By the Commission.

Nancy M. Morris,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2008–N–0231]

Medical Devices; Immunology and Microbiology Devices; Classification of Plasmodium Species Antigen Detection Assays

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying *Plasmodium* species antigen detection assays into class II (special controls). The special control that will apply to the device is the guidance document entitled ''Class II Special Controls Guidance Document: *Plasmodium* Species Antigen Detection Assays.'' The agency is classifying 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 document that will serve as the special control for this device.

DATES: This rule is effective June 19, 2008. The classification was effective June 13, 2007.

FOR FURTHER INFORMATION CONTACT: Freddie M. Poole, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0712.

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 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) 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 the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing this classification (section 513(f)(2) of the act).

In accordance with section 513(f)(1) of the act, FDA issued an order on February 22, 2007, classifying the Binax NOW® Malaria Test 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 which was subsequently reclassified into class I or class II. On March 22, 2007, Binax, Inc., submitted a petition requesting classification of the Binax NOW® Malaria Test under section 513(f)(2) of the act. The manufacturer recommended that the device be classified into class II (Ref. 1).

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 Binax NOW® Malaria Test 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 ''*Plasmodium* species antigen detection assays.'' It is identified as a device that employs antibodies for the detection of specific malaria parasite antigens, including histidine-rich protein-2 (HRP2) specific antigens, and pan malarial antigens in human whole blood. These devices are used for testing specimens from individuals who have signs and symptoms consistent with malaria infection. The detection of these antigens aids in the clinical laboratory diagnosis of malaria caused by the four malaria species capable of infecting humans: *Plasmodium falciparum*, *Plasmodium vivax*, *Plasmodium ovale*, and *Plasmodium malariae*, and aids in the differential diagnosis of *P. falciparum* infections from other less virulent *Plasmodium* species. The device is intended for use in conjunction with other clinical laboratory findings.

FDA has identified the following risks to health associated with the device. Failure of the test to perform as indicated may lead to improper patient management and/or inappropriate public health responses. For example, false negative results may lead to delays in providing, or even failure to provide, definitive diagnosis and appropriate treatment. A false positive test result may subject individuals to unnecessary and/or inappropriate treatment for malaria, and failure to appropriately diagnose and treat the actual disease condition. The unnecessary use of alternative drugs, such as quinine, mefloquine and artemisinin, typically used in high resistance areas outside the United States, is problematic because these drugs are less safe than the first and second line treatments.

In addition, malaria is a significant public health issue and is a reportable disease to the Centers for Disease Control and Prevention. Local and state health departments are required to conduct case investigations upon receiving a report of a malaria infection. A false positive test result could place an undue burden on local and state health department resources and could also lead to unnecessary public health actions (e.g., unnecessary or inappropriate treatment and management of others in the community). On the other hand, a false negative result could lead to a delay in recognition of increased transmission of the parasitic infection.

An error in interpretation of results could also pose a risk, especially decisions about treatment without confirmation of negative results by

microscopy, which is more sensitive than antigen detection assays for detecting malaria parasites in blood.

TABLE 1.—RISKS TO HEALTH AND MITIGATION MEASURES

Identified Risks	Mitigation Measures
Failure of the assay to perform properly, i.e., false negative or false positive results which can lead to improper patient management and/or inappropriate public health responses	Section 6. of the guidance—Performance Characteristics Section 7. of the guidance—Labeling
Failure to properly interpret test results	Section 6. of the guidance—Performance Characteristics Section 7. of the guidance—Labeling

FDA believes the class II special controls guidance document generally addresses the risks to health identified in the previous paragraphs. FDA believes the class II special controls guidance document will aid in mitigating potential risks by providing recommendations on labeling and validation of performance characteristics. The guidance document also provides information on how to meet 510(k) premarket notification submission requirements for the device. FDA believes that the special controls, in addition to general controls, address the risks to health identified previously and provide reasonable assurances of the safety and effectiveness of the device type. Therefore, on June 13, 2007, FDA issued an order to the petitioner classifying the device into class II (Ref. 2). FDA is codifying this classification by adding 21 CFR 866.3402.

Following the effective date of this final classification rule, any firm submitting a premarket notification submission for a *Plasmodium* species antigen detection assay will need to address the issues covered in the special controls guidance. However, the firm need only show that its device meets the recommendations of the guidance, 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 notification is necessary to provide a 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 *Plasmodium* species antigen detection assays 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 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 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 $127 million, using the most current (2006) 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. 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.

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

This final rule contains no new information collection provisions. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 is not required.

VI. What References Are on Display?

The following references have 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 Binax, Inc., dated March 22, 2007.

2. Order classifying Binax NOW® Malaria Test, dated June 13, 2007.

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 866.3402 is added to subpart D to read as follows:

§ 866.3402 Plasmodium species antigen detection assays.

