Rulemaking Distribution System, which describes the application procedure.

Background

On February 7, 2005, the FAA published in the **Federal Register** a final rule establishing V–623 (70 FR 6336). However, navigation aid signal coverage problems were identified, which could not be resolved, so the FAA revoked the airway on June 3, 2005 (70 FR 32484). Subsequently, a segment of the airway was redesigned along a satisfactory navigation aid radial. Therefore, the FAA is again proposing to establish V–623.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 to establish V–623 between the Sparta, NJ, VORTAC and the Carmel, NY, VOR/DME. The proposed airway is needed to enhance the management of air traffic transiting from the New England area to airports in the Newark, NJ, area.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9N, Airspace Designations and Reporting Points, dated September 1, 2005, and effective September 15, 2005, is amended as follows:

Paragraph 6010(a)—Domestic VOR Federal Airways

* * * * *

V–623 [New]

From Sparta, NJ; INT Sparta, NJ 060°(M) 047°(T) and Carmel 275°(M) 263°(T) radials; Carmel.

* * * * *

Issued in Washington, DC, on December 30, 2005.

Edith V. Parish,

Manager, Airspace and Rules.

[FR Doc. E6–69 Filed 1–6–06; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. 2005N–0471]

Immunology and Microbiology Devices; Reclassification of Herpes Simplex Virus (Types 1 and/or 2) Serological Assays

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify herpes simplex virus (HSV) (types 1 and/or 2) serological assays from class III (premarket approval) to class II (special controls). HSV serological assays (types 1 and/or 2) are intended for testing specimens from individuals who have signs and symptoms of infection consistent with HSV 1 and/or 2 or for determining if an individual has been previously infected with HSV 1 and/or 2, as well as for providing epidemiological information about these infections. The detection of HSV antibodies, in conjunction with other clinical laboratory findings, aids in the clinical laboratory diagnosis of an infection by HSV 1 and/or 2. FDA is proposing this reclassification on its own initiative based on new information. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance document that would serve as the special control, if FDA reclassifies this device.

DATES: Submit written or electronic comments by April 10, 2006.

ADDRESSES: You may submit comments, identified by Docket No. 2005N–0471, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

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 or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and docket number 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.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, 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.fda.gov/ohrms/dockets/default.htm* 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: Sally Hojvat, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither

Rd., Rockville, MD 20850, 240–276–0496 x114.

SUPPLEMENTARY INFORMATION:

I. Background

A. Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (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), the Safe Medical Devices Act of 1990 (SMDA) (Public Law 101–629), the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115), and the Medical Device User Fee and Modernization Act (Public Law 107–250), 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, 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 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 act).

Under section 513 of the 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 act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval 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 act, as amended by FDAMA; or (3) issues an order finding the device to be substantially equivalent, under section 513(i) of the 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 act (21 U.S.C. 360(k)) and 21 CFR part 807.

A person may market a preamendments device that has been classified into class III through premarket notification procedures, without submission of a premarket approval application (PMA), until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Section 513(e) of the act governs reclassification of classified devices. This section provides that FDA may, by rulemaking, reclassify a device based upon ''new information.'' FDA can initiate a reclassification under section 513(e) of the act or an interested person may petition FDA to reclassify a preamendments device. The term ''new information,'' as used in section 513(e) of the act, includes information developed as a result of a reevaluation of the data before the agency when the device was originally classified, as well as information not presented, not available, or not developed at that time (see, e.g., *Holland Rantos* v. *United States Department of Health, Education, and Welfare*, 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch*, 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard*, 366 F.2d 177 (7th Cir. 1966)).

