certain information on its projected subcontracting activities with its proposal. Absent the reporting under this clause, the Government would be vulnerable to charges from prime contractors related to subcontract activity which did not provide commensurate or even any value to the contract.

Comment: The respondent commented that the agency did not accurately estimate the public burden challenging that the agency's methodology for calculating it is insufficient and inadequate and does not reflect the total burden. The respondent stated the estimate of a half hour per response per respondent is understated, and that a more realistic estimate would be in the range of 40 to 80 hours per response. For this reason, the respondent provided that the agency should reassess the estimated total burden hours and revise the estimate upwards to be more accurate, as was done in FAR Case 2007–006. The respondent also provided that the burden of compliance with the information collection requirement outweighs any potential utility of the extension.

Response: Serious consideration is given, during the open comment period, to all comments received and adjustments are made to the paperwork burden estimate based on reasonable considerations provided by the public. This is evidenced, as the respondent notes, in FAR Case 2007–006 where an adjustment was made from the total preparation hours from three to 60. This change was made considering particularly the hours that would be required for review within the company, prior to release to the Government.

The burden is prepared taking into consideration the necessary criteria in OMB guidance for estimating the paperwork burden put on the entity submitting the information. For example, consideration is given to an entity reviewing instructions; using technology to collect, process, and disclose information; adjusting existing practices to comply with requirements; searching data sources; completing and reviewing the response; and transmitting or disclosing information. The estimated burden hours for a collection are based on an average between the hours that a simple disclosure by a very small business might require and the much higher numbers that might be required for a very complex disclosure by a major corporation. Also, the estimated burden hours should only include projected hours for those actions which a company would not undertake in the normal course of business. Careful consideration went into assessing the estimated burden hours for this collection, and although, the respondent provided estimates of responses and burden hours, the estimates cannot be confirmed with any degree of certainty to totally rely on the information. However, it is determined that an upward adjustment from the previously approved information collection is warranted at this time based upon consideration of the information provided in the public comment.

C. Annual Reporting Burden

There is no centralized database in the Federal Government that maintains information regarding the use of the clauses at FAR 52.215–22 and FAR 52.215–23. Therefore, subject matter experts were consulted to obtain additional information that helped in estimating the revised public burden.

For this information collection requirement data from Fiscal Year (FY) 2012 was retrieved from the Federal Procurement Data System—Next Generation (FPDS–NG). The parameters for this information collection were defined based on the prescription from the applicable clauses. Based on a comprehensive review of the prescriptions for the applicable clauses, it was determined that the types of contracts associated with this information collection are:

(1) For civilian agencies, cost-reimbursement type contracts and the total estimated contract or order value exceeds the simplified acquisition threshold (SAT).

(2) For DoD, the total estimated contract or order value exceeds the threshold for obtaining cost or pricing data in 15.403–4 ($700,000); and the contract type is expected to be any contract type except—

(i) A firm-fixed-price contract awarded on the basis of adequate price competition;

(ii) A fixed-price contract with economic price adjustment awarded on the basis of adequate price competition;

(iii) A firm-fixed-price contract for the acquisition of a commercial item;

(iv) A fixed-price contract with economic price adjustment, for the acquisition of a commercial item;

(v) A fixed-price incentive contract awarded on the basis of adequate price competition; or

(vi) A fixed-price incentive contract for the acquisition of a commercial item.

For civilian agencies, FPDS–NG shows 3,017 contracts awarded to 2,258 unique vendors were applicable to the clauses associated with this information collection. For DOD, FPDS–NG shows 1,376 contracts awarded to 1,119 unique vendors were applicable to the clauses associated with this information collection. This equates to a total of 4,393 contracts awarded to 3,377 unique vendors. Based on discussions with subject matter experts, it was determined that 4,393 contract awards was a sufficient baseline for estimating the number of solicitations that would include the applicable clause. It is estimated that 3 responses would be submitted in response to a solicitation that included the applicable clauses, for a total of 13,179 estimated respondents per year. The number of responses per respondent is estimated at one. It is also determined that the estimated time required to read and prepare a response is increased from 60 minutes to 120 minutes. This determination is based on the consideration of public comments.

