September 22, 2009

Note to OMB:

This is FDA's response to the outstanding issues that pertain to the information collection burden per our telecom this morning:

The only method we, FDA, are recommending is what is described in the concept paper. Therefore, we believe it is reasonable for us to assume that the burden we have calculated for the methods set forth in the concept paper would be sufficient to cover any burden associated with any alternative method.

The PRA estimates are based on our knowledge and experience with proprietary name submissions, and based on the many hours we have devoted to discussing with applicants during the public workshop and related meetings.

Additionally, we contacted two third party vendors who conduct name reviews for applicants and they provided their cost estimates for the evaluation of a proposed proprietary name. These companies were Drug Safety Institute and MedERRS recognition.

Email to OMB, September 23, 2009

These questions/answers were submitted to OMB for review.

I'm looking for FDA to assess the burden associated with the notice of information that should be emailed for registration and to participate in the pilot (the bullet points you emailed to me the other day). That burden should be a best guess of the # of applicants FDA plans to receive (not necessarily the # of applicants who will ultimately be enrolled in the pilot). Once you have that number, you should add that burden to the burden estimate already included in the supporting statement and then add it also to ICRAS/ROCIS.

Response: FDA's original estimate of hours per response had been intended to include the time required for registration as well as for the substantive submission. In light of our conversations, however, FDA has reconsidered whether the number of "registrants" may be greater than the number of entities who ultimately participate by making a full submission. It is our best guess estimate that we may receive 25 "registrations" per year, resulting in ultimately 20 full submissions. We estimate that the time per registration will be .5 hours, for a total burden of 12.5 hours.

I'm looking for FDA to clearly spell out what participants will need to provide to the FDA if they want to use an alternative method (i.e. what kind of information will they need to provide regarding the methodology, the study results, etc.). Then I need FDA to give a best guess on the number of the participants who may avail themselves of this

alternative, the burden associated with it, and then add that burden to the estimates already in the supporting statement.

Response:

For participants using an alternative method, we request the following information, described at Appendix B. VI of the Concept Paper (attached):

"If the methods used to assess the proposed proprietary name differ from those suggested in the concept paper for the PDUFA Pilot Project - Proprietary Name Review, submit the rationale for deviation, a full description of the methods, and all data generated and any analysis of this data from the alternative test methods)."

We anticipate that this would result in a similar burden to that associated with a submission using the concept paper methods, as Appendix B requests that all pilot participants provide descriptions of their methodologies and raw data. (See Appendix B.IV) We estimated that preparation of a submission, whether using the recommended methods or an alternative, would incur 480 hours of burden, with this estimate based on information regarding the DA FTE's involved in the current review process and 2 estimates from external vendors. With regard to the number of submissions anticipated to use alternate methodologies, at our prior public meetings, very few alternative methodologies were mentioned, so we do not anticipate that many pilot participants will use an alternative. If they do, again, we anticipate that their overall burden will be similar to that of participants using methods described in the concept paper, so that each such submission would still require 480 hours. Therefore, the estimate for the 20 submissions to be received annually already incorporates submissions using alternative methodologies and those using alternatives.

pdufaAPPENDIX B.doc (40 KB)