Public Comments for PET GMP Recordkeeping Burden

The Coalition would like to make PET drug manufacturers aware of an announcement from the FDA that appeared in the December 29, 2015, issue of the Federal Register. The notice announces the opportunity for public comment on the annual recordkeeping and third-party disclosure burdens associated with the PET drug Good Manufacturing Practice (GMP) regulations at 21 CFR part 212. The notice is in response to the Paperwork Reduction Act of 1995, which requires the FDA to estimate the recordkeeping burden required to comply with the PET GMPs.

The notice contains the FDA’s estimates of the recordkeeping and third-party disclosure burdens that are required to comply with the PET GMPs. In addition, the notice describes some of the methodology that the FDA used to develop these estimates. Through the notice, the FDA invites comments on the following specific 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;
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;
3. ways to enhance the quality, utility, and clarity of the information to be collected; and
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.

The comment period is open until February 29, 2016. The Coalition is considering options in response to this notice and will update this website as appropriate. Individuals, PET drug manufacturers, and any other stakeholder may submit comments. The notice is available at this URL: https://www.federalregister.gov/articles/2015/12/29/2015-32685/agency-information-collection-activities-proposed-collection-comment-request-current-good