overgrowth of granulocytes in the bone marrow) and reactions that resemble true leukemia, such as those occuring in severe infections and polycythemia (increased total red cell mass).

(b) *Classification.* Class I (general controls.

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. 80-27360 Filed 9-11-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 864

[Docket No. 78N-1899]

Classification of Leukocyte Peroxidase Tests

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying leukocyte peroxidase 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 53022) a proposed regulation to classify leukocyte peroxidase 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 peroxidase test into class I. The comment noted that an error in the test could result in inappropriate therapy for leukemia. 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. The comment stated that a performance standard is necessary to provide a reasonable assurance of the safety and effectiveness of the test. The comment recommended that these tests be placed into class II.

FDA disagrees with the comment and is classifying the 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 that meeting a representative of the Health Research Group (HRG) presented HRG's view that leukocyte peroxidase 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 tests. 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 the leukocyte peroxidase stain. The member also noted that 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 § 864.7675, to read as follows:

§ 864.7675 Leukocyte peroxidase test.

(a) *Identification.* A leukocyte peroxidase test is a device used to distinguish certain myeloid cells derived from the bone marrow, i.e., neutrophils, eosinophils, and monocytes, from lymphoid cells of the lymphatic system and erythroid cells of the red blood cell series on the basis of their peroxidase activity as evidenced by staining. The results of this test are used in the differential diagnosis of the leukemias.

(b) *Classification.* Class I (general controls).

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. 80-27361 Filed 9-11-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 864

[Docket No. 79P-0112]

Classification of Platelet Factor 4 Radioimmunoassays

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to codify its 1979 order reclassifying platelet factor 4 radioimmunoassays from class III (premarket approval) to class II (performance standards). FDA issued the order after reviewing 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 commercial distribution after enactment of the Medical Device Amendments and that is not substantially equivalent to a preamendments device. On July 31, 1978,

Abbott Laboratories, North Chicago, Illinois 60064, submitted to FDA a petition for reclassification of a device it intended to market as a radioimmunoassay procedure for the measurement of platelet factor 4 in human plasma. This device was classified into class III pursuant to section 513(f). On November 21 and 22, 1978, the Hematology Section of the Clinical Chemistry and Hematology Devices Panel (formerly the Hematology Device Classification Panel) reviewed the petition and requested additional data and information. The petitioner withdrew the petition on December 8, 1978, and resubmitted it with additional data and information on January 29, 1979. On February 16, 1979, the Hematology Section reviewed the submitted petition, assigned to this generic type of device the name "platelet factor 4 radioimmunoassay," and recommended that the device be reclassified into class II.

FDA published a notice of the Hematology Section's recommendation in the **Federal Register** of June 1, 1979 (44 FR 31714), 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 Hematology Section's recommendation, the agency granted the petition and reclassified the device into class II by order in the form of a letter to the sponsor dated July 18, 1979.

This regulation codifies the 1979 order. The order and the 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 18, 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 § 864.7695, to read as follows:

§ 864.7695 Platelet factor 4 radioimmunoassay.

(a) *Identification.* A platelet factor 4 radioimmunoassay is a device used to measure the level of platelet factor 4, a protein released during platelet activation, which may indicate a coagulation disorder, such as myocardial infarction or coronary artery disease.

(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. 80-27362 Filed 9-11-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 864

[Docket No. 78N-1900]

Classification of Prothrombin Consumption Tests

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying prothrombin consumption tests 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 53023) a proposed regulation to classify prothrombin consumption tests 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 premable 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 § 864.7720, to read as follows:

§ 864.7720 Prothrombin consumption test.

(a) *Identification.* A prothrombin consumption tests is a device that measures the patient's capacity to generate thromboplastin in the coagulation process. The test also is an indirect indicator of qualitative or quantitative platelet abnormalities. It is screening test for thrombocytopenia (decreased number of blood platelets) and hemophilia A and B.

(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. 80-27363 Filed 9-11-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 864

[Docket No. 78N-1901]

Classification of Prothrombin-Proconvertin Tests and Thrombotests

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying prothrombin-proconvertin tests and thrombotests 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 53024) a proposed regulation to classify prothrombin-proconvertin tests and thrombotests 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 § 864.7735, to read as follows:

§ 864.7735 Prothrombin-proconvertin test and thrombotest.

(a) *Identification.* The prothrombin-proconvertin test and thrombotest are devices used in the regulation of coumarin therapy (administration of a coumarin anticoagulant such as sodium warfarin in the treatment of venous thrombosis and pulmonary embolism) and as a diagnostic test in conjunction with, or in place of, the Quick prothrombin time test to detect coagulation disorders.

(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. 80-27364 Filed 9-11-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 864

[Docket No. 78N-1902]

Classification of Prothrombin Time Tests

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying prothrombin time tests 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 53025) a proposed regulation to classify prothrombin time tests 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 § 864.7750, to read as follows:

§ 864.7750 Prothrombin time test.

(a) *Identification.* A prothrombin time test is a device used as a general screening procedure for the detection of possible clotting factor deficiencies in the extrinsic coagulation pathway, which involves the reaction between coagulation factors III and VII, and to monitor patients receiving coumarin therapy (the administration of one of the coumarin anticoagulants in the treatment of venous thrombosis or pulmonary embolism).

(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. 80-27365 Filed 9-11-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 864

[Docket No. 78N-1903]

Classification of Sickle Cell Tests

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying sickle cell tests 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 Panal and the Pathology Device Classification Panel). FDA also published in that issue of the **Federal Register** (44 FR 53026) a proposed regulation to classify sickle cell tests into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

The one comment on the proposal noted that the identification section of the regulation states that a sickle cell test is used to determine the sickle cell hemoglobin content of human blood to detect sickle cell anemia. The comment suggested that a sickle cell solubility test does not detect sickle cell anemia. Instead it detects the presence of sickle cell hemoglobin, whether it is in the heterozygous or homozygous state.

FDA agrees with this comment. The agency has modified the identification to make it clear that the test detects sickle trait or sickle cell disease. Therefore, the proposed regulation is being adopted with 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 § 864.7825, to read as follows:

§ 864.7825 Sickle cell test.

(a) *Identification.* A sickle cell test is a device used to determine the sickle cell hemoglobin content of human blood to detect sickle cell trait or sickle cell diseases.

(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. 80-27366 Filed 9-11-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 864

[Docket No. 78N-1904]

Classification of Thrombin Time Tests

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying thrombin time tests 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 53027) a proposed regulation to classify thrombin time tests into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

In the one comment received on the proposal, a manufacturer of a bovine thrombin product stated that its product is used both for fibrinogen determination procedures and for clotting factor assays. The manufacturer is concerned that the product might be subject to two potentially conflicting standards due to the wording of the identification sections of the proposed regulations for fibrinogen determination systems and the thrombin time tests, Docket Numbers 78N-1886 and 78N-1904, respectively. The manufacturer requested that the proposed regulations be reworded so as to subject bovine thrombin to a single standard.

FDA does not believe that it is necessary to reword the regulations. If bovine thrombin is offered as a component of a system or as an accessory to a system, it must meet the performance standard applicable to that system. Therefore, it is conceivable that bovine thrombin will be subject to two standards. The matter of overlapping performance standards will receive careful consideration during the standard development process, so that the resultant standards will not impose an intolerable burden on the manufacturers of these products.

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