You can also get a copy by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267–9680. Make sure to identify the docket number, notice number, or amendment number of this rulemaking.

You may access all documents the FAA considered in developing this resission from the internet through the Federal eRulemaking Portal referenced in paragraph (1).

List of Subjects in 14 CFR Part 93

Air traffic control, Airports, Navigation (air), Recordkeeping and reporting requirements.

The Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends Chapter I of Title 14, Code of Federal Regulations, as follows:

PART 93—SPECIAL AIR TRAFFIC RULES

■ 1. The authority citation for part 93 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40109, 40113, 44502, 44514, 44701, 44719, 46301.

Subpart N—[Removed and Reserved]

■ 2. Remove and reserve Subpart N of Part 93.

Issued in Washington, DC, on October 1, 2009.

J. Randolph Babbitt,

Administrator.

[FR Doc. E9–24235 Filed 10–8–09; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2009–N–0119]

Medical Devices; Immunology and Microbiology Devices; Classification of Respiratory Viral Panel Multiplex Nucleic Acid Assay

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing the classification of the respiratory viral panel multiplex nucleic acid assay into class II (special controls). The special controls that will apply to the device are three guidance documents entitled: ''Class II Special Controls Guidance Document: Respiratory Viral Panel Multiplex Nucleic Acid Assay,'' as applicable, ''Class II Special Controls Guidance Document: Testing for Human Metapneumovirus (hMPV) Using Nucleic Acid Assays,'' and as applicable,''Class II Special Controls Guidance Document: Testing for Detection and Differentiation of Influenza A Virus Subtypes Using Multiplex Nucleic Acid Assays.'' The agency classified the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance documents that will serve as the special controls for this device.

DATES: This final rule is effective November 9, 2009. The classification was effective January 3, 2008.

FOR FURTHER INFORMATION CONTACT: Zivana Tezak, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5550, Silver Spring, MD 20993, 301–796–6204.

SUPPLEMENTARY INFORMATION:

I. What Is the Background of This Rulemaking?

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k) and part 807 (21 CFR part 807) of FDA's regulations.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification (section 513(f)(2) of the act).

In accordance with section 513(f)(1) of the act, FDA issued an order on November 30, 2007, classifying the Luminex Molecular Diagnostics, Inc., xTAG™ RVP (Respiratory Viral Panel) as class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device that was subsequently reclassified into class I or class II. On December 1, 2007, Luminex Molecular Diagnostics, Inc., submitted a petition requesting classification of the xTAG™ RVP under section 513(f)(2) of the act. The manufacturer recommended that the device be classified into class II.

In accordance with section 513(f)(2) of the act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the act. Devices are to be classified into class II if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition, FDA determined that the Luminex Molecular Diagnostics, Inc., xTAG™ RVP can be classified in class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of safety and effectiveness of the device.

The device is assigned the generic name ''respiratory viral panel multiplex nucleic acid assay.'' It is identified as a qualitative in vitro diagnostic device that is intended to simultaneously detect and identify multiple viral nucleic acids extracted from human respiratory specimens or viral culture. The detection and identification of a specific viral nucleic acid from individuals exhibiting signs and symptoms of respiratory infection aids in the diagnosis of respiratory viral infection when used in conjunction with other clinical and laboratory findings.

Respiratory illness caused by various commonly circulating respiratory viruses (e.g., Influenza A, RSV) can cause high morbidity and mortality, particularly in at-risk populations such as the elderly and the very young. Therefore, FDA has identified the following issues of safety or effectiveness requiring special controls for a respiratory viral panel multiplex nucleic acid assay, i.e. potential risks to health associated with this assay. These include (1) Failure of the device to perform as indicated, leading to inaccurate results or lack of results and (2) incorrect interpretation of results; both of these potential risks may lead to incorrect patient management decisions. For example, a false positive result could lead to unnecessary or inappropriate treatment for the misidentified viral illness, as well as delayed treatment of the actual infection, which may potentially be a more serious infection caused by bacteria or other pathogens. A false negative result could lead to failure to provide a diagnosis and the correct treatment, and may contribute to unnecessary treatment. A lack of result could lead to delayed diagnosis and inadequate treatment. Additionally, for assays that both detect Influenza A and differentiate between Influenza A subtypes, if a specimen yields a positive test result for Influenza A, but produces negative test results for all specific influenza A subtypes intended to be differentiated (i.e., H1 or H3), then local, state or federal public health authorities should be notified to determine whether the specimen represents a novel strain of Influenza A, in accordance with the Morbidity and Mortality Weekly Report (*http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5613a4.htm* and *http://www.cste.org/ps/2007pdfs/novelfluanndssjan10final23.pdf*).[1] Therefore, inaccurate results for influenza types and subtypes included in the respiratory viral panel may lead to inappropriate public health responses. Failure to interpret assay results in the context of the other laboratory results and the clinical presentation could lead to inappropriate or delayed treatment. The virus or viruses detected may not necessarily be the cause of the clinical symptoms, therefore positive assay results do not rule out bacterial co-infection, or co-infection with other viruses.

FDA believes the class II special controls guidance documents will help mitigate potential risks by providing recommendations for performance evaluation, labeling, and measures to address the effects of ancillary reagents (specific reagents required under instructions for use of the assay but not provided) on safety and effectiveness of respiratory viral panel multiplex nucleic acid assays. The guidance documents also provide information on how to meet premarket (510(k)) submission requirements for the device. FDA believes that following the class II special controls guidance documents generally addresses the risks to health identified in the previous paragraph. Therefore, on January 3, 2008, FDA issued an order to the petitioner classifying the device into class II. FDA is codifying this classification by adding 21 CFR 866.3980.

