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 862.3360 is added to subpart D to read as follows:

§ 862.3360 Drug metabolizing enzyme genotyping system.

(a) *Identification.* A drug metabolizing enzyme genotyping system is a device intended for use in testing deoxyribonucleic acid (DNA) extracted from clinical samples to identify the presence or absence of human genotypic markers encoding a drug metabolizing enzyme. This device is used as an aid in determining treatment choice and individualizing treatment dose for therapeutics that are metabolized primarily by the specific enzyme about which the system provides genotypic information.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Drug Metabolizing Enzyme Genotyping Test System.'' See § 862.1(d) for the availability of this guidance document.

Dated: March 2, 2005.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 05–4762 Filed 3–9–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. 2005N–0071]

Medical Devices; Clinical Chemistry and Clinical Toxicology Devices; Instrumentation for Clinical Multiplex Test Systems

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying instrumentation for clinical multiplex test systems 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: Instrumentation for Clinical Multiplex Test Systems.'' 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 publishing a notice of availability of a guidance document that is the special control for this device.

DATES: This rule is effective April 11, 2005. The classification was effective December 23, 2004.

FOR FURTHER INFORMATION CONTACT: Courtney Harper, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0443, ext. 159.

SUPPLEMENTARY INFORMATION:

I. Background

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 previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 (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 (21 U.S.C. 360c(a)(1)). 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 (section 513(f)(2) of the act).

In accordance with section 513(f)(1) of the act, FDA issued a notice on October 29, 2004, classifying the Affymetrix GENECHIP Microarray Instrumentation 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 to a device that was subsequently reclassified into class I or class II. On November 3, 2004, Affymetrix, Inc., submitted a petition requesting classification of the Affymetrix GENECHIP Microarray Instrumentation System under section 513(f)(2) of the act. The manufacturer recommended that the device be classified into class II.

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 Affymetrix GENECHIP Microarray Instrumentation System 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 ''instrumentation for clinical multiplex test systems.'' It is identified as a device intended to measure and sort multiple signals generated by an assay from a clinical sample. This instrumentation is used with a specific assay to measure multiple similar analytes that establish a single indicator to aid in diagnosis. Such instrumentation may be compatible with more than one specific assay. The device includes a signal reader unit, and may also integrate reagent handling, hybridization, washing, dedicated instrument control, and other hardware components, as well as raw data storage mechanisms, data acquisition software, and software to process detected signals.

FDA has identified the risks to health associated with this type of device as potentially inaccurate results or inaccurate reports which may lead to incorrect diagnoses or patient evaluation that could result in inappropriate and possibly dangerous patient management. Specifically,

failure of instrument components, including reagent introduction and hybridization systems, signal detection mechanisms, instrument control and data acquisition software, and raw data storage mechanisms could lead to inaccurate results. Likewise, failure of data management and database software could result in the compromise of patient identification or mis-matched results. Furthermore, failure of the instrumentation to generate any results at all can deny or delay beneficial, appropriate therapies.

FDA believes that following the class II special controls guidance document generally addresses the risks to health identified in the previous paragraph. The class II special controls guidance document also provides information on how to meet premarket (510(k)) submission requirements for the device, including recommendations on validation of performance characteristics and labeling. Therefore, on December 23, 2004, FDA issued an order to the petitioner classifying the device into class II. FDA is codifying this classification by adding 21 CFR 862.2570.

Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for instrumentation for clinical multiplex test systems 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 reasonable assurance of safety and effectiveness. FDA's review of performance characteristics, test methodology, and labeling to see that it satisfies the requirements of § 807.87(e), will provide reasonable assurance that acceptable levels of performance for both safety and effectiveness will be addressed before marketing clearance. Thus, persons who intend to market this type of device must submit to FDA a premarket notification containing information on the instrumentation for clinical multiplex test systems before marketing the device.

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 of 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), 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. Because classification of this device into class II will relieve manufacturers of the device 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 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 $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.

IV. 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.

V. Paperwork Reduction Act of 1995

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

VI. Reference

The following reference has 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 Affymetrix, Inc., dated November 3, 2004.

List of Subjects in 21 CFR Part 862

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 862 is amended as follows:

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 862.2570 is added to subpart C to read as follows:

§ 862.2570 Instrumentation for clinical multiplex test systems.

(a) *Identification.* Instrumentation for clinical multiplex test systems is a device intended to measure and sort multiple signals generated by an assay from a clinical sample. This instrumentation is used with a specific assay to measure multiple similar analytes that establish a single indicator to aid in diagnosis. Such instrumentation may be compatible with more than one specific assay. The device includes a signal reader unit, and may also integrate reagent handling, hybridization, washing, dedicated

instrument control, and other hardware components, as well as raw data storage mechanisms, data acquisition software, and software to process detected signals.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Instrumentation for Clinical Multiplex Test Systems.'' See § 862.1(d) for the availability of this guidance document.

