participants in other physical commodity swaps/trade options?

11. If so, why, and what should those protections be?

12. Would additional protections for agricultural swaps purchasers unduly restrict their risk management opportunities?

13. Should the Commission consider rules to make it easier for agricultural producers to participate in agricultural swaps—for example, by allowing producers who do not qualify as ECPs to purchase agricultural swaps?

Designated Contract Markets

14. Should agricultural swaps transactions be permitted to trade on DCMs to the same extent as all other swaps are permitted on DCMs?

15. If yes, why?

16. If no, what other requirements, conditions or limitations should apply?

Swap Execution Facilities

17. Should agricultural swaps transactions be permitted on SEFs to the same extent as all other swaps are permitted to transact on SEFs?

18. If yes, why?

19. If no, what other requirements, conditions or limitations should apply?

Trading Outside of DCMs and SEFs

20. Should agricultural swaps be permitted to trade outside of a DCM or SEF to the same extent as all other swaps?

21. If yes, why?

22. If no, what other requirements, conditions or limitations should apply?

23. Should agricultural swaps be permitted to trade outside of a DCM or SEF to a different extent than other swaps due to the nature of the products and/or participants in the agricultural swaps market?

24. In general, should agricultural swaps be treated like all other physical commodity swaps under Dodd-Frank?

25. If yes, why?

26. If no, are there any additional requirements, conditions or limitations not already discussed in other answers that should apply?

27. If agricultural swaps are generally treated like swaps in other physical commodities, are there specific agricultural commodities that would require special or different protections?

Issued in Washington, DC, on September 21, 2010, by the Commission.

David A. Stawick,

Secretary of the Commission.

[FR Doc. 2010–24198 Filed 9–27–10; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2010–N–0429]

Immunology and Microbiology Devices; Reclassification of the Herpes Simplex Virus Serological Assay Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the special controls for the herpes simplex virus (HSV) serological assay device type, which is classified as class II (special controls). These device types are devices that consist of antigens and antisera used in various serological tests to identify antibodies to herpes simplex virus in serum, and the devices that 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. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the revised draft guidance document entitled "Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays" that would serve as the special control for the device, if FDA amends the special controls. Because FDA is proposing to amend the special control for this device type, the agency is publishing the proposed rule that designates the revised guidance document as the special control for HSV serological devices.

DATES: Submit written or electronic comments on the proposed rule by November 29, 2010.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2010–N–0429, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB) (see the "Paperwork Reduction Act of 1995" section of this document).

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by email. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number(s), found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Haja Sittana El Mubarak, Center for Devices and Radiological Health, Bldg. 66, rm. 5519, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–6193.

SUPPLEMENTARY INFORMATION:

I. Regulatory Authorities

The act (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), Safe Medical Devices Act (SMDA) (Public Law 101–629), Food and Drug Administration Modernization Act (FDAMA) (Public Law 105–115), and the Medical Device User Fee and Modernization Act (MDUFMA) (Public Law 107–250), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c) established three categories (classes) of devices, defined

by the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the FD&C Act, FDA refers to devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), as preamendments devices. FDA classifies these devices after it takes the following steps: (1) Receives a recommendation from a device classification panel (an FDA advisory committee); (2) publishes the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) publishes a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution before May 28, 1976, generally referred to as postamendments devices are classified automatically by statute (section 513(f) of the FD&C Act) into class III without any FDA rulemaking process. Those devices remain in class III until FDA does the following: (1) Reclassifies the device into class I or II; (2) issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the FD&C Act; or (3) issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a legally marketed device that has been classified into class I or class II. The Agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

Under the 1976 amendments, class II devices were defined as devices for which there was insufficient information to show that general controls themselves would provide reasonable assurance of safety and effectiveness, but for which there was sufficient information to establish performance standards to provide such assurance. SMDA broadened the definition of class II devices to mean those devices for which the general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and any other appropriate actions the Agency deems necessary (section 513(a)(1)(B) of the FD&C Act).

II. Regulatory Background of the Device

In the **Federal Register** of April 3, 2007 (72 FR 15830), FDA published a final rule to reclassify HSV 1 and 2 serological assays into class II. These assays are used as an aid in the clinical laboratory diagnosis of diseases caused by HSV 1 and 2. FDA identified the guidance document entitled "Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays" as the special control.

III. Summary of the Reasons for Revising Special Controls

FDA believes that the special controls for HSV 1 and 2 serological assays should be revised because the new special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the device. FDA believes there is sufficient additional safety and efficacy profile information to justify revising the special controls to better provide such assurance. We have revised the existing guidance by rewriting the method comparison section and the sample selection inclusion and exclusion criteria section. The revisions defined and differentiated the required studies and the study populations for the assessment of the safety and effectiveness of the different types of HSV 1 and HSV 2 serological assays. Additionally, we made several corrections and clarifications throughout the document to ensure accuracy, consistency, and ease of reading.

IV. Special Controls

In addition to general controls, FDA believes that the revised draft guidance document entitled "Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays" (the class II special controls guidance document) is a special control that is adequate to address the risks to health associated with the use of the device. FDA believes that the revised class II special controls guidance document, which incorporates voluntary consensus standards and describes labeling recommendations, in addition to general controls, provides reasonable assurance of the safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of the revised draft class II special controls guidance document that the Agency would use as the special control for this device.

The revised draft class II special controls guidance document sets forth the information FDA believes should be included in premarket notification submissions (510(k)s) for HSV 1 and 2 serological assays. FDA believes that addressing these risks to health in a 510(k) in the manner identified in the revised class II special controls guidance document, or in an acceptable alternative manner, is necessary to provide reasonable assurance of the safety and effectiveness of the device.

V. FDA's Findings

As discussed previously in this document, FDA believes HSV 1 and 2 serological assays should be classified into class II because special controls, in addition to general controls, provide reasonable assurance of the safety and effectiveness of the device and because there is sufficient information to establish special controls to provide such assurance. FDA, therefore, is proposing to establish the revised draft class II special controls guidance document as a special control for the device.

Section 510(m) of the FD&C Act provides that a class II device may be exempt from the premarket notification requirements under section 510(k) of the FD&C Act, if the Agency determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this device, FDA believes that premarket notification is necessary to provide reasonable assurance of safety and effectiveness and, therefore, does not intend to exempt the device from the premarket notification requirements.

VI. Effective Date

FDA proposes that any final regulation based on this proposal become effective 30 days after its date of publication in the **Federal Register**.

VII. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this proposed reclassification action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public

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.