

DEPARTMENT OF DEFENSE

GENERAL SERVICES
ADMINISTRATIONNATIONAL AERONAUTICS AND
SPACE ADMINISTRATION

[OMB Control No. 9000-00XX; Docket 2010-0083, Sequence 17]

Submission for OMB Review; Use of Project Labor Agreements for Federal Construction Projects

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for public comments regarding a new OMB information clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Regulatory Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve a new information collection requirement regarding Use of Project Labor Agreements for Federal Construction Projects.

A request for public comments was published in the **Federal Register** at 74 FR 33953, on July 14, 2009. No comments were received.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

DATES: Submit comments on or before April 22, 2010.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the GSA Desk Officer, OMB, Room 10236, NEOB, Washington, DC 20503, and a copy to the Regulatory Secretariat (MVCB), General Services Administration, 1800 F Street, NW., Room 4041, Washington, DC 20405. Please cite OMB Control No. 9000-00XX, Use of Project Labor Agreements for Federal Construction Projects, in all correspondence.

FOR FURTHER INFORMATION CONTACT: Mr. Ernest Woodson, Procurement Analyst, Contract Policy Branch, at telephone (202) 501-3775 or via e-mail to ernest.woodson@gsa.gov.

SUPPLEMENTARY INFORMATION:

A. Purpose

FAR 22.501 prescribes policies and procedures to implement Executive Order 13502, February 6, 2009, which encourages Federal agencies to consider the use of a project labor agreement (PLA), as they may decide appropriate, on large-scale construction projects, where the total cost to the Government is more than \$25 million, in order to promote economy and efficiency in Federal procurement. A PLA is a pre-hire collective bargaining agreement with one or more labor organizations that establishes the terms and conditions of employment for a specific construction project. FAR 22.503(b) provides that an agency may, if appropriate, require that every contractor and subcontractor engaged in construction on the project agree, for that project, to negotiate or become a party to a project labor agreement with one or more labor organizations if the agency decides that the use of project labor agreements will—

(1) Advance the Federal Government's interest in achieving economy and efficiency in Federal procurement, producing labor-management stability, and ensuring compliance with laws and regulations governing safety and health, equal employment opportunity, labor and employment standards, and other matters; and,

(2) Be consistent with law.

B. Annual Reporting Burden

Respondents: 70.
Responses per Respondent: 1.
Annual Responses: 70.
Hours per Response: 1.
Total Burden Hours: 70.

Obtaining Copies of Proposals:

Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVCB), 1800 F Street, NW., Room 4041, Washington, DC 20405, telephone (202) 501-4755. Please cite OMB Control No. 9000-00XX, Use of Project Labor Agreements for Federal Construction Projects, in all correspondence.

Dated: March 18, 2010.

Al Matera,

Director, Acquisition Policy Division.

[FR Doc. 2010-6404 Filed 3-22-10; 8:45 am]

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DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0146]

Draft Guidance for Industry on Irritable Bowel Syndrome—Clinical Evaluation of Products for Treatment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Irritable Bowel Syndrome—Clinical Evaluation of Products for Treatment." This guidance addresses the following three main topics regarding irritable bowel syndrome (IBS) sign and symptom assessment for IBS with diarrhea (IBS-D) and IBS with constipation (IBS-C): The evolution of primary endpoints for IBS clinical trials, interim recommendations for IBS clinical trial design and endpoints, and the future development of patient-reported outcome (PRO) instruments for use in IBS clinical trials. This guidance is intended to assist the pharmaceutical industry and other investigators who are conducting new product development for the treatment of IBS.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by May 24, 2010.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Ruyi He, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire

Justification for Collection
OMB Control No. 9000-00XX, Use of Project Labor Agreements
for Federal Construction Projects

A. JUSTIFICATION

1. Administrative requirements. This is a request for emergency approval of a new information collection requirement. The FAR Council is issuing an interim rule amending the Federal Acquisition Regulation Supplement (FAR) to implement Executive Order (E.O.) 13502, dated February 6, 2009, entitled "Use of Project Labor Agreements for Federal Construction Projects". This E.O. was issued to mitigate the adverse impacts of labor-management instability on large construction contracts thereby allowing efficient and timely completion of such projects. Therefore, the E.O. directs the FAR Council to amend the FAR within 120 days to implements the provisions of the Order. On July 14, 2009, the Councils published for public comment a proposed rule to provide a new FAR Subpart 22.5, Use of Project Labor Agreements for Federal Construction Projects, to implement the provisions of E.O. 13502 (73 FR 33953).

This final rule gives agencies the discretion to determine if using project labor agreements in connection with large scale construction contracts (over \$25M) will promote economy and efficiency by minimizing labor-management unrest.

The decision to use or not use a project labor agreement is completely discretionary on the part of the agency under the final rule, agencies may choose from among three options. Submission may be required: (1) when offers are due, (2) prior to award (by the apparent successful offeror), or (3) after award.