Reevaluation of the data previously before the agency is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of newly available regulatory authority (see *Bell* v. *Goddard*, supra, 366 F.2d at 181; *Ethicon, Inc.* v. *FDA*, 762 F.Supp. 382, 389–91 (D.D.C. 1991)), or in light of changes in ''medical science'' (see *Upjohn* v. *Finch*, supra, 422 F.2d at 951). Whether data before the agency are past or new, the ''new information'' to support reclassification under section 513(e) of the act must be ''valid scientific evidence,'' as defined in section 513(a)(3) of the act and 21 CFR 860.7(c)(2) (see, e.g., *General Medical Co.* v. *FDA*, 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Assoc.* v. *FDA*, 766 F.2d 592 (D.C. Cir.), cert. denied, 474 U.S. 1062 (1985)).

FDA relies upon valid scientific evidence in the classification process to determine the level of regulation for devices. To be considered in the reclassification process, the valid scientific evidence upon which the agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending PMA (see section 520(c) of the act (21 U.S.C. 360j(c)).

FDAMA added section 510(m) to the act that provides that a class II device may be exempted from the premarket notification requirements under section 510(k) of the act if the agency determines that premarket notification is not necessary to assure the safety and effectiveness of the device.

B. Regulatory History of the Device

In the **Federal Register** of April 22, 1980 (45 FR 27258), FDA published a proposed rule to classify the preamendment HSV serological reagents into class II. FDA received three comments on the proposal. All three comments expressed concern about the health of newborn infants, specifically regarding risks associated with infection with HSV. Two comments requested that FDA apply class III controls to this device because of these risks to health and because medical practitioners would rely on the accuracy of the test results to make important clinical decisions, such as whether or not to perform a cesarean section delivery of an infant. The third comment urged that, before performance standards are established, clinical data be obtained that compare the sensitivity and specificity of HSV serological reagents with the accuracy of diagnosis of the infection by viral culture.

A final rule classifying HSV devices into class III published in the **Federal Register** of November 9, 1982 (47 FR 50814). The agency determined that class III was appropriate because the device presented a potential unreasonable risk of illness or injury because failure to accurately identify the virus or its antibodies may result in a serious risk to the health of the newborn infant. In addition, inaccurate results may cause a practitioner to perform an unnecessary cesarean section delivery of

an infant that may result in a serious risk to the health of the mother. The agency decided that until standards were established, clinical data should be obtained that compare the sensitivity and specificity of HSV serological reagents with the accuracy of diagnosis of the infection by viral culture. At that time, FDA believed there were insufficient data to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. FDA also changed the scope of the classification to reflect a revised panel recommendation and comments received in response to the proposed rule. The final rule classified direct fluorescent antibody reagents, as well as all reagents employed in more recently developed laboratory methods (e.g., enzyme immunoassays) of testing for HSV antibodies in patients' serum, into class III.

In the **Federal Register** of August 14, 1995 (60 FR 41984 and 60 FR 41986), FDA published two orders for certain class III devices requiring the submission of safety and effectiveness information in accordance with the Preamendments Class III Strategy for implementing section 515(i) of the act. Each of the orders described in detail the format for submitting the type of information required by section 515(i) of the act so that the information submitted would clearly support reclassification or indicate that a device should remain in class III. The orders also scheduled the required submissions in groups of nine devices at 6-month intervals beginning August 14, 1996. The August 14, 1995, orders included the device proposed for reclassification in this proposed rule. In response, 11 manufacturers, in 16 submissions, submitted information supporting FDA reclassification of the device from class III to class II.

In accordance with sections 513(e) of the act and 21 CFR 860.130(b)(1), based on new information with respect to the device, FDA, on its own initiative, is now proposing to reclassify this device from class III to class II when HSV 1 and/or 2 assays are used for the following purposes: (1) Testing specimens from individuals who have signs and symptoms of infection consistent with HSV 1 and/or 2, (2) determining if an individual has been previously infected with HSV 1 and/or 2, or (3) providing epidemiological information about these infections. Additionally, FDA is proposing to modify the description of the device to clarify terminology.

C. Device Description

HSV serological assays are devices that consist of antigens and antisera used in various serological tests to identify antibodies to HSV in serum. Additionally, some of the assays consist of HSV antisera conjugated with a fluorescent dye (immunofluorescent assays) used to identify HSV directly from clinical specimens or tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by HSV and provides epidemiological information on these diseases. HSV 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 mild infection to severe generalized disease with a fatal outcome.

