Draft Guidance for Industry, Researchers, Patient Groups, and Food and Drug Administration Staff on Meetings With the Office of Orphan Products Development

0910-NEW

A. Justification

1. Circumstances Making the Collection of Information Necessary

   FDA is seeking approval for the information collection in, "Draft Guidance for Industry, Researchers, Patient Groups, and Food and Drug Administration Staff on Meetings With the Office of Orphan Products Development." The draft guidance describes three collections of information: (1) The submission of a meeting request (for informal and formal meeting), (2) the submission of a meeting package (for formal meetings), and (3) the submission of draft meeting minutes (for formal and certain informal meetings.)

   The collection of information described in this guidance is intended to provide background information in support of consistent procedures to promote well-managed meetings between OOPD and stakeholders. In some cases, these meetings may represent a critical point in the orphan product development process and may even have an impact on the eventual availability of products for patients with rare diseases and conditions. It is therefore important that these meetings be scheduled within a reasonable time, conducted effectively, and documented where appropriate.
2. Purpose and Use of the Information Collection

   This draft guidance provides recommendations to industry, researchers, patient groups, and other stakeholders (collectively referred to as "stakeholders") interested in requesting a meeting with FDA's Office of Orphan Products Development (OOPD) on issues related to orphan drug designation requests, humanitarian use device (HUD) designation requests, rare pediatric disease designation requests, funding opportunities through the Orphan Products Grants Program and the Pediatric Device Consortia Grants Program, and orphan product patient-related topics of concern. This guidance document is intended to assist these groups with requesting, preparing, scheduling, conducting, and documenting meetings with OOPD and will provide for more productive meetings with stakeholders.
3. Use of Improved Information Technology and Burden Reduction

   FDA estimates that 100% of the respondents will use electronic means to fulfill the agency's requirement or request.
4. Efforts to Identify Duplication and Use of Similar Information

   This information collection is not duplicative.
5. Impact on Small Businesses or Other Small Entities

This rule primarily clarifies current practice and any costs would be very small. FDA certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

6. Consequences of Collecting the Information Less Frequently

Respondents will send in their requests for meetings on a case by case, as needed basis.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of April 9, 2014 (79 FR 19624). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

There is no payment or gift to respondents.

10. Assurance of Confidentiality Provided to Respondents

Information received in meeting requests will be kept private and only used for the purposes outlined in section A2 of this supporting statement.

11. Justification for Sensitive Questions

No sensitive information is being requested.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden

Meeting requests, packages and minutes	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Meeting requests (informal)	2,120	1	2,120	3	6,360
Meeting Requests (formal)	46	1	46	10	460
Meeting Packages	46	1	46	18	828

Table 1.--Estimated Annual Reporting Burden					
Meeting requests, packages and minutes	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Meeting Minutes	67	1	67	8	536
Total					8,184

12b. Annualized Cost Burden Estimate

Estimates of annualized cost burden should be provided in chart form as indicated by HHS in the example below. This chart should relate directly back to the burden chart.

Respondents	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Stakeholders	8,184	$46.00	$376,464

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

FDA assumes review of stakeholders requests and agendas for informal and formal meetings as well as any documentation of meetings afterwards would require 1 hour of time from a GS-14 Regulatory Management Officer to collect and process each. At a benefit-adjusted hourly wage of $65, the cost to collect and process each is $65. Based on the experience with submission of requests for informal and formal meetings, FDA estimates 2,212 requests each year. The submission of meeting minutes as a result of formal meetings with FDA is estimated to be at 67 per year. The estimated annual cost to the Federal Government to collect and process will be $148,135.

The estimates are based on knowledge of resources used by the FDA Office of Orphan Products Development in implementing the Orphan Drug Act over the last 29 years. Because the number of requests for meetings are expected to continue at the same or similar annual rate, past FDA experience will be a good predictor of future resource needs.

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

The objectives of the collection are not for publication of statistical material and do

not employ statistical methods.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

    FDA is not seeking approval not to display the expiration date of OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

    There are no exceptions to the certification.