

and add in its place the phrase "owner of record".

§ 5.19 [Corrected]

21. On page 51135, in the third column, in the text of § 5.19(d), remove the word "publishing" and add in its place the word "publish".

§ 5.20 [Corrected]

22. On page 51136, in the first column, in the text of § 5.20(b)(2), paragraph (b)(2)(iii) is redesignated as paragraph (b)(3).

§ 5.22 [Corrected]

23. On page 51136, in the second column, in the text of § 5.22(a), introductory text, the word "filing" is removed.

24. On page 51136, in the second column, in the text of § 5.22(a)(1), remove the phrase "or § 5.21;" and add in its place the phrase "or § 5.21);".

§ 5.24 [Corrected]

25. On page 51137, in the first column, in the text of § 5.24(c), remove the phrase "and should" and add in its place the phrase "as should".

§ 5.27 [Corrected]

26. On page 51138, in the first column, in the text of § 5.27(d), remove the reference "§ 5.23" and add in its place the reference "§ 5.22".

§ 5.28 [Corrected]

27. On page 51138, in the second column, in the text of § 5.28(c), remove the phrase "§ 5.23" and add in its place the phrase "§ 5.22".

PART 9—TRANSFER OF LICENSE OR LEASE OF PROJECT PROPERTY

§ 9.10 [Corrected]

28. On page 51139, in the second column, above instruction 29, correct the section heading to read: "§ 9.10 [Amended]".

PART 16—PROCEDURES RELATING TO TAKEOVER AND RELICENSING OF LICENSED PROJECTS

§ 16.8 [Corrected]

■ 29. On pages 51140–141, in the third column of page 51140 and the first column of page 51141, in the amendment to § 16.8, redesignate Instructions h. through p. as Instructions i. through q., respectively, and add after Instruction g. the following instruction:

■ h. In paragraph (c)(2), remove the reference "(b)(4)(i)–(vi)" and add in its place the reference "(b)(5)(i)–(vi)."

30. On page 51141, in the first column, the text of § 16.8(b)(2) add after the word "exemption" the following phrase: "or a potential applicant which

elects to use the licensing procedures of Parts 4 or 16 of this chapter prior to July 23, 2005;".

31. On page 51143, in the first column, in the note preceding Appendix A, "will appear" is corrected to read "will not appear".

Dated: October 24, 2003.

Magalie R. Salas,

Secretary.

[FR Doc. 03–27405 Filed 10–29–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. 2003P–0450]

Medical Devices; Immunology and Microbiology Devices; Classification of the West Nile Virus IgM Capture Elisa Assay

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the West Nile Virus IgM Capture Elisa assay into class II (special controls). The agency is taking this action in response to a petition submitted under the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Medical Device Amendments of 1976 (the amendments), the Safe Medical Devices Act of 1990, and the Food and Drug Administration Modernization Act of 1997 (FDAMA). The agency is classifying this 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 a guidance document that will serve as the special control for the device.

DATES: This rule is effective December 1, 2003.

FOR FURTHER INFORMATION CONTACT: Sally Hojvat, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–2096.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of 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 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 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 of the FDA 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) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. 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 issuing an order classifying the device, FDA must publish a notice in the **Federal Register** announcing the classification.

On July 3, 2003, FDA received a petition submitted under section 513(f)(2) of the act by PANBIO, Ltd. seeking an evaluation of the automatic class III designation of its West Nile Virus IgM Capture Elisa Assay. In accordance with section 513(f)(1) of the act, FDA issued an order automatically classifying the West Nile Virus IgM Capture Elisa Assay in 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 II. After reviewing information submitted in the petition, FDA determined that the West Nile Virus IgM Capture Elisa Assay can be classified in class II under the generic name, West Nile Virus, Serological Reagents, with the establishment of special controls. West Nile virus serological reagents are devices that consist of antigens and antisera for the detection of anti-West Nile virus IgM antibodies, in human serum, from individuals that have signs and symptoms consistent with viral meningitis/encephalitis. The detection aids in the clinical laboratory diagnosis