of the term “pilot” is potentially misleading to industry members. A “pilot” typically involves a small group of participants who evaluate a process or procedure in order to finalize it using “fake” data. The actual

¹ CHPA, founded in 1881, is a national trade association representing manufacturers and distributors of over-the-counter medicines and dietary supplements.

program presented by FDA in the Draft Guidance concerns using “live” data in a “live” system. In order to clarify the intent of the Pilot Program, the sub-team recommends that FDA adopt new terminology to refer to this process, such as “Transition Program” or “Voluntary Compliance Program” and explain clearly that any submission made through this process is considered to be an official submission. Furthermore, the agency should inform stakeholders that participation in the “pilot or transition” program precludes paper submissions for that particular listing or registration from being made in the future.

II. Who Must Submit a Drug Listing

The Draft Guidance appears to be consistent with current regulations regarding who is required to submit a drug listing (21 CFR 207.12(a)) and implies that FDA expects to receive only one SPL submission for each National Drug Code (NDC) number. We request additional clarification on how the agency defines or interprets “one SPL submission.” Specifically, the SPL OTC sub-team requests clarification on the following points:

- A. Is our interpretation that FDA expects to receive only one SPL submission per product NDC correct?
- B. If our interpretation is correct (*i.e.*, there should be one SPL submission per product), the possibility exists that FDA could receive multiple SPL files (*i.e.*, different Set IDs) for the same NDC number. The SPL OTC sub-team requests clarification about how validation would occur if the agency received multiple submissions as described above. Would *all* submissions pass initial validation, and if yes, how would the situation be handled by FDA once discovered?

III. Information Required to be Submitted in the Electronic Drug Listing

A. Advertisements for OTC Drugs

In section IV.B.2. (page 6), the Draft Guidance discusses the information required to be submitted in the electronic drug listing. Included in the list of required drug listing information are labels, labeling, and/or advertisements. Currently, advertisements are not required to be submitted to FDA for OTC drug products as OTC advertisements are under the jurisdiction of the Federal Trade Commission (FTC) rather than FDA. Therefore, we would not be submitting advertisements for OTC drug products for the electronic drug listing.

B. Inactive Ingredients

Section IV.B.3. of the Draft Guidance (pages 6-7) discusses the information that is recommended to be submitted in the drug listing, including a quantitative listing (*i.e.*, strength or amount) of inactive ingredients. The applicable regulation (21 CFR §207.31(b)) states that “it is requested but not required that a qualitative listing of the inactive ingredients be submitted for all listed drugs.” A quantitative listing of inactive ingredients has not been previously required or requested by the agency. We request that FDA confirm that a qualitative listing of inactive ingredients will continue to be recommended but not required for OTC drug product listings. In addition, clarification is requested on whether the electronic system can validate the inactive ingredients section of the SPL if only the name of an ingredient, but not the quantity, is provided.

C. D-U-N-S[®] Numbers

The Draft Guidance includes Data Universal Numbering System (D-U-N-S[®]) numbers in the information that is recommended to be included in the electronic drug listing. The SPL OTC sub-team requests clarification on whether the SPL submission will pass validation upon receipt by FDA if D-U-N-S[®] numbers are not provided. We also request that FDA describe how it will manage the drug listing process if the SPL submission will pass validation if/when D-U-N-S[®] numbers are not provided.

IV. Drug Listings Not Affected by the Renewal

The Draft Guidance indicates that electronic submission of drug establishment registrations and drug listings are mandatory after June 1, 2009. After the implementation date, companies are expected to submit all changes in SPL format that have occurred since the last renewal during the renewal process. However, there is no clear indication in the Draft Guidance what will occur for products for which no changes have occurred and therefore are not subject to the renewal process (see section II., page 2 of the Draft Guidance). The SPL OTC sub-team requests clarification of how these “unchanged” or “unaffected” products should be handled during the renewal. Is it FDA’s intent to have listings made after June 1, 2009, include the “unchanged” or “unaffected” products during the initial submission as an “update” or is there no obligation to submit SPL drug listing until a change occurs?

V. Implementation

The majority of the OTC industry stakeholders do not have extensive experience with SPL as OTC products are not currently subject to any SPL submission requirements. Outreach continues in order to make all impacted companies aware of the electronic requirements. However, most companies are in the beginning phases of understanding SPL, how it will be used for registration and listing, and identifying the best solution for each company.

The Draft Guidance does not make electronic submission of drug establishment registrations mandatory until the next renewal which is after June 1, 2009, implementation date. However, many companies utilize third parties in their supply chain. These third parties may be unaware of the electronic registration requirements. If they *are* aware, it is unlikely that these parties understand that they must submit their drug establishment license and labeler code verifications electronically *before* the distributor of the product can perform the drug listing, which in theory could occur prior to the June 1, 2009, implementation date. While the burden to communicate these submission requirements will lie with the distributors, who are themselves only beginning to understand SPL and the electronic submission process, we may not be able to fulfill these communications for electronic registrations prior to the June 1, 2009, implementation date.

We are concerned that the complexity of this change and the degree of education that is still needed will make it very challenging to meet the June 1, 2009, implementation date. In order to accommodate the concerns of industry while still meeting FDA milestones with regards to implementation of an electronic registration and listing system, the SPL OTC sub-team proposes that FDA adopt a dual-phase implementation strategy. The first phase would require that all drug establishment registrations and labeler code verifications be submitted electronically by June 1, 2009. The second phase would require that all drug listings after December 1, 2009, be completed via electronic submission.

The sub-team feels a phased-in approach has three advantages. First, industry will be able to continue their outreach efforts to identify and educate all companies impacted by electronic registration and listing, and focus on the first phase of compliance, which would be the site registrations and the Electronic Submissions Gateway (EGS) validations. Second, companies who are submitting drug listings that utilize third parties in their supply chain will have sufficient time to establish communications with these companies and coordinate drug listing efforts in order comply with the timeframe communicated in the Draft Guidance. And finally, this dual-phase approach will provide sufficient time for companies to identify the SPL solution that best fits the individual needs of each company and to ensure that the solution is fully capable before the compliance date.

The SPL OTC sub-team thanks the FDA for the opportunity to provide comments about the Draft Guidance providing regulatory submissions in electronic format. We respectfully request that the agency address the questions and recommendations outlined in this submission when the final guidance document is released. The sub-team appreciates FDA's efforts to communicate with, and provide educational opportunities for, industry and looks forward to continued collaboration with the agency on this complex topic.

Sincerely;

A handwritten signature in cursive script, reading "Marcia D. Howard". The ink is a reddish-brown color.

Marcia D. Howard, Ph.D., SPL OTC sub-team liaison
Director, Regulatory & Scientific Affairs
Consumer Healthcare Products Association

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