

references to specific standards under U.S. GAAP in the Commission's rules and staff guidance.

It should be noted that although the FASB has stated that the FASB Codification supersedes existing references in U.S. GAAP, the FASB Codification does not supersede Commission rules or regulations. We understand that the FASB Codification, as a service to users, includes references to some Commission rules and staff guidance. However, the FASB Codification is not the authoritative source for such content, nor does its inclusion in the FASB Codification affect how such content may be updated in the future.

### III. Codification Update

The "Codification of Financial Reporting Policies" announced in Financial Reporting Release No. 1 (April 15, 1982) [47 FR 21028] is updated by adding at the end of Section 101, under the Financial Reporting Number (FR-80A) assigned to this interpretive release, the text in Sections I and II of this release.

The Codification is a separate publication of the Commission. It will not be published in the **Federal Register**/Code of Federal Regulations.

#### List of Subjects

##### 17 CFR Part 211

Reporting and recordkeeping requirements, Securities.

##### 17 CFR Parts 231 and 241

Securities.

#### Amendments to the Code of Federal Regulations

■ For the reasons set out in the preamble, the Commission is amending title 17, chapter II of the Code of Federal Regulations as set forth below:

#### PART 211—INTERPRETATIONS RELATING TO FINANCIAL REPORTING MATTERS

■ Part 211, Subpart A, is amended by adding Release No. FR-80A and the release date of August 18, 2009 to the list of interpretive releases.

#### PART 231—INTERPRETATIVE RELEASES RELATING TO THE SECURITIES ACT OF 1933 AND GENERAL RULES AND REGULATIONS THEREUNDER

■ Part 231 is amended by adding Release No. 33-9062A and the release date of August 18, 2009 to the list of interpretive releases.

#### PART 241—INTERPRETATIVE RELEASES RELATING TO THE SECURITIES EXCHANGE ACT OF 1934 AND GENERAL RULES AND REGULATIONS THEREUNDER

■ Part 241 is amended by adding Release No. 34-60519A and the release date of August 18, 2009 to the list of interpretive releases.

By the Commission.

Dated: August 19, 2009.

**Florence E. Harmon,**

*Deputy Secretary.*

[FR Doc. E9-20381 Filed 8-24-09; 8:45 am]

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Food and Drug Administration

##### 21 CFR Part 866

[Docket No. FDA-2009-N-0344]

#### Microbiology Devices; Reclassification of Herpes Simplex Virus Types 1 and 2 Serological Assays

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Direct final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is implementing a direct final rule correcting the regulation classifying herpes simplex virus (HSV) serological assays by removing the reference to HSV serological assays other than type 1 and type 2. When reclassifying this device, FDA mistakenly distinguished between HSV serological assays type 1 and type 2 and all other HSV serological assays. At that time, and today, the only preamendments HSV serological assays which FDA was aware of were type 1 and type 2 and, therefore, the classification of HSV assays other than type 1 and type 2 was incorrect. FDA is correcting the classification of this device to eliminate possible confusion resulting from this error. Elsewhere in this issue of the **Federal Register**, we are publishing a companion proposed rule under FDA's usual procedure for notice and comment to provide a procedural framework to finalize the rule in the event we receive significant adverse comment and withdraw this direct final rule.

**DATES:** This rule is effective December 7, 2009. Submit written or electronic comments on the direct final rule by October 8, 2009. If we receive no significant adverse comments within the specified comment period, we intend to

publish a document confirming the effective date of the final rule in the **Federal Register** within 30 days after the comment period on this direct final rule ends. If we receive any timely significant adverse comment, we will withdraw this final rule in part or in whole by publication of a document in the **Federal Register** within 30 days after the comment period ends.

**ADDRESSES:** You may submit comments, identified by Docket No FDA-2009-N-0344, by any of the following methods: *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 e-mail. 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:** Scott McFarland, Center for Devices and Radiological Health WO/66, rm. 5543, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD, 301-796-6217.

**SUPPLEMENTARY INFORMATION:**

## I. What Is the Background of the Rule?

The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (SMDA) (Public Law 101–629), the Food and Drug Modernization Act of 1997 (FDAMA) (Public Law 105–115), and the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110–85), among other amendments, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on 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).

Devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), are commonly referred to as “preamendments devices.” Under section 513 of the act, FDA classifies preamendments devices according to the following steps: (1) FDA receives a recommendation from a device classification panel (an FDA advisory committee); (2) FDA publishes the panel’s recommendation for comment, along with a proposed regulation classifying the device; and (3) FDA 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, are commonly referred to as “postamendments devices.” These devices are classified automatically by statute (section 513(f) of the act (21 U.S.C. 360c(f)) into class III and require premarket approval, unless and until: (1) FDA reclassifies the device into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the act; or (3) FDA issues an order under section 513(i) of the act (21 U.S.C. 360c(i)) finding the device to be substantially equivalent to a predicate device that does not require premarket approval.

In the **Federal Register** of November 9, 1983 (47 FR 50823), FDA classified the preamendments devices, herpes simplex virus serological reagents, into class III (§ 866.3305 (21 CFR 866.3305)). At the time FDA classified the device, the only preamendments HSV serological assays FDA was aware of

were type 1 and type 2 HSV serological assays. Since that time, FDA has not become aware of any other preamendments HSV serological assays, nor has it received a premarket notification for a HSV serological assay other than a type 1 or type 2 HSV serological assay.

In the **Federal Register** of April 3, 2007 (72 FR 15828), FDA published a final rule reclassifying the preamendments device HSV serological assays from class III to class II. In that rulemaking FDA identified the device being reclassified as type 1 and type 2 HSV serological assays and identified other HSV serological assays as class III devices. However, as stated previously, the only preamendments HSV serological assays of which FDA is aware are type 1 and type 2 HSV serological assays. To avoid any possible confusion, FDA is correcting the regulation to accurately describe this generic type of device. This direct final rule corrects the classification regulation by removing the reference to HSV serological assays other than type 1 and type 2.

## II. What Does This Direct Final Rulemaking Do?

In this direct final rule, FDA is correcting § 866.3305 by removing from the regulation the reference to HSV serological assays other than type 1 and type 2.

## III. What Are the Procedures for Issuing a Direct Final Rule?

In the **Federal Register** of November 21, 1997 (62 FR 62466), FDA announced the availability of the guidance document entitled “Guidance for FDA and Industry: Direct Final Rule Procedures” that described when and how FDA will employ direct final rulemaking. We believe that this rule is appropriate for direct final rulemaking because it is intended to make noncontroversial changes to existing regulations. We anticipate no significant adverse comment. Consistent with FDA’s procedures on direct final rulemaking, we are publishing elsewhere in this issue of the **Federal Register** a companion proposed rule that is identical to the direct final rule. The companion proposed rule provides a procedural framework within which the rule may be finalized in the event the direct final rule is withdrawn because of any significant adverse comment. The comment period for this direct final rule runs concurrently with the comment period of the companion proposed rule. Any comments received in response to the companion proposed rule will also be considered as

comments regarding this direct final rule.

We are providing a comment period on the direct final rule of 75 days after the date of publication in the **Federal Register**. If we receive any significant adverse comment, we intend to withdraw this final rule before its effective date by publication of a notice in the **Federal Register** within 30 days after the comment period ends. A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule’s underlying premise or approach, or would be ineffective or unacceptable without change. In determining whether an adverse comment is significant and warrants withdrawing a direct final rulemaking, we will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process in accordance with section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553). Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. For example, a comment recommending an additional change to the rule will not be considered a significant adverse comment, unless the comment states why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to part of a rule and that part can be severed from the remainder of the rule, we may adopt as final those parts of the rule that are not the subject of a significant adverse comment. If we withdraw the direct final rule, all comments received will be considered under the companion proposed rule in developing a final rule under the usual notice-and-comment procedures under the APA (5 U.S.C. 552a *et seq.*). If we receive no significant adverse comment during the specified comment period, we intend to publish a confirmation document in the **Federal Register** within 30 days after the comment period ends.

## IV. What is the Legal Authority for This Rule?

FDA is issuing this direct final rule under the device and general administrative provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 360i, 371, and 374).

## V. What is the Environmental Impact of This Rule?

FDA has determined under 21 CFR 25.30(i) and 25.34(b) that this 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.

#### 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]

**BILLING CODE 7565–01–P**