Currently marketed HSV 1 and/or 2 serological assays are usually based on manual enzyme-linked immunosorbent assay, enzyme immunoassay, immunofluorescence assay, or enzyme-linked virus induction assay. FDA has also approved a test based on a chemiluminescent enzyme immunoassay. Serological assays typically rely on specific binding of specimen antibodies to a fixed HSV antigen, which is then detected by a labeled secondary (anti-IgM or anti-IgG) antibody. Serum and plasma are the common matrices for currently marketed tests for detecting HSV 1 and/or 2 antibodies. Antigen detection assays rely on specific binding of labeled antibodies to an HSV antigen, which is then detected by a reader or immunofluorescent microscope.

II. Proposed Rule

FDA is proposing to reclassify HSV (types 1 and/or 2) serological assays from class III to class II (special controls). These devices are used for testing specimens from individuals who have signs and symptoms of infection caused by HSV 1 and/or 2, determining if an individual has been previously infected with HSV 1 and/or 2, or providing epidemiological information about these infections. FDA believes that class II with a special controls guidance document will provide reasonable assurance of safety and effectiveness. FDA has considered HSV (types 1 and/or 2) serological assays in accordance with section 510(m) of the act and determined that the device does need premarket notification to assure the safety and effectiveness of HSV (types 1 and/or 2) serological assays.

HSV serological assays of types other than type 1 and/or 2 will remain in class III. HSV nucleic acid amplification assays are not within the device types classified in 21 CFR 866.3305.

FDA is also proposing to modify the description of the device by replacing the word ''reagents'' with the word ''assays'' to differentiate serological assays from replacement reagents and analyte-specific reagents.

III. Risks to Health

After considering the information received from the 11 manufacturers, the published literature, FDA's experience with HSV 1 and/or 2 serological assays, and the medical device reports filed on HSV 1 and/or 2 serological assays, FDA has determined that failure of HSV 1 and/or 2 serological assays to perform as indicated, or an error in interpretation of results, may lead to improper patient management. False positive results may subject pregnant women or a newborn to unnecessary treatment with antiviral drugs, which could place both the mother and the fetus/infant at risk, or it may lead to an unnecessary cesarean delivery of the fetus. False positive results may also lead to potentially toxic therapy in immunocompromised patients who may be at risk for reactivation of latent herpes virus infection and/or disseminated HSV infection. False negative results in pregnant women may lead to neonatal transmission of a primary herpes infection during vaginal delivery, which may result in life-threatening conditions such as encephalitis. False negative results in pretransplant and/or immunocompromised populations could falsely identify transplant donors, which could lead to the transplant of herpes positive organs to nonimmune patients.

IV. Summary of Reasons for Reclassification

FDA believes that HSV 1 and/or 2 serological assays should be reclassified into class II because special controls, in addition to general controls, can provide reasonable assurance of the safety and effectiveness of the device, and there is now sufficient information to establish special controls. FDA review of performance characteristics will provide reasonable assurance that acceptable levels of performance for both safety and effectiveness are addressed before marketing clearance.

V. Summary of Data Upon Which the Reclassification Is Based

The effectiveness of HSV 1 and/or 2 serological assays has been well-established over the past 25 years. The

sensitivities of these tests for detection of HSV antibodies vary from 80 percent to 98 percent and the specificities of these assays are usually greater than or equal to 95 percent. Technological improvements have increased the reliability and performance of these devices for clinical sensitivity and specificity. Further information on the performance of these assays has been established by comparison with a masked, characterized serum panel obtained from the Centers for Disease Control and Prevention.

Based on the available information, FDA believes that the special control discussed in section VI of this document is capable of providing reasonable assurance of the safety and effectiveness of HSV (types 1 and/or 2) serological assays with regard to the identified risks to health of this device.

