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

sulfhemoglobin (a compound of sulfur and hemoglobin) content of human blood as an aid in the diagnosis of sulfhemoglobinemia (presence of sulfhemoglobin in the blood due to drug administration or exposure to a poison). This measurement may be made using methods such as spectroscopy, colorimetry, spectrophotometry, or 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. 80-27357 Filed 9-11-80; 8:45 am]

BILLING CODE 4110-03-M

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12 CFR Part 864

[Docket No. 78N-1896]

Classification of Whole Blood Hemoglobin Assays

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying whole blood 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 53019) a proposed regulation to classify whole blood 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. One comment suggested that including the purpose of the assay is not necessary to identify the device.

FDA disagrees with this comment. Examples of the diagnostic uses of products have been included because FDA believes that by doing so it has provided a more complete identification of the diagnostic product.

2. One manufacturer suggested that due to the language in the proposed regulations for automated hemoglobin system (44 FR 52983) and whole blood hemoglobin assays (44 FR 53019), its automated hemoglobin system would be subject to two potentially conflicting performance standards. The comment noted that the language in the proposed regulation for automated hemoglobin systems appears to encompass all the devices described in the proposed regulation for whole blood hemoglobin assays. The comment requested that the language be modified so that this system is subject to a single rule.

FDA agrees with this comment. The identification section of the regulation for automated hemoglobin systems has been modified so that the regulation applies only to automated systems. That regulation is published elsewhere in this issue of the **Federal Register**. The identification section of this regulation has been modified to exclude automated assays.

3. FDA also received one comment supporting the proposed classification into class II and suggesting that the slit width of the colorimeter or spectrophotometer used in these assays be specified in any standards developed.

FDA will consider addressing this matter when a standard for the device is developed.

Accordingly, the regulation has been modified to include the changes noted.

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 § 864.7500, to read as follows:

§ 864.7500 Whole blood hemoglobin assays.

(a) *Identification.* A whole blood hemoglobin assay is a device consisting or reagents, calibrators, controls, or photometric or spectrophotometric instrumentation used to measure the hemoglobin content of whole blood for the detection of anemia. This generic device category does not include automated hemoglobin systems.

(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. 80-27358 Filed 9-11-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 864

[Docket No. 78N-1897]

Classification of Heparin Assays

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying heparin 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 53020) a proposed regulation to classify heparin 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 § 864.7525, to read as follows:

§ 864.7525 Heparin assay.

(a) *Identification.* A heparin assay is a device used to determine the level of the anticoagulant heparin in the patient's circulation. These assays are quantitative clotting time procedures using the effect of heparin on activated coagulation factor X (Stuart factor) or procedures based on the neutralization of heparin by protamine sulfate (a protein that neutralizes heparin).

(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. 80-27359 Filed 9-11-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 864

[Docket No. 78N-1898]

Classification of Leukocyte Alkaline Phosphatase Tests

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying leukocyte alkaline phosphatase tests into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. 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 53021) a proposed regulation to classify leukocyte alkaline phosphatase tests into class I (general controls). A period of 60 days was provided for interested persons to submit written comments to FDA.

The one comment received on the proposal disagreed with the proposed classification of the leukocyte alkaline phosphatase test into class I. The comment noted that an error in the test may result in failure to diagnose leukemia or the labeling of normal cells as leukemic. The comment cited the Panel's contention that stains are hard to standardize, vary from lot-to-lot, and 10 to 25 percent of stain lots are unusable. Because proper functioning of this test is so important to the patient's health, a performance standard is essential to provide a reasonable assurance of safety and effectiveness. Therefore, the comment recommended that these tests be placed into class II.

FDA disagrees with the comment and is classifying these tests into class I as proposed.

On November 19, 1979, FDA held a public meeting of the Hematology Devices Section of the Clinical Chemistry and Hematology Devices Panel. At the meeting, a representative of the Health Research Group (HRG) presented HRG's view that leukocyte alkaline phosphatase tests should be classified into class II rather than class I as proposed.

After considering the comment, the testimony, and the Section's recommendation to classify the device into class I as proposed, FDA has concluded that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

During FDA's meeting of the Section, one of the Section members pointed out that the comment's figure of 10 to 25 percent for unusable stain lots refers to the acid phosphatase stain and not to alkaline phosphatase stain. The member also noted that an evaluation of the stain kits for this test had shown them to be very reliable.

Accordingly, FDA is adopting the proposed regulation 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 § 864.7660, to read as follows:

§ 864.7660 Leukocyte alkaline phosphatase test.

(a) *Identification.* A leukocyte alkaline phosphatase test is a device used to identify the enzyme leukocyte alkaline phosphatase in neutrophilic granulocytes (granular leukocytes stainable by neutral dyes). The cytochemical identification of alkaline phosphatase depends on the formation of blue granules in cells containing alkaline phosphatase. The results of this test are used to differentiate chronic granulocytic leukemia (a malignant disease characterized by excessive