some other way provides equivalent assurances of safety and effectiveness.

FDA is now codifying the classification for HAV serological assays by adding new § 866.3310. For the convenience of the reader, 21 CFR 866.1 informs the reader where to find guidance documents referenced in 21 CFR part 866.

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, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device and, therefore, this type of device is not exempt from premarket notification requirements. 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 HAV serological assay they intend to market.

V. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this 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.

VI. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, 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. Reclassification of HAV serological assays from class III into class II will relieve manufacturers of the cost of complying with the premarket approval requirements in section 515 of the act. Because reclassification will reduce regulatory costs with respect to these devices, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs.

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 final rule to result in any 1-year expenditure that would meet or exceed this amount.

VII. Federalism

FDA has analyzed this 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

VIII. Paperwork Reduction Act of 1995

FDA concludes that this rule contains no new collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

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, 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 866.3310 is added to subpart D to read as follows:

§ 866.3310 Hepatitis A virus (HAV) serological assays.

(a) *Identification.* HAV serological assays are devices that consist of antigens and antisera for the detection of hepatitis A virus-specific IgM, IgG, or total antibodies (IgM and IgG), in human serum or plasma. These devices are used for testing specimens from individuals who have signs and symptoms consistent with acute hepatitis to determine if an individual has been previously infected with HAV, or as an aid to identify HAV-susceptible individuals. The detection of these antibodies aids in the clinical laboratory diagnosis of an acute or past infection by HAV in conjunction with other clinical laboratory findings. These devices are not intended for screening blood or solid or soft tissue donors.

(b) *Classification.* Class II (special controls). The special control is ''Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Hepatitis A Virus Serological Assays.'' See § 866.1(e) for the availability of this guidance document.

Dated: February 1, 2006.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 06–1206 Filed 2–8–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AM03

Eligibility for Health Care Benefits for Certain Filipino Veterans in the United States

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: Department of Veterans Affairs (VA) medical regulations describe veterans who are eligible to receive health care from VA in the United States. This document amends VA medical regulations to provide eligibility for VA hospital care, nursing home care, and outpatient services for any Filipino Commonwealth Army veteran, including those recognized by authority of the U.S. Army as belonging to organized Filipino guerilla forces, and for any veteran of the new Philippine Scouts, provided that any such veteran resides in the U.S. and is either a citizen of the U.S. or is lawfully

admitted to the United States for permanent residence. Under this regulatory provision, these certain veterans are eligible for VA hospital care, nursing home care, and outpatient medical services in the United States in the same manner and subject to the same terms and conditions as apply to U.S. veterans.

DATES: *Effective Date*: March 13, 2006.

FOR FURTHER INFORMATION CONTACT: Roscoe Butler, Chief Business Office (163), Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 254–0329. (This is not a toll free number.)

SUPPLEMENTARY INFORMATION: In a document published in the **Federal Register** on January 11, 2005, (70 FR 1841), VA proposed to amend VA medical regulation 38 CFR 17.39 to include Filipino Commonwealth Army veterans, including those who were recognized by authority of the U.S. Army as belonging to organized Filipino guerilla forces, and new Philippine Scouts who reside in the U.S. and who are citizens, or lawfully admitted to the United States for permanent residence as persons who are eligible for VA health care benefits within the United States on the same basis as U.S. veterans. This proposed rule also established requirements for proof of citizenship or lawful permanent residency status that veterans must provide in order to be eligible for VA health care benefits.

The public comment period ended on March 14, 2005, and VA received comments from three individuals. Two commenters applauded the Secretary for taking this action and one commenter opposed this action. The one opposing commenter alleged non-payment of taxes by Filipino veterans and raised concerns regarding cost and the number of non-Filipino American citizens who do not have health insurance. The proposed rule reflects statutory requirements set forth at 38 U.S.C. 1734 and VA has no authority to deny health care to Filipino veterans who reside in the United States and who are eligible for these benefits by statute. Moreover, the commenter's assertion that these veterans do not pay taxes appears incorrect because they must be either citizens or legal residents of the United States to qualify for benefits.

Based on the rationale set forth in the proposed rule and those contained in this document, we are adopting the provisions of the proposed rule as a final rule with the addition of an authority citation and information collection approval number added at the end of § 17.39.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before developing any rule that may result in expenditure by state, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any given year. This rule would have no such effect on State, local, or tribal governments, or the private sector.

Paperwork Reduction Act

The Office of Management and Budget (OMB) has approved the collection of information requirement related to this rulemaking proceeding under OMB control number 2900–0091.

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. This final rule would not directly affect any small entities. Only individuals could be directly affected. Therefore, pursuant to 5 U.S.C. 605(b), this final rule is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Catalog of Federal Domestic Assistance Numbers

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are 64.006, Grants to States for the Construction of State Homes; 64.007, Blind Rehabilitation Centers; 64.008, Veterans Domiciliary Care; 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; 64.011, Veterans Dental Care; 64.012, Veterans Prescription Service; 64.013, Veterans Prosthetic Appliances; 64.014, Veterans State Domiciliary Care; 64.015, Veterans State Nursing Home Care; 64.016, Veterans State Hospital Care; 64.018, Sharing Specialized Medical Resources; 64.019, Veterans Rehabilitation Alcohol and Drug Dependence; and 64.022, Veterans Home Based Primary Care.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Foreign relations, Government contracts, Grant programs—health, Grant programs—veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Philippines, Reporting and recordkeeping requirements, Scholarships and fellowships, Travel and transportation expenses, Veterans.

Approved: February 3, 2006.

Gordon H. Mansfield,

Deputy Secretary of Veterans Affairs.

■ For the reasons set out in the preamble, 38 CFR part 17 is amended as follows:

PART 17—MEDICAL

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 38 U.S.C. 501, 1721, unless otherwise noted.

■ 2. Revise § 17.39 to read as follows:

§ 17.39 Certain Filipino veterans.

(a) Any Filipino Commonwealth Army veteran, including one who was recognized by authority of the U.S. Army as belonging to organized Filipino guerilla forces, or any new Philippine Scout is eligible for hospital care, nursing home care, and outpatient medical services within the United States in the same manner and subject to the same terms and conditions as apply to U.S. veterans, if such veteran or scout resides in the United States and is a citizen or lawfully admitted to the United States for permanent residence. For purposes of these VA health care benefits, the standards described in 38 CFR 3.42(c) will be accepted as proof of U.S. citizenship or lawful permanent residence.

(b) Commonwealth Army Veterans, including those who were recognized by authority of the U.S. Army as belonging to organized Filipino guerilla forces, and new Philippine Scouts are not eligible for VA health care benefits if they do not meet the residency and citizenship requirements described in § 3.42(c).

(The Office of Management and Budget has approved the information collection requirements in this section under control number 2900–0091.)

(Authority: 38 U.S.C. 501, 1734)

[FR Doc. 06–1221 Filed 2–8–06; 8:45 am]

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