Any firm submitting a 510(k) premarket notification for a respiratory viral panel multiplex nucleic acid assay will need to address the issues covered in the special controls guidances. However, the firm need only show that its device meets the recommendations of the guidances, or in some other way provides equivalent assurance of safety and effectiveness.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, however, FDA has determined that premarket review of the system's key performance characteristics, test methodology, labeling, and other requirements as outlined in § 807.87, will provide reasonable assurance that acceptable levels of performance for both safety and effectiveness will be addressed before marketing clearance. Thus, persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the respiratory viral panel multiplex nucleic acid assay they intend to market.

II. What Is the Environmental Impact of This Rule?

The agency has determined under 21 CFR 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.

III. What Is the Economic Impact of This Rule?

FDA has examined the impacts of the 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 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 classification of these devices into class II will relieve manufacturers of the device of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs, 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 $130 million, using the most current (2007) 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.

IV. Does This Final Rule Have Federalism Implications?

FDA has analyzed this final 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

[1] (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

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. 21 U.S.C. 360k; *Medtronic* v. *Lohr*, 518 U.S. 470 (1996); *Riegel* v. *Medtronic*, 128 S. Ct. 999 (2008). The special controls established by this final rule 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. (*Papike* v. *Tambrands, Inc.*, 107 F.3d 737, 740–42 (9th Cir. 1997)).

V. How Does This Rule Comply With the Paperwork Reduction Act of 1995?

This final rule establishes as special controls three guidance documents that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control no. 0910–0120. The collections of information in 21 CFR part 801 and 21 CFR 809.10, regarding labeling, have been approved under OMB control no. 0910–0485.

VI. What References Are on Display?

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Luminex Molecular Diagnostics, Inc., dated December 1, 2007.

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, 21 CFR part 866 is 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. Section 866.3980 is added to subpart D to read as follows:

§ 866.3980 Respiratory viral panel multiplex nucleic acid assay.

(a) *Identification.* A respiratory viral panel multiplex nucleic acid assay is a qualitative in vitro diagnostic device intended to simultaneously detect and identify multiple viral nucleic acids extracted from human respiratory specimens or viral culture. The detection and identification of a specific viral nucleic acid from individuals exhibiting signs and symptoms of respiratory infection aids in the diagnosis of respiratory viral infection when used in conjunction with other clinical and laboratory findings. The device is intended for detection and identification of a combination of the following viruses:

(1) Influenza A and Influenza B;

(2) Influenza A subtype H1 and Influenza A subtype H3;

(3) Respiratory Syncytial Virus subtype A and Respiratory Syncytial Virus subtype B;

(4) Parainfluenza 1, Parainfluenza 2, and Parainfluenza 3 virus;

(5) Human Metapneumovirus;

(6) Rhinovirus; and

(7) Adenovirus.

(b) *Classification.* Class II (special controls). The special controls are:

(1) FDA's guidance document entitled ''Class II Special Controls Guidance Document: Respiratory Viral Panel Multiplex Nucleic Acid Assay;''

(2) For a device that detects and identifies Human Metapneumovirus, FDA's guidance document entitled ''Class II Special Controls Guidance Document: Testing for Human Metapneumovirus (hMPV) Using Nucleic Acid Assays;'' and

(3) For a device that detects and differentiates Influenza A subtype H1 and subtype H3, FDA's guidance document entitled ''Class II Special Controls Guidance Document: Testing for Detection and Differentiation of Influenza A Virus Subtypes Using Multiplex Nucleic Acid Assays.'' See § 866.1(e) for the availability of these guidance documents.

Dated: October 1, 2009.

Jeffrey Shuren,

Acting Director, Center for Devices and Radiological Health.

[FR Doc. E9–24432 Filed 10–8–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

25 CFR Parts 542 and 543

RIN 3141–AA–37

Minimum Internal Control Standards for Class II Gaming

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 for Minimum Internal Control Standards for Class II Gaming. The final rule was published in the **Federal Register** on October 10, 2008. The Commission has changed the effective date for the amendments to §§ 542.7 and 542.16 as well as the date for operations to implement tribal internal controls found in 543.3(c)(3) to October 13, 2010, in order to extend the transition time.

DATES: *Effective Date:* The effective date for the amendments to §§ 542.7 and 542.16 for the final rule published October 10, 2008, at 73 FR 60492, is delayed from October 13, 2009, until October 13, 2010. The effective date for the amendment to § 543.3(c)(3) is October 9, 2009.

FOR FURTHER INFORMATION CONTACT: John R. Hay, 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 that superseded specified sections of established Minimum Internal Control Standards and replaced them with a new part titled Minimum Internal Control Standards Class II Gaming, that was published in the **Federal Register** on October 10, 2008 (73 FR 60492). The final rule provided an effective date for amendments to §§ 542.7 and 542.16 of October 13, 2009. The NIGC is extending the effective date for these amendments to October 13, 2010. The rule at § 543.3(c)(3) also set a deadline of within six months of the date the tribal gaming regulatory authorities' enactment of tribal internal controls for tribal operators to come into compliance with tribal internal controls. This deadline has likewise been extended to October 13, 2010.