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 53015) a proposed regulation to classify carboxyhemoglobin 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 § 864.7425, to read as follows:

§ 864.7425 Carboxyhemoglobin assay.

(a) *Identification.* A carboxyhemoglobin assay is a device used to determine the carboxyhemoglobin (the compound formed when hemoglobin is exposed to carbon monoxide) content of human blood as an aid in the diagnosis of carbon monoxide poisoning. This measurement may be made using methods such as spectroscopy, colorimetry, spectrophotometry, and gasometry.

(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. 80-27353 Filed 9-11-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 864

[Docket No. 78N-1892]

Classification of Electrophoretic Hemoglobin Analysis Systems

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying electrophoretic hemoglobin analysis systems 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 53016) a proposed regulation to classify electrophoretic hemoglobin analysis systems 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 43016). 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 of class I will not establish acceptable performances 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 § 864.7440, to read as follows:

§ 864.7440 Electrophoretic hemoglobin analysis system.

(a) *Identification.* An electrophoretic hemoglobin analysis system is a device that electrophoretically separates and identifies normal and abnormal hemoglobin types as an aid in the diagnosis of anemia or erythrocytosis (increased total red cell mass) due to a hemoglobin abnormality.

(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. 80-27354 Filed 9-11-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 864

[Docket No. 78N-1893]

Classification of Fetal Hemoglobin Assays

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying fetal 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 53017) a proposed regulation to classify fetal hemoglobin 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 § 864.7455, to read as follows:

§ 864.7455 Fetal hemoglobin assay.

(a) *Identification.* A fetal hemoglobin assay is a device that is used to determine the presence and distribution of fetal hemoglobin (hemoglobin F) in red cells or to measure the amount of fetal hemoglobin present. The assay may be used to detect fetal red cells in the maternal circulation or to detect the elevated levels of fetal hemoglobin exhibited in cases of hemoglobin abnormalities such as thalassemia (a hereditary hemolytic anemia characterized by a decreased synthesis of one or more types of hemoglobin polypeptide chains). The hemoglobin determination may be made by methods such as electrophoresis, alkali denaturation, column chromatography, or radial immunodiffusion.

(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. 80-27355 Filed 9-11-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 864

[Docket No. 78P-0155]

Classification of Glycosylated Hemoglobin Assays

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to codify its 1978 order reclassifying glycosylated hemoglobin assays from class III (premarket approval) into class II (performance standards). FDA issued the order after receiving a manufacturer's reclassification petition and publishing for comment the

recommendation of an FDA advisory committee. 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: Section 513(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)) classifies into class III (premarket approval) a device that is first offered for commerical distribution after enactment of the Medical Device Amendments and that is not substantially equivalent to a preamendments device. On February 21, 1978, Helena Laboratories, Beaumont, Texas 77704, submitted to FDA a petition for reclassification of a column chromatographic procedure that it intended to market for the measurement of the glycosylated hemoglobins, a device reclassified into class III pursuant to section 513(f). FDA reviewed the petition and requested additional data. On May 24, 1978, the manufacturer submitted the requested data as a supplement to the petition. The agency mailed copies of the petition to voting members of the Hematology and Pathology Device Section of the Clinical Chemistry and Hematology Devices Panel and asked the members to mail their recommendations to FDA. By August 31, 1978, all the members had responded. The Panel recommended that the device be reclassified into class II.

FDA published a notice of the Panel recommendation in the **Federal Register** of September 26, 1978 (43 FR 43555), and provided a period of 30 days for interested persons to submit written comments to FDA.

FDA received no comments on the recommendation. Because FDA agreed with the Panel recommendation, FDA granted the petition and reclassified the device into class II by order in the form of a letter to the sponsor dated November 6, 1978.

This regulation codifies the 1979 order. The order and regulation apply to any device that is substantially equivalent to the reclassified device. FDA determines substantial equivalence by reviewing premarket notification submissions under section 510(k) of the act (21 U.S.C. 360(k)) and Subpart E of Part 807 of the regulations (21 CFR Part 807, Subpart E).

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 § 864.7470, to read as follows:

§ 864.7470 Glycosylated hemoglobin assay.

(a) *Identification.* A glycosylated hemoglobin assay is a device used to measure the glycosylated hemoglobins (A_{1a}, A_{1b}, and A_{1c}) in a patient's blood by a column chromatographic procedure. Measurement of glycosylated hemoglobin is used to assess the level of control of a patient's diabetes and to determine the proper insulin dosage for a patient. Elevated levels of glycosylated hemoglobin indicate uncontrolled diabetes in a patient.

(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. 80-27356 Filed 9-11-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 864

[Docket No. 78N-1895]

Classification of Sulfhemoglobin Assays

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying sulfhemoglobin 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 53018) a proposed regulation to classify sulfhemoglobin 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 § 864.7490, to read as follows:

§ 864.7490 Sulfhemoglobin assay.

(a) *Identification.* A sulfhemoglobin assay is a device consisting of the reagents, calibrators, controls, and instrumentation used to determine the