the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. What is the Economic Impact of This Rule?

FDA has examined the impacts of the direct final 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 direct final rule is not a significant regulatory action under 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 we do not believe any companies are currently selling or producing these devices, the agency certifies 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 $133 million, using the most current (2008) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1–year expenditure that would meet or exceed this amount.

VII. How Does the Paperwork Reduction Act of 1995 Apply to This Rule?

This direct final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

VIII. What are the Federalism Impacts of This Rule?

FDA has analyzed this direct final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

IX. How Do You Submit Comments on This Rule?

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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

Biologics, Laboratories, and 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 to amend 21 CFR part 866 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. Section 866.3305 is amended by removing paragraph (c) and by revising paragraph (b) to read as follows:

§ 866.3305 Herpes simplex virus serological assays.

* * * * *

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

Dated: August 17, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–20411 Filed 8–24–09; 8:45 am]

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DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

25 CFR Parts 502, 514, 531, 533, 535, 537, 539, 556, 558, 571, and 573

RIN 3141–0001

Amendments to Various National Indian Gaming Commission Regulations

AGENCY: National Indian Gaming Commission.

ACTION: Final rule; delay of effective date.

SUMMARY: The National Indian Gaming Commission (''NIGC'') announces the extension of the effective date on the final rule concerning various amendments to the National Indian Gaming Commission regulations. The final rule was published in the **Federal Register** on July 27, 2009. The Commission has changed the effective date to December 31, 2009, in order to extend the transition time.

DATES: *Effective Date:* The effective date for the final rule published July 27, 2009, at 74 FR 36926, is delayed from August 26, 2009, until December 31, 2009.

FOR FURTHER INFORMATION CONTACT: Rebecca Chapman, Staff Attorney, Office of General Counsel, at (202) 632–7003; fax (202) 632–7066 (not toll-free numbers).

SUPPLEMENTARY INFORMATION: Congress established the National Indian Gaming Commission under the Indian Gaming Regulatory Act of 1988 (25 U.S.C. 2701–21) (''IGRA'') to regulate gaming on Indian lands. The NIGC issued a final rule updating various NIGC regulations and streamlining procedures, which was published in the **Federal Register** on July 27, 2009 (74 FR 36926). The final rule provided an effective date of August 26, 2009. The NIGC is extending the effective date to December 31, 2009.

Philip N. Hogen,

Chairman.

Norman H. DesRosiers,

Vice Chairman.

[FR Doc. E9–20511 Filed 8–24–09; 8:45 am]

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