(a) *Identification.* A *Plasmodium* species antigen detection assay is a device that employs antibodies for the detection of specific malaria parasite antigens, including histidine-rich protein-2 (HRP2) specific antigens, and pan malarial antigens in human whole blood. These devices are used for testing specimens from individuals who have signs and symptoms consistent with malaria infection. The detection of these antigens aids in the clinical laboratory diagnosis of malaria caused by the four malaria species capable of infecting humans: *Plasmodium falciparum*, *Plasmodium vivax*, *Plasmodium ovale*, and *Plasmodium malariae*, and aids in the differential diagnosis of *Plasmodium falciparum* infections from other less virulent *Plasmodium* species. The device is intended for use in conjunction with other clinical laboratory findings.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance document entitled ''Class II Special Controls Guidance Document: *Plasmodium* species Antigen Detection Assays.'' See § 866.1(e) for the availability of this guidance document.

Dated: April 30, 3008.

Daniel G. Schultz,

Director, Center for Devices and Radiological Health.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9399]

RIN 1545–BE93

Guidance Under Section 7874 for Determining the Ownership Percentage in the Case of Expanded Affiliated Groups

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulation.

SUMMARY: This document contains final regulations under section 7874 of the Internal Revenue Code (Code) relating to the disregard of certain affiliate-owned stock in determining whether a corporation is a surrogate foreign corporation under section 7874(a)(2)(B) of the Code.

DATES: *Effective Date:* These regulations are effective on May 20, 2008.

Applicability Date: For the date of applicability, see § 1.7874–1(g).

FOR FURTHER INFORMATION CONTACT: Milton Cahn, 202–622–3860 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

Section 7874 provides rules for expatriated entities and their surrogate foreign corporations. An expatriated entity is defined in section 7874(a)(2)(A) as a domestic corporation or partnership with respect to which a foreign corporation is a surrogate foreign corporation, and any U.S. person related (within the meaning of section 267(b) or section 707(b)(1)) to such domestic corporation or partnership. Generally, a foreign corporation is a surrogate foreign corporation under section 7874(a)(2)(B) if, pursuant to a plan or a series of related transactions, certain conditions are met. One such condition depends on the percentage of owner continuity in the foreign corporation after the acquisition. This condition is satisfied if, after the acquisition, at least 60 percent of the stock (by vote or value) of the foreign corporation is held (in the case of an acquisition with respect to a domestic corporation) by former shareholders of the domestic corporation by reason of holding stock in the domestic corporation, or (in the case of an acquisition with respect to a domestic partnership) by former partners of the domestic partnership by reason of holding a capital or profits interest in the domestic partnership. See section 7874(a)(2)(B)(ii).

The treatment of expatriated entities and surrogate foreign corporations varies depending on this percentage (ownership fraction). If the ownership fraction is 80 percent or more, the surrogate foreign corporation is treated as a domestic corporation for all purposes of the Code. If the ownership fraction is 60 percent or more (but less than 80 percent), the surrogate foreign corporation is treated as a foreign corporation, but certain income or gain recognized by the expatriated entity generally cannot be offset by net operating losses or credits from the first date properties are acquired pursuant to the plan through the end of the 10-year period following the completion of the acquisition.

Section 7874(c)(2)(A) provides that stock held by members of the ''expanded affiliated group'' which includes the foreign corporation is not taken into account for purposes of the ownership fraction (affiliate-owned stock rule). Section 7874(c)(1) defines the term expanded affiliated group (EAG) as an affiliated group defined in section 1504(a), but without regard to the exclusion of foreign corporations in section 1504(b)(3) and with a reduction of the 80 percent ownership threshold of section 1504(a) to a more-than-50 percent threshold.

Section 7874(g) provides that ''[t]he Secretary shall provide such regulations as are necessary to carry out this section, including regulations providing for such adjustments to the application of this section as are necessary to prevent the avoidance of the purposes of this section, including the avoidance of such purposes through * * *. the use of related persons, pass-through or other noncorporate entities, or other intermediaries * * *.'' Section 7874(c)(6) provides that ''[t]he Secretary shall prescribe such regulations as may be appropriate to determine whether a corporation is a surrogate foreign corporation, including regulations * * * to treat stock as not stock.''

On December 28, 2005, a temporary regulation (TD 9238) was published in the **Federal Register** (70 FR 76685) that related to the disregard of affiliate-owned stock under section 7874(c)(2)(A). A notice of proposed rulemaking (REG–143244–05) cross-referencing the temporary regulation was published in the **Federal Register** for the same day (70 FR 76732). No public hearing was requested or held. Written and electronic comments responding to the notice of proposed rulemaking were received. After consideration of all the comments, the proposed regulation is adopted, as amended by this Treasury decision, as final, and the corresponding temporary regulation is removed. The revisions are discussed below.

Summary of Comments and Revisions

A. Temporary and Proposed Regulations

Treasury regulation § 1.7874–1T provides guidance under the affiliated-owned stock rule. Generally, § 1.7874–1T provides that stock owned by members of an EAG is excluded from both the numerator and denominator of the ownership fraction. However, affiliate-owned stock is excluded from the numerator of the ownership fraction, but is included in the denominator of the ownership fraction, in two instances: (1) Certain transactions occurring as part of an internal group restructuring involving a domestic entity; and (2) certain acquisitive business transactions between unrelated