VI. Special Controls

FDA believes that, in addition to general controls, the class II special control guidance document entitled ''Class II Special Controls Guidance Document: Herpes Simplex Virus Type 1 and 2 Serological Assays'' is adequate to control the risks to health described in section III of this document. The class II special controls draft guidance provides information on how to meet premarket notification requirements for the assays in sections that discuss performance characteristics and labeling. The performance characteristics section describes studies integral to the demonstration of appropriate performance and, in this way, controls against assays that may fail to meet current standards. The labeling section addresses factors such as directions for use, quality control, and precautions for use and interpretation, which will help mitigate errors in the interpretation of results. FDA tentatively believes that complying with the act and following the recommendations in the draft special controls guidance document will provide reasonable assurance of safety and effectiveness of these devices and adequately address the risks to health identified in section III of this document.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance document that would serve as the special control, if FDA reclassifies these devices. If implemented, following the effective date of a final rule classifying the devices, any firm submitting a premarket notification under section 510(k) of the act for these devices would need to address the issues covered in the class II special controls guidance document. However, the firm need only show that its device meets the recommendations of the guidance document or in some other way provides equivalent assurances of safety and effectiveness.

VII. Environmental Impact

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.

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 (Pub. L. 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 classification of this device 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, and may permit small potential competitors to enter the marketplace by lowering their costs, the agency certifies that the proposed 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 $115 million, using the most current (2003) 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.

IX. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed 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.

X. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520) is not required.

FDA also tentatively concludes that the special controls guidance document identified by this proposed rule 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 the draft guidance document entitled ''Class II Special Controls Guidance Document: Herpes Simplex Virus Type 1 and 2 Serological Assays''; the notice contains an analysis of the paperwork burden for the draft guidance.

XI. Comments

Interested persons may submit to the Division of Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comment, 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.

XII. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 am. and 4 pm., Monday through Friday.

1. Arvin, A.M. and C.G. Prober, ''Herpes Simplex Viruses,'' *Manual of Clinical Microbiology*, 6th edition, Eds: E.J. Baron,

M.A. Pfaller, F.C Tenover, and R.H. Yolken, ASM Press, Washington, DC, pp. 876–883, 1995.

2. Ashley, R., ''Herpes Simplex Viruses,'' *Diagnostic Procedures for Viral, Rickettsial, and Chlamydial Infections*, 7th edition, Eds: E.H. Lenette, D.A. Lenette, and E.T. Lenette, American Public Health Association, Inc., New York, NY, pp. 375–395, 1995.

3. ''Screening for Genital Herpes Simplex, Recommendation,'' *Guide to Clinical Preventive Services*, 2nd edition, Report of the U.S. Preventive Services Task Force, Eds: C. DiGuiseppi, D. Atkins, and S.H. Woolf, International Medical Publishing, Alexandria, VA, pp. 335–345, 1996.

4. Prober, C.G., et al., ''The Management of Pregnancies Complicated by Genital Infections with Herpes Simplex Virus,'' *Clinical Infectious Diseases*, 15:1031–1038, 1992.

5. Ashley, R., et al., ''Inability of Enzyme Immunoassays to discriminate Between Infections with Herpes Simplex Virus Types 1 and 2,'' *Annals of Internal Medicine*, 115:520–526, 1991.

6. Stewart, J.A., ''Herpes Simplex Virus,'' *Manual of Clinical Laboratory Immunology*, 4th edition, American Society for Microbiology, Washington, DC, pp. 554–559, 1992.

7. Whitley, R.J., ''Herpes Simplex Viruses,'' *Fields Virology*, 3rd edition, Eds: B.N. Fields, et al., Lippincott-Raven, Philadelphia, PA, pp. 2297–2333, 1996.

8. Prober, C.G., et al., ''Low Risk of Herpes Simplex Virus Infections in Neonates Exposed to the Virus at the Time of Vaginal Delivery to Mothers with Recurrent Genital Herpes Simplex Virus Infections,'' *New England Journal of Medicine*, 316(5):240–244, 1987.

