Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this proposed rule is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the changes to the guidance are minimal, the Agency proposes to certify that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $135 million, using the most current (2009) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

The changes to the guidance include adding specific recommendations on appropriate comparators for tests for antibodies and antigens, as well as recommendations for sample selection inclusion and exclusion criteria to define the target populations for HSV 1 and HSV 2 serological assays. These recommended changes would increase the usefulness of the guidance while imposing a minimal burden.

IX. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires agencies to "construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute." Federal law includes an express preemption provision that preempts certain state requirements "different from or in addition to" certain Federal requirements applicable to devices. (See section 521 of the FD&C Act (21 U.S.C. 360k); *Medtronic* v. *Lohr* 518 U.S. 470 (1996); and *Riegel* v. *Medtronic*, 128 S. Ct. 999 (2008)). If this proposed rule is made final, the special controls established by the final rule would create "requirements" for specific medical devices under 21 U.S.C. 360k, even though product sponsors have some flexibility in how they meet those requirements (see *Papike* v. *Tambrands, Inc.*, 107 F.3d 737, 740–742 (9th Cir. 1997)).

X. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no new collections of information. Therefore, clearance by OMB under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520) is not required.

This proposed rule designates a revised guidance document as a special control. FDA also tentatively concludes that the revised draft special control guidance document does not contain new information collection provisions that are subject to review and clearance by OMB under the PRA. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing the availability of that revised draft guidance document entitled "Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays," which contains an analysis of the paperwork burden for the draft guidance.

XI. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 866

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 866 be amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

1. The authority citation for 21 CFR part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Revise § 866.3305 to read as follows:

§ 866.3305 Herpes simplex virus serological assays.

(a) *Identification.* Herpes simplex virus serological assays are devices that consist of antigens and antisera used in various serological tests to identify antibodies to herpes simplex virus in serum. Additionally, some of the assays consist of herpes simplex virus antisera conjugated with a fluorescent dye (immunofluorescent assays) used to identify herpes simplex virus directly from clinical specimens or tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by herpes simplex viruses and provides epidemiological information on these diseases. Herpes simplex viral infections range from common and mild lesions of the skin and mucous membranes to a severe form of encephalitis (inflammation of the brain). Neonatal herpes virus infections range from a mild infection to a severe generalized disease with a fatal outcome.

(b) *Classification.* Class II (special controls). The device is classified as class II (special controls). The special control for the device is FDA's revised guidance document entitled "Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays." For availability of the revised guidance document, see § 866.1(e).

Dated: September 16, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–23639 Filed 9–27–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Chapter I

No Child Left Behind School Facilities and Construction Negotiated Rulemaking Committee—Notice of Meeting

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Negotiated Rulemaking Committee meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Bureau of Indian Affairs is announcing that the No Child Left Behind School Facilities and Construction Negotiated Rulemaking Committee will hold its fourth meeting in Bloomington, Minnesota. The purpose of the meeting is to continue working on reports and recommendations to Congress and the Secretary as required under the No Child Left Behind Act of 2001.

DATES: The Committee's fourth meeting will begin at 8 a.m. on October 12, 2010, and end at 12:30 p.m. on October 15, 2010.

ADDRESSES: The meeting will be held at the Ramada Mall of America Hotel, 2300 East American Boulevard, Bloomington, Minnesota 55425.

FOR FURTHER INFORMATION CONTACT: The Designated Federal Official, Michele F. Singer, Director, Office of Regulatory Affairs and Collaborative Action, Office of the Assistant Secretary—Indian Affairs, 1001 Indian School Road, NW., Suite 312, Albuquerque, NM 87104; telephone (505) 563–3805; fax (505) 563–3811.

SUPPLEMENTARY INFORMATION: The No Child Left Behind School Facilities and Construction Negotiated Rulemaking Committee was established to prepare and submit to the Secretary a catalog of the conditions at Bureau-funded schools, and to prepare reports covering: The school replacement and new construction needs at Bureau-funded school facilities; a formula for the equitable distribution of funds to address those needs; a list of major and minor renovation needs at those facilities; and a formula for equitable distribution of funds to address those needs. The reports are to be submitted to Congress and to the Secretary. The Committee also expects to draft proposed regulations covering construction standards for heating, lighting, and cooling in home-living (dormitory) situations.

