Regulatory Flexibility Act, as amended, 5 U.S.C. 601, *et seq.* Therefore, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, as amended, is not required.

Paperwork Reduction Act

These final regulations will impose no additional information collection requirements requiring OMB clearance under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, *et seq.*

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security—Disability Insurance; 96.002, Social Security—Retirement Insurance; 96.004, Social Security—Survivors Insurance.)

List of Subjects in 20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-age, survivors and disability insurance, Reporting and recordkeeping requirements, Social Security.

Dated: December 2, 2004.

Jo Anne B. Barnhart,

Commissioner of Social Security.

■ For the reasons stated in the preamble, we are amending subpart N of part 404 of Title 20 of the Code of Federal Regulations as follows:

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950—)

Subpart N—[Amended]

■ 1. The authority citation for subpart N of part 404 continues to read as follows:

Authority: Secs. 205(a) and (p), 210(l) and (m), 215(h), 217, 229, and 702(a)(5) of the Social Security Act (42 U.S.C. 405(a) and (p), 410(l) and (m), 415(h), 417, 429, and 902(a)(5)).

§ 404.1301 [Amended]

■ 2. In § 404.1301, at the end of the fifth sentence in paragraph (a), add ''through 2001.''

§ 404.1302 [Amended]

■ 3. In § 404.1302, in the definition of ''Wage credit,'' the second sentence is revised by removing the words ''after 1956'' and adding in their place ''from 1957 through 2001.''

§ 404.1341 [Amended]

■ 4. In § 404.1341, in the first sentence of paragraph (a), remove the words ''after 1956'' and add in their place ''from 1957 through 2001'' and in paragraph (b)(1), remove the words ''after 1977'' and add in their place ''from 1978 through 2001.''

[FR Doc. 05–4638 Filed 3–9–05; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. 2005N–0067]

Medical Devices; Clinical Chemistry and Clinical Toxicology Devices; Drug Metabolizing Enzyme Genotyping System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying drug metabolizing enzyme (DME) genotyping 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: Drug Metabolizing Enzyme Genotyping System.'' 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), request FDA to classify the device under the criteria set forth in section 513(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 December 17, 2004, classifying the Roche Amplichip CYP450 Test (2D6) 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 December 20, 2004, Roche Molecular Systems, Inc., submitted a petition requesting classification of the Roche Amplichip CYP450 Test (2D6) 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). 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 Roche Amplichip CYP450 Test (2D6) 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 ''drug metabolizing enzyme genotyping system.'' It is identified as 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 DME. 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.

FDA has identified the risks to health associated with this type of device as failure to correctly identify the DME genotype, which could result in incorrect patient management decisions. In these situations a patient might be prescribed an incorrect drug or drug dose with concomitant increased risk of adverse reactions due to increased or decreased drug metabolism. Likewise, failure to properly interpret genotyping results could lead to incorrect prediction of phenotype and result in incorrect patient management decisions. The information provided by this type of genetic test should only be used to supplement other tools for therapeutic decisionmaking in conjunction with routine monitoring by a physician.

The effect that a specific DME allele has on drug metabolism may vary depending on the specific drug, even for drugs within a specific class. Effects of specific alleles on drug metabolism are well-documented for some drugs; for other drugs, they are less well-documented. Therefore, clinicians should use professional judgment when interpreting results from this type of test. In addition, results from this type of assay should not be used to predict a patient's response to drugs in cases where either (1) the DME activity of the allele has not been determined or (2) the drug's metabolic pathway has not been clearly established.

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. FDA believes that following the class II special controls guidance document generally addresses the risks to health identified above. 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 862.3360.

Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for a DME genotyping system 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), 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 review of performance characteristics, test methodology, and labeling to satisfy 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 DME genotyping system 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 Roche Molecular Systems, Inc., dated December 20, 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 862.3360 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]

BILLING CODE 4160–01–S

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,