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 (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, 360c, 360e, 360j, 360k, 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 viruses 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).


Leslie Kux,

Acting Assistant Commissioner for Policy.

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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.
ACTON: 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