9. Nahmias, A.J., et al., ''Herpes Simplex Viruses 1 and 2,'' *Viral Infections of Humans—Epidemiology and Control*, 3rd edition, Eds: A.S. Evans, Plenum Medical Book Co., New York, NY, pp. 393–417, 1991.

10. National Committee for Clinical Laboratory Standards, ''Specifications for Immunological Testing for Infectious Diseases; Approved Guideline,'' I/LA18–A, 1994

11. National Committee for Clinical Laboratory Standards, ''Statistical Control for Quantitative Measurements: Principles and Definitions; Approved Guideline—Second Edition,'' C24–A, 1999.

12. National Committee for Clinical Laboratory Standards, ''Assessment of the Clinical Accuracy of Laboratory Tests Using Receiver Operating Characteristics (ROC) Plots; Approved Guideline, GP10–A, 1995.

13. National Committee for Clinical Laboratory Standards, Evaluation of ''Precision Performance of Clinical Chemistry Devices; Approved Guideline,'' EP5–A, 1999.

14. National Committee for Clinical Laboratory Standards, ''Molecular Diagnostic Methods for Infectious Diseases; Approved Guideline,'' MM3–A, 1995.

15. FDA Microbiology Branch Guidance Document, ''Review Criteria for in vitro Diagnostic Devices for Detection of IgM Antibodies to Viral Agents.''

16. Centers for Disease Control and Prevention, ''HSV IgG Panel of Well Characterized Sera (for Device Validation Available From CDC).''

17. ''Case Definitions for Public Health Surveillance,'' *Morbidity and Mortality Weekly Report*, Recommendations and Reports, 39:RR–13, 1990.

18. Arkin, C.F. and M.S. Wachtel, ''How Many Patients are Necessary to Access Test Performance?'', *Journal of the American Medical Association*, 263:275–278, 1990.

19. Centers for Disease Control and Prevention, ''Sexually Transmitted Diseases Guidelines, Genital Herpes Simplex Virus Infections,'' *Morbidity and Mortality Weekly Report*, 51:RR–6, 2002.

20. Brown, Z.A., et al. ''Effect of Serologic Status and Cesarean Delivery on Transmission Rates of Herpes Simplex Virus From Mother to Infant,'' *Journal of the American Medical Association*, 289:203–209, 2003.

21. De Tiege, X., et al. ''Limits of Early Diagnosis of Herpes Simplex Encephalitis in Children: A Retrospective Study of 38 Cases, Brief Report,'' *Clinical Infectious Diseases*, 36:1335–1339, 2003.

List of Subjects in 21 CFR Part 866

Biologics, laboratories, 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. Section 866.3305 is revised 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.* (1) Class II (special controls). The device is classified as class II if the herpes simplex virus serological assay is type 1 and/or 2. The special control for the device is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Herpes Simplex Virus Type 1 and 2 Serological Assays.'' For availability of the guidance document, see § 866.1(e).

(2) Class III (premarket approval). The device is classified as class III if the herpes simplex virus serological assay is a type other than type 1 and/or 2.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established for the requirement for premarket approval for the devices described in paragraph (b)(2) of this section. See § 866.3.

Dated: December 21, 2005.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 06–173 Filed 1–6–06; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2002–0051; FRL–8020–2]

RIN 2060–AJ78

National Emission Standards for Hazardous Air Pollutants From the Portland Cement Manufacturing Industry

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; extension of public comment period and announcement of a public hearing.

SUMMARY: EPA is announcing that the comment period on the proposed amendments to National Emission Standards for Hazardous Air Pollutants From the Portland Cement Manufacturing Industry, published on December 2, 2005, is being extended until February 23, 2006, and that a public hearing on the proposed amendments will be held on January 24, 2006.

DATES: *Comments.* The comment period has been extended from January 17, 2006. Comments must now be received on or before February 23, 2006.

Public Hearing. A public hearing is scheduled for January 24, 2006, from 10 a.m. until 5 p.m. Eastern Standard Time.