EFFECTIVE DATE: October 14, 1980.

FOR FURTHER INFORMATION CONTACT: Kaiser Aziz, Bureau of Medical Devices (HFK–440), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of September 11, 1979 (44 FR 52950), a proposed regulation explaining the development of the proposed regulations classifying hematology and pathology devices, the medical device classification procedures, and the activities of the Hematology and Pathology Device Section of the Clinical Chemistry and Hematology Devices Panel (formerly the Hematology Device Classification Panel and the Pathology Device Classification Panel). FDA also published in that issue of the **Federal Register** (44 FR 53010) a proposed regulation to classify erythrocytic glucose-6-phosphate dehydrogenase assays into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and with a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). Further information regarding the device advisory committees and a list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 864 in Subpart H by adding new § 864.7360, to read as follows:

§ 864.7360 Erythrocytic glucose-6-phosphate dehydrogenase assay.

(a) *Identification.* An erythrocytic glucose-6-phosphate dehydrogenase assay is a device used to measure the activity of the enzyme glucose-6-phosphate dehydrogenase or of glucose-6-phosphate dehydrogenase isoenzymes. The results of this assay are used in the diagnosis and treatment of nonspherocytic congenital hemolytic anemia or drug-induced hemolytic anemia associated with a glucose-6-phosphate dehydrogenase deficiency. This generic device includes assays based on fluorescence, electrophoresis, methemoglobin reduction, catalase inhibition, and utlraviolet kinetics.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 14, 1980.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)))

Dated: August 15, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-27349 Filed 9-11-80; 8:45 am]

BILLING CODE 4110-03-M

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12 CFR Part 864

[Docket No. 78N-1888]

Classification of Glutathione Reductase Assays

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying glutathione reductase assays into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 14, 1980.

FOR FURTHER INFORMATION CONTACT: Kaiser Aziz, Bureau of Medical Devices (HFK–440), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of September 11, 1979 (44 FR 52950), a proposed regulation explaining the development of the proposed regulations classifying hematology and pathology devices, the medical device classification procedures, and the activities of the Hematology and Pathology Device Section of the Clinical Chemistry and Hematology Devices Panel (formerly the Hematology Device Classification Panel and the Pathology Device Classification Panel). FDA also published in that issue of the **Federal Register** (44 FR 53011) a proposed regulation to glutathione reductase assays into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and with a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). Further information regarding the device advisory committees and a list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 864 in Subpart H by adding new § 864.7375, to read as follows:

§ 864.7375 Glutathione reductase assay.

(a) *Identification.* A glutathione reductase assay is a device used to determine the activity of the enzyme glutathione reductase in serum, plasma, or erythrocytes by such techniques as fluorescence and photometry. The results of this assay are used in the diagnosis of liver disease, glutathione reductase deficiency, or riboflavin deficiency.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 14, 1980.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)))

Dated: August 15, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-27350 Filed 9-11-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 864

[Docket No. 78N-1889]

Classification of Hemoglobin A_2 Assays

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying hemoglobin A_2 assays

into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 14, 1980.

FOR FURTHER INFORMATION CONTACT: Kaiser Aziz, Bureau of Medical Devices (HFK-440), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

SUPPLEMENTARY INFORMATION: FDA published in the Federal Register of September 11, 1979 (44 FR 52950), a proposed regulation explaining the development of the proposed regulations classifying hematology and pathology devices, the medical device classification procedures, and the activities of the Hematology and Pathology Device Section of the Clinical Chemistry and Hematology Devices Panel (formerly the Hematology Device Classification Panel and the Pathology Device Classification Panel). FDA also published in that issue of the Federal Register (44 FR 53013) a proposed regulation to classify hemoglobin A_2 assays into class II. A period of 60 days was provided for interested persons to submit written comments to FDA.

The following is a summary of the comments recieved on the proposal and the agency's response to them:

1. A manufacturer suggested that its electrophoresis equipment and kits might be subject to three potentially conflicting performance standards due to the language in the proposed regulations for hemoglobin A_2 assays (44 FR 53013), abnormal hemoglobin assays (44 FR 53014), and electrophoretic hemoglobin analysis systems (44 FR 53016). The manufacturer suggested that compliance with three different, and possibly conflicting, standards would be an immense regulatory burden with no benefit to the patient. The comment requested that the language in the proposed rules be modified so that its products and similar products are subject to a single regulation.

FDA agrees that electrophoresis equipment and kits could be subject to three performance standards. FDA believes that a product sold to perform a specific assay should be required to meet any performance standards applicable to that assay. Because the standards will all apply to electrophoresis procedures, FDA believes that the differences will be minor. The matter of overlapping performance standards will recieve careful consideration during the standards development process, so that the resultant standards will not impose an intolerable burden on the manufacturers of the devices.

2. One comment suggested that class II is appropriate for electrophoresis control materials, but that all other electrophoresis materials and equipment be placed into class I. The comment suggested that class I is appropriate because electrophoresis materials and equipment have worked well in the past. Because there is no direct patient contact, there is no possibility of immediate harm to the patient. The use of control materials will detect minor difficulties and nearly eliminate the risk of misdiagnose. Because many of the abnormal hemoglobins sought to be detected are genetic in origin, a minor error will not result in drastic or immediate changes in treatment, therefore minimizing the risk to the patient's health. The comment also argues that is a standard is developed for control materials, any difficulties with equipment or materials could be easily detected or corrected. The comment also stated that there are so many variations in procedure that development of a standard would be nearly impossible and would be an inappropriate form of regulation of electrophoresis equipment and materials.

