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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. 00P-0931]

Clinical Chemistry Devices; Classification of the Biotinidase Test System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the biotinidase test system into class II (special controls). The special control that will apply to this device is restriction to sale, distribution, and use as a prescription device. 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 Safe Medical Devices Act of 1990, and the Food and Drug Administration Modernization Act of 1997. The agency is classifying these devices into class II (special controls) in order to provide a reasonable assurance of the safety and effectiveness of the devices.

DATES: This rule is effective [*insert date 30 days after date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Carol C. Benson, 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 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 class 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 the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification.

In accordance with section 513(f)(1) of the act, FDA issued an order on November 19, 1999, classifying the Wallac Neonatal Biotinidase Test Kit 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 December 20, 1999, FDA filed a petition submitted by PerkinElmer

requesting classification of the Wallac Neonatal Biotinidase Test Kit into class II under section 513(f)(2) of the act.

After review of the information submitted in the petition, FDA determined that the Wallac Neonatal Biotinidase Test Kit can be classified in class II with the establishment of special controls. This device is intended for use in the semiquantitative in vitro determination of biotinidase activity in blood specimens collected onto filter paper to screen newborns for biotinidase deficiency, an inborn error of metabolism. 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.

In addition to the general controls of the act, Wallac Neonatal Biotinidase Test Kit is subject to the following special control: The sale, distribution, and use of this device are restricted to prescription use in accordance with § 801.109 (21 CFR 801.109). 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. FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device and, therefore, the device is not exempt from the premarket notification requirements. The test is widely used in newborn screening programs and FDA review of data sets and labeling ensure that minimum levels of performance are obtained before marketing and are subject to impartial external quality control before labeling is put into place. Thus, persons who intend to market this device must submit to FDA a premarket notification submission containing information on the biotinidase test system before marketing the device.

On February 15, 2000, FDA issued an order to the petitioner classifying the Wallac Neonatal Biotinidase Test Kit, and substantially equivalent devices of this generic type, into class II under the generic name, biotinidase test system. FDA identifies this generic type of device as a biotinidase test system, which is intended to measure the activity of the enzyme biotinidase deficiency, an inborn error of metabolism in infants, characterized by the inability to utilize dietary protein bound

vitamin, or to recycle endogenous biotin, and may result in irreversible neurological impairment. This order also identifies the following special control applicable to this device: Sale, distribution, and use of this device are restricted in accordance with the prescription device requirements in § 801.109.

II. 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.

III. Analysis Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121), 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 consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so it is not subject to review 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. The agency knows of only one manufacturer of this device. Without this rule, the manufacturer would be required to obtain approval of a premarket approval application from FDA before marketing this device. Therefore, this rule reduces an economic burden for this manufacturer and any future manufacturers of this type of device. The agency, therefore, certifies that this final rule will not have a significant

economic impact on a substantial number of small entities. In addition, this final rule will not impose costs of \$100 million or more on either the private sector or state, local, and tribal governments in the aggregate, and therefore a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform act is not required.

IV. Paperwork Reduction Act of 1995

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

Therefore, under the Federal Food, Drug, and Cosmetic Act under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 862 is amended as follows:

List of Subjects in 21 CFR Part 862

Medical devices.

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

1. The authority citation for 21 CFR part 862 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 862.1118 is added to subpart B to read as follows:

§ 862.1118 Biotinidase test system.

(a) *Identification.* The biotinidase test system is an in vitro diagnostic device intended to measure the activity of the enzyme biotinidase in blood. Measurements of biotinidase are used in the treatment and diagnosis of biotinidase deficiency, an inborn error of metabolism in infants, characterized by the inability to utilize dietary protein bound vitamin or to recycle endogenous biotin. The deficiency may result in irreversible neurological impairment.

(b) *Classification*. Class II (special controls). The special control is sale, distribution, and use in accordance with the prescription device requirements in § 801.109 of this chapter.

Dated: MAR 13 2000

Linda S. Kahan

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