Providing these three options allows agencies with project labor agreement experience to continue with the model they have found most helpful, and other agencies to craft an approach unique to each project, and, as experience is gained, follow best demonstrated practices. If an agency decides that permitting execution of the PLA after award is the best approach, the contractor will be required to submit an executed copy of the agreement to the contracting officer. This language is a change from the proposed rule,

which only required the contractor to "bargain in good faith." In the Councils' view, this language unnecessarily puts part of the government's acquisition strategy at risk and therefore fails to adequately protect the Government's procurement interests.

2. Use of information. This information is required to determine if the otherwise apparently successful offeror has submitted a sufficient project labor agreement that conforms with all statutes, regulations and Executive Orders. Failure to collect this information would result in a lack of sufficient information needed by the contracting officer to make an award decision.

3. Use of information technology. Improved information technology will be used to the maximum extent practicable. Where offerors or contractors have automated systems that contain the information needed to report this requirement, they may submit the information in formats that are compatible with the automated systems.

4. Describe efforts to identify duplication. This information collection does not duplicate any other requirement.

5. If the collection of information impacts small businesses (item 5) describes any methods used to minimize the burden. The rule will apply to large-scale construction projects where the cost to the Government is \$25 million or more and where agencies have determined that use of a project labor agreement will promote economy and efficiency in the resulting procurement by minimizing labor-management unrest. Most prime contractors for such projects are large business concerns, and only the prime contractor is responsible for the collection of information. Additionally, the rule gives agencies the flexibility to consider additional criteria to minimize the rules impact of non-unionized contractors and subcontractors, both small and large businesses.

6. Describe the Consequences to Federal activities if the collection is not conducted or is conducted less frequently. Collection frequency is minimal, but required as directed by Federal agencies in their solicitation documents. If the collection is not conducted as required, work on the agency's construction project could be delayed.

7. Special circumstances for collection. Collection is consistent with the guidelines in 5 CFR 1320.5(d). The information will not be collected in a manner that requires an explanation of special circumstances.

8. Efforts to consult with persons outside the agency. A request for comments were be solicited in the Federal Register (73 FR 33953), as required by 5 CFR 1320.8(d). A subsequent information collection package to be submitted under regular processing timeframes will address any comments received on the information collection portion of the FAR rulemaking. The proposed rule published in the *Federal Register* at 74 Fr 33953, on July 14, 2009. **No** comments were received.

9. Explanation of any decision to provide any payment or gift to respondents, other than remuneration of contractors or guarantees. No payment or gift will be provided to respondents, other than remuneration of contractors under their contracts.

10. Describe assurance of confidentiality provided to respondents. The information collected will be disclosed only to the extent consistent with prudent business practice, current regulations, and statutory requirements. No assurance of confidentiality is provided to respondents.

11. Additional justification for questions of a sensitive nature. No sensitive questions are involved.

12. Estimated total annual public hour burden. **Based on fiscal year 2009 data** regarding the types of contracts to which this information collection applies, **it is estimated that there are approximately 246 large-scale construction contracts (including Architectural and Engineering contracts) exceeding \$25M that could be subject to an agency decision for use of project labor agreement.** Given consideration to the option, in the rule to have offerors submit the PLA with its bid, we estimate of about **70 PLAs per year will be submitted to submitted to the Government for consideration.** Using the second option which allow the PLA to be submitted by the successful offeror, or the third option which would allow a PLA to be submitted after contract award, would greatly reduce the number of respondents to which public burden would apply. Therefore, the estimated time for reporting of this information is 1 hour to cover copying and submitting the

agreement to the Government. The rule and the burden does not require the contractor to keep records regarding the development, negotiation, or submission of the PLA.

We have estimated not more than 70 respondents, 1 response per respondent, 1 hour per response, and an estimated cost of \$29 per hour (the equivalent of a GS-09, step 5 salary plus 36.45 percent burden): Computations are provided below.

Respondents	70
Responses/respondent	x <u>1</u>
Responses	70
Hours per response	x <u>1</u>
Total hours	70
Cost per hour	x \$ <u>29</u>
Total annual cost to public	\$ 2,030

13. Estimated total annual public cost burden. We estimate that the contracting officer will be able to determine whether the project labor agreement is compliant without requesting additional evidence from the offeror. Therefore, we estimate 70 respondents, 1 response per respondent and .5 hours per response, and an estimated cost of \$36 per hour (the equivalent of a GS-11 step 5 salary plus 36.45 percent burden):

Respondents	70
Responses/respondent	x <u>1</u>
Responses	70
Hours per response	x <u>.5</u>
Total hours	35
Cost per hour	x \$ <u>36</u>
Total annual cost to the Gov't	\$ 1,260

14. Estimated cost to the Government. The FAR Council does not estimate any annual cost burden apart from the hour burden in Item 13.

15. Explain reasons for program changes or adjustment reported in Item 13 or 14. Data was estimated using the Federal Procurement Data System (FPDS) for FY08 and FY10.

16. Outline plans for published results of information collection. This is a new information collection requirement.

17. Approval not to display expiration date. Results of this information collection will not be tabulated or published.

18. Explanation of exception to certification statement. The FAR Council does not seek approval to not display the expiration dates for OMB approval of the information collection.

B. Collections of Information Employing Statistical Methods

Statistical methods will not be employed.