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 J by adding new § 864.9320, to read as follows:

§ 864.9320 Copper sulfate solution for specific gravity determinations.

(a) *Identification.* A copper sulfate solution for specific gravity determinations is a device used to determine whether the hemoglobin content of a potential donor's blood meets the required level (12.5 grams per 100 milliliters of blood for women and 13.5 grams per 100 milliliters of blood for men).

(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. 80-27394 Filed 9-11-80; 8:45 am]

BILLING CODE 4110-03-M

---

21 CFR Part 864

[Docket No. 78N-1933]

Classification of Stabilized Enzyme Solutions

AGENCY: Food and Drug Administration.

ACTION: Final rule

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying stabilized enzyme solutions 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 53055) a proposed regulation to classify stabilized enzyme solutions 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 with a minor clarifying 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 J by adding new § 864.9400, to read as follows:

§ 864.9400 Stabilized enzyme solution.

(a) *Identification.* A stabilized enzyme solution is a reagent intended for medical purposed that is used to enhance the reactivity of red blood cells with certain antibodies, including antibodies that are not detectable by other techniques. These enzyme solutions include papain, bromelin, ficin, and trypsin.

(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. 80-27395 Filed 9-11-80; 8:45 am]

BILLING CODE 4110-03-M

---

21 CFR Part 864

[Docket No. 78N-1935]

Classification of Lectins and Protectins

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a filnal rule classifying lectins and protectins 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 safet and effectiveness of the devise. 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 Clinical Chemistry and Hematology Device Panel (formerly the Hematology Device Classification Panel and Pathology Device Classifiction Panel). FDA also published in that issue of the Federal Register (44 FR 53057) a proposed regulation to classify lectins and protectins 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 adoped 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 Drugs is amending Part 864 in Subpart J by adding new § 864.9550, to read as follows:

§ 864.9550 Lectins and protectins.

(a) *Identification.* Lectins and protectins are proteins derived from plants and lower animals that cause cell agglutination in the presence of certain antigens. These substances are used to detect blood group antigens for in vitro diagnostic purposes.

(b) *Classification.* Class II (preformance 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. 80-27396 Filed 9-11-80; 8:45 am]

BILLING CODE 4110-03-M

---

21 CFR Part 864

[Docket No. 78N-1936]

Classification of Environmental Chambers for Storage of Platelet Concentrate

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying environmental chambers for storage of platelet concentrate 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 53058) a proposed regulation to classify environmental chambers for storage of platelet concentrate into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

The one comment received on the proposal suggested that insufficient information exists to write a performance standard that would provide reasonable assurance of the safety and effectiveness of the device. The comment cited the controversy over the proper conditions for platelet storage as evidence that a standard cannot be written. The comment also stated that FDA gives no indication of an acceptable methodology for determining which of the two types of storage conditions provides the greater assurance of safety and effectiveness. The comment suggested that these devices be provisionally placed into class III until FDA recognizes an acceptable methodology for making this determination.

FDA disagrees with the comment and is classifying the device into class II as proposed.

On November 19, 1979, FDA held a public meeting of the Hematology 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 environmental chambers for storage of platelet concentrate should be classified into class III rather than class II as proposed.

After considering the comments, the additional testimony presented at the meeting, and the Section's recommendation to classify the device into class II, FDA has concluded that there is sufficient information available to establish a performance standard for the device and is classifying the device into class II as proposed. Although 22° C may be a better storage temperature than 4° C, these devices must merely be able to hold either of these temperatures, and a performance standard assuring the ability to hold a given temperature can be written.

In addition, as suggested in an article by Holme et al. (Ref. 1), there are a number of in vitro tests that may be utilized to assess the viability of platelets stored under differing conditions.

Therefore, 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.

Reference

1. Holme, S., K. Vaidja, and S. Murphy, "Platelet Storage at 22° C: Effect of Type of Agitation on Morphology, Viability, and Function In Vitro," *Blood*, 52(2):425–435, 1978.

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 J by adding new § 864.9575, to read as follows:

§ 864.9575 Environmental chamber for storage of platelet concentrate.

(a) *Identification.* An environmental chamber for storage of platelet concentrate is a device used to hold platelet-rich plasma within a preselected temperature range.

(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. 80-27397 Filed 9-11-80; 8:45 am]

BILLING CODE 4110-03-M

---

21 CFR Part 864

[Docket No. 78N-1937]

Classification of Potentiating Media for in Vitro Diagnostic Use

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying potentiating media for in vitro diagnostic use 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 53059) a proposed regulation to classify potentiating media for in vitro diagnostic use 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 J by adding new § 864.9600, to read as follows:

§ 864.9600 Potentiating media for in vitro diagnostic use.

(a) *Identification.* Potentiating media for in vitro diagnostic use are media, such as bovine albumin, that are used to suspend red cells and to enhance cell reactions for antigen-antibody testing.

(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. 80–27398 Filed 9–11–80; 8:45 am]

BILLING CODE 4110–03–M

---

21 CFR Part 864

[Docket No. 78N–1938]

Classification of Quality Control Kits For Blood Banking Reagents

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying quality control kits for blood banking reagents 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 Hematoloy 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 53060) a proposed regulation to classify quality control kits for blood banking reagents 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 with a minor clarifying 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 J by adding new § 864.9650, to read as follows:

§ 864.9650 Quality control kit for blood banking reagents.

(a) *Identification.* A quality control kit for blood banking reagents is a device that consists of sera, cells, buffers, and antibodies used to determine the specificity, potency, and reactivity of the cells and reagents used for blood banking.

(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. 80–27399 Filed 9–11–80; 8:45 am]

BILLING CODE 4110–03–M

---

21 CFR Part 864

[Docket No. 78N–1939]

Classification of Blood Storage Refrigerators and Blood Storage Freezers

AGENCY: Food and Drug Administration.

ACTION: Final rule.