

or alternate participant because an individual's disability or blindness benefits are continued based on his or her participation in a VR program which we have determined will increase the likelihood that he or she will not return to the disability rolls.

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§ 416.2203 [Amended]

■ 39. Amend § 416.2203 by removing the definition of *Good cause for VR refusal*.

§ 416.2209 [Amended]

■ 40. Amend § 416.2209 by removing paragraph (c) and redesignating paragraphs (d) through (h) as paragraphs (c) through (g).

§ 416.2213 [Removed]

■ 41. Remove § 416.2213.

§ 416.2216 [Amended]

■ 42. In § 416.2216, remove paragraph (c).

■ 43. Amend § 416.2217 by revising the introductory text and paragraph (f) to read as follows:

§ 416.2217 What costs will be paid.

In accordance with section 1615(d) and (e) of the Social Security Act, the Commissioner will pay the State VR agency or alternate participant for the VR services described in § 416.2214 which were provided during the period described in § 416.2215 and which meet the criteria in § 416.2211 or § 416.2212, but subject to the following limitations:

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(f) Payment for VR services or costs may be made under more than one of the VR payment provisions described in §§ 416.2211 and 416.2212 of this subpart and similar provisions in §§ 404.2111 and 404.2112 of subpart V of part 404. However, payment will not be made more than once for the same VR service or cost; and

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. 2003D-0209]

Medical Devices; Clinical Chemistry and Clinical Toxicology Devices; Classification of the Breath Nitric Oxide Test System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the breath nitric oxide test system 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 1976 amendments), the Safe Medical Devices Act of 1990 (the SMDA), 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 August 6, 2003.

FOR FURTHER INFORMATION CONTACT: Jean Cooper, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-1243.

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 March 17, 2003, FDA received a petition submitted under section 513(f)(2) of the act by Aerocrine AB, through Certified Software Solutions, Inc., seeking an evaluation of the automatic class III designation of its NIOX BREATH NITRIC OXIDE TEST SYSTEM. In accordance with section 513(f)(1) of the act, FDA issued an order automatically classifying the NIOX BREATH NITRIC OXIDE TEST SYSTEM 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 NIOX BREATH NITRIC OXIDE TEST SYSTEM can be classified in class II with the establishment of special controls. This device is intended to aid in evaluating an asthma patient's response to anti-inflammatory therapy by measuring changes in fractional exhaled nitric oxide concentration in asthma patients, as an adjunct to established clinical and laboratory assessments of asthma. FDA believes that class II special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

FDA has identified the risk to health associated specifically with this type of device as improper patient management. Therefore, in addition to the general controls of the act, the device is subject to a special controls guidance document entitled "Class II Special Controls Guidance Document: Breath Nitric Oxide Test System."

The class II special controls guidance provides information on how to meet