Response to Federal Register Notice (Docket No. FDA-2013-N-0242-0001)

Comments are under each of the 4 topics:

(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.

We feel that this collection of information will not have any practical utility unless the reason for the proposed collection is for the FDA to better understand the PET drug production industry, to facilitate upcoming inspections and to work with PET facilities in meeting areas of compliance under 21 CFR 212.

(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.

We feel that the information published in the notice is inaccurate for the following reasons:

1. The number of PET drug production facilities is not reflective of the current number of registered PET production facilities operating in the U.S. The estimated data from the collection of information (recordkeeping burden and 3rd party disclosure) is based on the 129 PET drug production facilities surveyed. Had the FDA communicated with the actual number of PET producers (150 PET facilities and counting), would the published estimates have been more accurate? In addition, the FDA does not breakdown these PET drug production facilities into commercial sites versus academic sites. Did the FDA communicate mainly to PET drug producers from commercial sites versus academic sites? In other words, is the data a fair representation of both types of production facilities (academic and commercial)? Commercial sites have a substantial advantage of being able to hire a team of personnel dedicated to compliance for many distributed sites. Therefore, the time devoted to each site could be far too low and unrealistic due to their economy of scale. Individual sites, like the academic labs, must perform the same functions with a much smaller staff.

2. The data published for the time spent in complying with recordkeeping requirements may not be accurate. The reason for this inaccuracy is because each facility will compile their records differently and will either use a paper-based method or an electronic method for their recordkeeping. The published notice did not specify how many PET drug facilities are using paper-based records versus how many are using electronic based records. If the majority of the PET drug production facilities surveyed are using electronic based records (computer software) then the time spent for recordkeeping will be a lot less as compared to other facilities using a paper-based approach. Those facilities using electronic records will be much more efficient at collecting the required information. An electronic method will decrease the time spent for the recordkeeping burden in creating, generating and maintaining records and 3rd party disclosures. Since the method for recordkeeping (paper or electronic) is not specified in the notice, the data may not be a fair representation of all PET facilities for time spent in complying with recordkeeping requirements.

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

1. The published notice had two tables which were not well defined. For the 21 CFR Part 212 sections listed on the table, it was not clear which section covered which appropriate record. Table 1 and table 2 would have been clear had the tables listed the appropriate record instead of the CFR section. For example, 21 CFR Sections 212.20(c) through (e), 212.50(a) through (c) and 212.80(c) could have been listed as *Batch Production and Control Records* so that it would have been easier match up the appropriate record with the corresponding data from each column on the table.

2. For the 129 PET drug production facilities surveyed, it would have been helpful to see the list of questions from the survey for the time spent in complying with recordkeeping requirements.

(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.

Could the FDA establish an on-line database to minimize the burden of collection of information on respondents? This database would be accessible with a required login (user name and password).