Dated: March 2, 2005.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

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DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 206

RIN 1010–AD05

Federal Gas Valuation

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Final rule.

SUMMARY: The MMS is amending the existing regulations governing the valuation of gas produced from Federal leases for royalty purposes, and related provisions governing the reporting thereof. The current regulations became effective on March 1, 1988, and were amended in 1996 and 1998. These amendments primarily affect the calculation of transportation deductions and the changes necessitated by judicial decisions since the regulations were last amended.

DATES: *Effective date:* June 1, 2005.

FOR FURTHER INFORMATION CONTACT: Sharron L. Gebhardt, Lead Regulatory Specialist, Chief of Staff Office, Minerals Revenue Management, MMS, telephone (303) 231–3211, fax (303) 231–3781, or e-mail *sharron.gebhardt@mms.gov*.

The principal authors of this rule are Geoffrey Heath of the Office of the Solicitor, Larry E. Cobb, Susan Lupinski, Mary A. Williams, and Kenneth R. Vogel of Minerals Revenue Management, MMS, Department of the Interior.

SUPPLEMENTARY INFORMATION:

I. Background

The MMS is amending the existing regulations at 30 CFR 206.150 *et seq.*, governing the valuation of gas produced from Federal leases for royalty purposes, and related provisions governing the reporting thereof. The current regulations became effective on March 1, 1988 (53 FR 1230) (1988 Gas Rule).

After conducting several public workshops, MMS issued a proposed rule that was published in the **Federal Register** on July 23, 2004 (69 FR 43944). The comment period for the proposed rule closed on September 21, 2004.

The amendments do not alter the basic structure or underlying principles of the 1988 Gas Rule.

II. Comments on the Proposed Rule

Comments received favored most of the proposed changes. The MMS received some unfavorable comments regarding future valuation agreements between the MMS Director and the lessee, some of the specifications of allowable transportation costs, and our proposal to change the rate of return on undepreciated capital investment in calculating non-arm's-length transportation allowances. Generally, we grouped the comments received and the MMS responses according to the order of the issues and proposed revisions on which we requested comments. We also addressed miscellaneous technical changes.

A. Spot Market Prices

In the proposed rule, we requested comments on (1) ''whether publicly available spot market prices for natural gas are reliable and representative of market value'' and whether MMS should value natural gas production that is not sold at arm's-length using spot market prices and, if so, (2) ''how these spot market prices should be adjusted for location differences between the index pricing point and the lease.''

Summary of Comments: One producer supported using index pricing, stating that index pricing provides the most accurate and transparent gas pricing information available and, therefore, increases royalty valuation certainty.

Industry trade associations supported the use of index pricing for gas valuation and questioned why index pricing does not apply to arm's-length gas sales.

One state and the State and Tribal Royalty Audit Committee (STRAC) did not support using index pricing to value gas. The state claimed that publicly available spot prices are not a true representation of arm's-length market value because non-arm's-length sales are included within the index. The state proposed that MMS publish a new gas rule requiring a Federal lessee to value natural gas and associated products based on the first arm's-length sale of the gas or products.

MMS Response: The written comments received continue to reflect disparate and conflicting views of industry and states. At the present time, MMS has decided not to change existing regulations for valuing production that is not sold at arm's-length and will continue to evaluate the issues.

B. Section 206.150—Purpose and Scope

The MMS proposed to amend the Federal gas valuation rule to match the June 2000 Federal oil valuation rule, which provides that, if a written agreement between a lessee and the MMS Director establishes a production valuation method for any lease that MMS expects at least would approximate the value otherwise established under this subpart, the written agreement will govern to the extent of any inconsistency with the regulations. This provision is intended to provide flexibility to both MMS and the lessee in those few unusual circumstances where a separate written agreement is reached, while at the same time maintaining the integrity of the regulations. The MMS used this provision in the June 2000 Federal oil valuation rule to address unexpectedly difficult royalty valuation problems.

Summary of Comments: Industry producers and industry trade associations support this change.

Two states and STRAC do not support the use of written valuation agreements. One state commented that it is not in the public's best interest to allow the MMS Director to avoid the regulations that are subject to notice and comment. The states claimed that, at the very minimum, state approval should be necessary if this provision is implemented. STRAC commented that the provision is not clear and that state approval should be required if state royalties are affected.

MMS Response: The MMS is mindful of the states' concerns, but does not believe that written valuation agreements should be subject to state approval (or veto). Such agreements are not an avenue to avoid the rules, but rather a tool to provide certainty and reduce administrative costs in appropriate circumstances. The rule requires that value under such an agreement at least approximate the value that would be derived under the regulations. Therefore, these agreements should not result in significant revenue consequences to the Federal Government or to the states.

C. Section 206.151—Definitions

The MMS proposed adding a definition of ''affiliate'' and revising the definition of ''arm's-length contract'' to