

Madeline Palla
Manager, Regulatory Affairs

May 30, 2006

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

**Re: Docket No. 2006N-0104; Agency Information Collection Activities;
Proposed Collection; Comment Request; Requirements for Submission
of Labeling for Human Prescription Drugs and Biologics in Electronic
Format.**

The ANIMAL HEALTH INSTITUTE (“AHI”) submits these comments to Docket No. 2006N-0104; Agency Information Collection Activities; Proposed Collection; Comment Request; Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format. AHI is the national trade association representing manufacturers of animal health products -- the pharmaceuticals, biological products and feed additives used in modern food production, and the medicines that keep livestock and pets healthy. AHI member companies represent the majority of animal pharmaceuticals and animal insecticides, as well as serving a significant segment of the world market. As such we have a tremendous interest in the development of policy affecting the submission of labels in electronic format.

FDA’s progress in the submission of labels in electronic format is to be commended. To advance animal health product approvals, AHI and its member companies closely monitor and support post-approval activities by promoting and cultivating electronic communications and processes between government agencies and industry sponsors. Because the development of guidelines and regulations for Human Prescription Drugs and Biologics foreshadows, in many cases, the development of guidelines and regulations for animal drugs, the time and cost burden of significant changes required to submit label information is of great concern. AHI would like to respond to the invitation for comments in the following areas:

1. Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility:

Comments: While AHI does not oppose FDA’s request that OMB extend approval under the PRA for the information collection contained in the final rule entitled “Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format” (68 FR 69009, December 11, 2003), it is important to be mindful that the data from the original collection of information will be

substantially different since the mandatory change to a new electronic format per the April 2005 guidance. The collection of information is justified by a need to be responsive to technological advances, and AHI hopes that the following comments, if incorporated in the future information collection, will assist by enhancing the practical utility.

2. The accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used:

Comments: The original data collection focused only on the *additional reoccurring reporting burdens associated with the electronic submission of the content of labeling in the final rule*. FDA does not take into account the amount of time required to obtain/install/update the program required to create the electronic files. Because the original format accepted for these submissions was PDF, the aforementioned time burden was minimal. AHI anticipates, however, a significant alteration to the estimated time burden generated by the analysis of data dated October 31, 2005 and forward as October 31, 2005 is the date CDER eliminated PDF as an acceptable format for the submission of content of labeling and made Health Level Seven (HL7) Structured Product Labeling (SPL) in XML format the only acceptable electronic format for the submission of the content of labeling.

The revised format in which the FDA is accepting labeling submissions is, and will continue to be for some time to come, an additional burden on the sponsor companies that is not reflected in the data (note the radical difference between "year one" and "subsequent years" figures at the end of Table 1 in the December 2003 publication--even with the relatively simple and inexpensive PDF implementation).

In the March 29, 2006 notice, the FDA has neglected to mention the mandatory change in the acceptable electronic format or to estimate the "year one" burden -- indicating the SPL startup costs -- accurately. The implicit assumption is that there have not been any changes since the final rule issued in December 2003. How is the data on the "paper-to-SPL" startup effort or the "PDF-to-SPL" transition effort reflected in the collection of information, if at all? XML and SPL were not mentioned in the December 2003 estimates; only PDF was mentioned. The new data should reflect the changeover to XML/SPL format in order to obtain an accurate estimate of the burden.

3. Ways to enhance the quality, utility, and clarity of the information to be collected:

Comments: At the time the original rule (December 11, 2003, 68 Federal Register 69009-69020) was written, PDF was the only format the FDA was prepared to accept. References were made to the affordability (\$300-500) of this readily

available and easily obtainable solution (the economic impact of converting the information to PDF was detailed on pp 69018 and 69019). Although the original collection of information likely did not focus on the economic burden to industry or government because it was a fairly predictable expense, SPL cost burdens can vary.

Furthermore, the original December 11, 2003 Federal Register notice elaborated on the time required for the additional steps needed for electronic submission of the information and on the additional proofreading (i.e., verification or validation) time needed. In a table footnote, the FDA did, however, acknowledge that there would be "...one-time capital costs to: (1) Acquire computer software; (2) train employees to use the software; and (3) convert certain labeling to an electronic format." All of the data was based on the use of PDF. Does FDA plan to calculate the same capital costs for SPL implementation?

The content of the information in XML format may be the same as that which was provided in other formats or by other means prior to the October 31, 2005 rule update. The new format initially adds a substantial burden. In fact, because several companies are now using third-party services to reformat the information, the additional burden will recur until in-house systems are redesigned to accommodate the new format. No reference is made to the cost of obtaining these services or to the cost of implementing in-house systems and training the users, as was the case with the original rule. How does FDA plan to estimate the time burden for companies that use third-party vendors for SPL? Will FDA collect data from drug manufacturers only or a combination of manufacturers and third-party vendors?

4. Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology:

Comments: While AHI is aware that comments on the economic impact of SPL implementation are not specifically requested in this particular docket, feasibility of the submission of labels in electronic format (PDF) is indeed one of the supporting arguments in the December 2003 final rule. That is, if in the future SPL format is mandated by CVM as it is in CDER, it will be implemented at a cost to industry (and to CVM). Just as CVM leadership has stated that all new electronic submission initiatives have to be cost-justified in the context of the Animal Drug User Fee Act (ADUFA), industry has to justify the additional costs versus benefits as well. Though it may not minimize the burden of the collection of information on respondents nor the analysis of the data by government employees, collection of economic burden information will greatly enhance the accuracy and utility of the burden estimates.

At the moment, the animal health industry is working to identify benefits that manufacturers and/or consumers will obtain from the implementation of SPL submissions. It is difficult to justify a rapid changeover to the new format given the number of submissions that were not successfully loaded by CDER according to "SPL at FDA: A Progress Report" containing data from November 1, 2005 to March 21, 2006.

As stated before, the development of guidelines and regulations for Human Prescription Drugs and Biologics foreshadows, in many cases, the development of guidelines and regulations for animal drugs. It is not that AHI opposes SPL, but it is imperative that manufacturers, including our members, have an honest appraisal of the economic impact of the changes that have been mandated since the original rule was published. Should you have any questions, please do not hesitate to contact AHI at (202) 637-2440.

Sincerely,

A handwritten signature in cursive script that reads "Madeline Palla".

Madeline Palla

Manager, Regulatory Affairs