FDA disagrees with this comment. These assays were proposed for classification into class II because FDA and the Panel recognized the need to establish acceptable ranges for the performance characteristics of these assays. FDA believes that the general controls under class I will not assume the establishment of acceptable performance ranges. FDA believes that these standards should address control materials as well as the other equipment and materials. System features such as pH, electrolytes employed, support media, voltage, staining material, and duration of electophoresis must be addressed in a performance standard. The potential for patient harm is in misdiagonosis or the failure to detect a hemoglobin disorder and subsequent inappropriate therapy or failure to institute therapy. A serious hemoglobin disorder, whether genetic in origin or not, may require drastic or immeidate measures in treatment in order to prevent harm to the patient. FDA agrees that there are variations in procedure, but these differences should not preclude the development of standards.

Accordingly, the proposed rule is being adopted without change.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and with a new structure. FDA published notices of these changes in the Federal Register of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). Further information regarding the device advisory committees and a list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the Federal Register.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 864 in Subpart H by adding new § 864.7400, to read as follows:

§ 864.7400 Hemoglobin A_2 assay.

(a) *Identification.* A hemoglobin A_2 assay is a device used to determine the hemoglobin A_2 content of human blood. The measurement of hemoglobin A_2 is used in the diagnosis of the thalassemias (hereditary hemolytic anemias characterized by decreased synthesis of one or more types of hemoglobin polypeptide chains).

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 14, 1980.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a)))

Dated: August 15, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-27351 Filed 9-11-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 864

[Docket No. 78N-1890]

Classification of Abnormal Hemoglobin Assays

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying abnormal hemoglobin assays into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 14, 1980.

FOR FURTHER INFORMATION CONTACT: Kaiser Aziz, Bureau of Medical Devices

(HFK–440), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of September 11, 1979 (44 FR 52950), a proposed regulation explaining the development of the proposed regulations classifying hematology and pathology devices, the medical device classification procedures, and the activities of the Hematology and Pathology Device Section of the Clinical Chemistry and Hematology Devices Panel (formerly the Hematology Device Classification Panel and the Pathology Device Classification Panel). FDA also published in that issue of the **Federal Register** (44 FR 53014) a proposed regulation to classify abnormal hemoglobin assays into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

The following is a summary of the comments received on the proposal and the agency's response to them:

1. A manufacturer suggested that its electrophoresis equipment and kits might be subject to three potentially conflicting performance standards due to the language in the proposed regulations for hemoglobin A_2 assays (44 FR 53013), abnormal hemoglobin assays (44 FR 53014), and electrophoretic hemoglobin analysis systems (44 FR 53016). The manufacturer suggested that compliance with three different, and possibly conflicting, standards would be an immense regulatory burden with no benefit to the patient. The comment requested that the language in the proposed rules be modified so that its products and similar products are subject to a single regulation.

FDA agrees that electrophoresis equipment and kits could be subject to three performance standards. FDA believes that a product sold to perform a specific assay should be required to meet any performance standards applicable to that assay. Because the standards will all apply to electrophoresis procedures, FDA believes that the differences will be minor. The matter of overlapping performance standards will receive careful consideration during the standards development process, so that the resultant standards will not impose an intolerable burden on the manufacturers of the devices.

2. One comment suggested that class II is appropriate for electrophoresis control materials, but that all other electrophoresis materials and equipment be placed into class I. The comment suggests that class I is appropriate because electrophoresis materials and equipment have worked well in the past. Because there is no direct patient contact, there is no possibility of immediate harm to the patient. The use of control materials will detect minor difficulties and nearly eliminate the risk of misdiagnosis. Because many of the abnormal hemoglobins sought to be detected are genetic in origin, a minor error will not result in drastic or immediate changes in treatment, therefore minimizing the risk to the patient's health. The comment also argued that if a standard is developed for control materials, any difficulties with equipment or materials could be easily detected or corrected. The comment also states that there are so many variations in procedure that development of a standard would be nearly impossible and would be an inappropriate form of regulation of electrophoresis equipment and materials.

FDA disagrees with this comment. These assays were proposed for classification into class II because FDA and the Panel recognized the need to establish acceptable ranges for the performance characteristics of these assays. FDA believes that the general controls under class I will not establish acceptable performance ranges. FDA believes that these standards should address control materials as well as the other equipment and materials. System features such as pH, electrolytes employed, support media, voltage, staining material, and duration of electrophoresis must be addressed in a performance standard. The potential for patient harm is in misdiagnosis or the failure to detect a hemoglobin disorder and subsequent inappropriate therapy or failure to institute therapy. A serious hemoglobin disorder, whether genetic in origin or not, may very well require drastic or immediate measures in treatment in order to prevent harm to the patient. FDA agrees that there are variations in procedure, but these differences should not preclude the development of standards.

Accordingly, the proposed rule is being adopted without change.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and with a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). Further information regarding the device advisory committees and a list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 864 in Subpart H by adding new § 864.7415, to read as follows:

§ 864.7415 Abnormal hemoglobin assay.

(a) *Identification.* An abnormal hemoglobin assay is a device consisting of the reagents, apparatus, instrumentation, and controls necessary to isolate and identify abnormal genetically determined hemoglobin types.

(b) *Classification.* Class II (performance standards).

Effective date. This regulation shall be effective October 14, 1980.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)))

Dated: August 15, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-27352 Filed 9-11-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 864

[Docket No. 78N-1891]

Classification of Carboxyhemoglobin Assays

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying carboxyhemoglobin assays into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 14, 1980.

FOR FURTHER INFORMATION CONTACT: Kaiser Aziz, Bureau of Medical Devices (HFK–440), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of September 11, 1979 (44 FR 52950), a proposed regulation explaining the development of the proposed regulations