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, and a copy to the Regulatory Secretariat (MVCB), General Services Administration, 1800 F Street, NW., Room 4041, Washington, DC 20405.

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.

Food and Drug Administration

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BILLING CODE 6820–EP–P

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