These revisions represent an increase from the previously approved information collection.

Respondents: 13,179.

Responses per Respondent: 1.

Total Responses 13,179.

Hours per Response: 2.

Total Burden Hours: 26,358.

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., 2nd floor, Washington, DC 20405, telephone (202) 501–4755. Please cite OMB Control No. 9000–0173, Limitations on Pass-Through Charges, in all correspondence.

Dated: July 24, 2013.

Karlos Morgan,

Acting Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2013–18218 Filed 7–29–13; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0980]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance on Reagents for Detection of Specific Novel Influenza A Viruses

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing

that a collection of information entitled ''Guidance on Reagents for Detection of Specific Novel Influenza A Viruses'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: On March 20, 2013, the Agency submitted a proposed collection of information entitled ''Guidance on Reagents for Detection of Specific Novel Influenza A Viruses'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0584. The approval expires on April 30, 2016. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: July 24, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–18227 Filed 7–29–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0164]

Guidance for Industry: Safety Labeling Changes—Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Safety Labeling Changes—Implementation of Section 505(o)(4) of the FD&C Act.'' The Food and Drug Administration Amendments Act of 2007 (FDAAA) added new provisions to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) authorizing FDA to require certain drug and biological product application holders to make safety-related labeling changes based upon new safety information that becomes available after the drug or biological product is approved under the FD&C Act or the Public Health Service Act (the PHS Act). This final guidance provides information on the implementation of section 505(o)(4) of the FD&C Act, including a description of the types of safety labeling changes that ordinarily might be required under this section; how FDA plans to determine what constitutes new safety information; the procedures involved in requiring safety labeling changes; and enforcement of the requirements for safety labeling changes.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this 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; or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kristen Everett, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6484, Silver Spring, MD 20993–0002, 301–796–0453; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Safety Labeling Changes—Implementation of Section 505(o)(4) of the FD&C Act.'' In the past, FDA has requested that holders of applications for approved products make labeling changes related to safety after approval to address serious risks. In most cases, application holders responded to these requests by negotiating appropriate language with FDA staff to address the concerns and then submitting a supplement or amended supplement to obtain approval of the change. However, negotiations were often protracted, and FDA had few tools available at its disposal to end negotiations and require the changes. Congress recognized the limitations of FDA's authority in this area and, in FDAAA, gave FDA new authorities to require safety labeling changes in certain circumstances.

Title IX, section 901 of FDAAA (Pub. L. 110–85) amended the FD&C Act by adding new section 505(o)(4) (21 U.S.C. 355(o)(4)). Section 505(o)(4) authorizes FDA to require, and if necessary, order labeling changes if FDA becomes aware of new safety information that FDA believes should be included in the labeling of certain prescription drug and biological products approved under section 505 of the FD&C Act or section 351 of the PHS Act (42 U.S.C. 262). Specifically, section 505(o)(4) of the FD&C Act applies to prescription drug products with an approved new drug application (NDA) under section 505(b) of the FD&C Act, biological products with an approved biologics license application (BLA) under section 351 of the PHS Act, or prescription drug products with an approved abbreviated new drug application (ANDA) under section 505(j) of the FD&C Act if the NDA reference listed drug is not currently marketed. The safety labeling changes provisions in section 505(o)(4) apply to the previously listed products, including products that are not marketed, unless approval of the NDA, BLA, or ANDA has been withdrawn in the **Federal Register.** FDAAA imposes timeframes for application holders to submit and FDA staff to review safety labeling changes, and gives FDA new enforcement tools to bring about timely and appropriate labeling changes.

In the **Federal Register** of April 13, 2011 (76 FR 20686), FDA announced the availability of a draft guidance for industry entitled ''Safety Labeling Changes—Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act.'' The notice gave interested parties the opportunity to comment by July 12, 2011. FDA carefully considered all of the comments received, and revised the guidance as appropriate. This guidance is intended to clarify how FDA will implement section 505(o)(4) of the FD&C Act, including providing a description of the types of safety labeling changes that ordinarily might be required under this section; how FDA plans to determine what