The following items will be on the agenda:

- Review and approve July 2010 meeting summary;
- General update from September group meeting and progress made;
- Discussion of workgroup drafts, including a section-by-section analysis and organization of content;
- Drafting of full report;
- Planning for January 2011 meeting; and
- Public comments.

Written comments may be sent to the Designated Federal Official listed in the **FOR FURTHER INFORMATION CONTACT** section above. All meetings are open to the public; however, transportation, lodging, and meals are the responsibility of the participating public.

Dated: September 20, 2010.

Larry Echo Hawk,

Assistant Secretary—Indian Affairs.

[FR Doc. 2010–24107 Filed 9–27–10; 8:45 am]

BILLING CODE 4310–W7–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 85, 86, and 600

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 575

[EPA–HQ–OAR–2009–0865; FRL–9208–1; NHTSA–2010–0087]

RIN 2060–AQ09; RIN 2127–AK73

Public Hearing Locations for the Proposed Fuel Economy Labels

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public hearings.

SUMMARY: EPA and NHTSA are announcing the location addresses for the public hearings to be held for "Revisions and Additions to Motor Vehicle Fuel Economy Label," published in the **Federal Register** on September 23, 2010. The goal of a revised label will be to provide consumers with simple, straightforward comparisons across all vehicles types, including electric vehicles (EV), plug-in hybrid electric vehicles (PHEV), and conventional gasoline and diesel vehicles. NHTSA and EPA are proposing these changes in compliance with the Energy Independence and Security Act (EISA) of 2007, which imposes several new labeling requirements. Also, the agencies believe that the current labels can be improved to help consumers make more informed vehicle purchase decisions and to address the entrance of advanced technology vehicles into the U.S. market. The new labels are proposed to be displayed on new vehicles beginning with the 2012 model year.

DATES: NHTSA and EPA will jointly hold two public hearings on the following dates: Thursday, October 14, 2010, in Chicago, Illinois, and Thursday, October 21, 2010, in Los Angeles, California. The hearing sessions will be from 12 p.m. to 4 p.m. and 6 p.m. to 10 p.m. local time and continue until everyone has had a chance to speak. Note that the times have changed from those indicated in the proposed rule.

ADDRESSES: NHTSA and EPA will jointly hold two public hearings at the following locations: Wyndham Hotel, 633 North St. Clair St., Chicago, Illinois 60611 on Thursday, October 14, 2010; and Sheraton Los Angeles Downtown Hotel, 711 South Hope Street, Los Angeles, California 90017 on Thursday, October 21, 2010.

FOR FURTHER INFORMATION CONTACT: EPA: Lucie Audette, Office of Transportation and Air Quality, Assessment and Standards Division, Environmental Protection Agency, 2000 Traverwood Drive, Ann Arbor, MI 48105; telephone number: 734–214–4850; fax number: 734–214–4816; e-mail address: *audette.lucie@epa.gov,* or Assessment and Standards Division Hotline; telephone number (734) 214–4636; e-mail address: *asdinfo@epa.gov.* NHTSA: Gregory Powell, National Highway Traffic Safety Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590. Telephone: (202) 366–5206; Fax: (202) 493–2990; e-mail address: *gregory.powell@dot.gov*.

SUPPLEMENTARY INFORMATION: The purpose of the public hearings is to obtain public testimony or comment on the Agency's proposed revisions and additions to the motor vehicle fuel economy label.[1] If you would like to present testimony at the public hearings, we ask that you notify the EPA and NHTSA contact persons listed under **FOR FURTHER INFORMATION CONTACT** at least ten days before the hearing. Once EPA and NHTSA learn how many people have registered to speak at the public hearing, we will allocate an appropriate amount of time to each participant, allowing time for necessary breaks throughout the hearing. For planning purposes, each speaker should anticipate speaking for approximately ten minutes, although we may need to adjust the time for each speaker if there is a large turnout. We suggest that you bring copies of your statement or other material for the EPA and NHTSA panels and the audience. It would also be helpful if you send us a copy of your statement or other materials before the hearing. To accommodate as many speakers as possible, we prefer that speakers not use technological aids (*e.g.,* audio-visuals, computer slideshows). However, if you

[1] FR–9197–3; EPA–HQ–OAR–2009–0865; NHTSA–2010–0087.