

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 53036) a proposed regulation to classify blood cell diluents into class I (general controls). 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 endorsed the proposed classification into class I and the reasoning set forth in the proposed regulation.

FDA is classifying the device into class I as proposed.

One manufacturer suggested that blood cell diluents be placed in class II. The comment noted that these products are critical to the effective and reliable use of cell counting devices, calibrators, and quality control mixtures, all of which were placed in class II or class III. The comment suggested that the Panel recommendation was made on the basis of data concerning sodium azide diluents, whose performance was unchanging and reliable. The comment notes that in the past 2 years there has been a shift to azide-free diluents. The resulting changes in preservatives and formula modifications have affected certain cell indices such as the mean corpuscular volume (MCV). The comment cites an article by Fujii, et al. (Ref. 1), demonstrating that different preservatives affect cell shape in various ways. The use of different diluents have resulted in 10-30 μ^3 differences between the MCV's of commercial control cells measured with impedance type counters and those measured with optical type counters. The comment suggested that placing these diluents into class II would not create hardship for the manufacturer or

adversely affect the economics of their production and control.

FDA disagrees with this comment. FDA does not believe that it is necessary to place blood cell diluents in class II. The effects of diluents should be addressed as part of the standards development process for automated cell counters. Accordingly, the proposed regulation is being adopted without change.

Reference

1. Fujii, T., T. Sato, A. Tamura, M. Wakatsuki, and Y. Kanoh, "Shape Changes of Human Erythrocytes Induced by Various Amphipathic Drugs Acting on the Membrane of the Intact Cells," *Biochemical Pharmacology*, 28:613-620, 1979.

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 I by adding new § 864.8200, to read as follows:

§ 864.8200 Blood cell diluent.

(a) *Identification.* A blood cell diluent is a device used to dilute blood for further testing, such as blood cell counting.

(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. 80-27375 Filed 9-11-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 864

[Docket No. 78N-1914]

Classification of Lymphocyte Separation Media

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying lymphocyte separation media 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 53037) a proposed regulation to classify lymphocyte separation media into class I (general controls). 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 I by adding new § 864.8500, to read as follows:

§ 864.8500 Lymphocyte separation medium.

(a) *Identification.* A lymphocyte separation medium is a device used to isolate lymphocytes from whole blood.

(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. 80-27376 Filed 9-11-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 864

[Docket No. 78N-1915]

Classification of Red Cell Lysing Reagents

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying red cell lysing reagents 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 53037) a proposed regulation to classify red cell lysing reagents into class I (general controls). A period of 60 days was provided for interested persons to submit written comments to FDA.

Two comments were received on the proposal. The following is a summary of

these comments and the agency's response to them:

1. One comment noted that the lysing reagent does not physically remove red blood cells from the solution. Cellular debris remains suspended in the solution or it is dissolved. The comment suggested that the concept of red cell removal be deleted from the identification.

FDA agrees with this comment. The identification has been modified to correct the misstatement in the proposed regulation.

2. FDA received one comment in support of the Panel's recommendation and in agreement with the reasoning set forth in the proposed regulation.

Accordingly, 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 I by adding new § 864.8540, to read as follows:

§ 864.8540 Red cell lysing reagent.

(a) *Identification.* A red cell lysing reagent is a device used to lyse (destroy) red blood cells for hemoglobin determinations or aid in the counting of white blood cells.

(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. 80-27377 Filed 9-11-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 864

[Docket No. 78N-1916]

Classification of Hematology Quality Control Mixtures

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying hematology quality control mixtures 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 Device 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 53038) a proposed regulation to classify hematology quality control mixtures 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 stated that the proposed class II classification is not necessary to ensure the safety and effectiveness of these products. The comment disputed the view that a laboratory would not know that its reagents had deteriorated or that an instrument was malfunctioning. The comment noted that the instrument provides warnings to the user independent of the quality control mixture. The comment recommended that FDA comment on current labeling deficiencies concerning system malfunction and customer alerts. The comment admitted that performance

standards may be necessary for assays carried out entirely by manual methods but the quality control mixtures used or recommended for use with automated systems may be adequately regulated under the class I provisions.

FDA disagrees with this comment. FDA believes that a defective quality control material can mask instrument malfunction or reagent deterioration. If it were true, as the comment asserted, that sufficient warnings are provided by the instrument, quality control mixtures would not be required. This is not the case. FDA does not believe it is necessary to comment on current labeling concerning instrument malfunctions and customer alerts. FDA believes that quality control materials are marketed for use in both manual and automated procedures and that class II is appropriate to use in both types of procedures. FDA does not believe that general controls will adequately regulate quality control materials because general controls do not specify acceptable ranges for the precision and accuracy of these materials. This specification can be accomplished only through performance standards. FDA acknowledges, however, that until a performance standard is promulgated in final form, these devices will be regulated as class I devices.

2. One comment noted that the Panel based its recommendation upon its members' clinical experience and did not consider the comments of the industry or product users.

FDA disagrees with this comment. The agenda of the Hematology Devices Section of the Clinical Chemistry and Hematology Devices Panel were announced in the *Federal Register*, the manufacturers and the public were afforded an opportunity to participate in these meetings, and their interests were also represented by industry and consumer representatives at the Panel meetings.

3. FDA received one comment in support of the proposed class II classification. The comment also stated that a performance standard for these devices should provide for an alternative method for the verification of the accuracy of the assay values.

FDA will consider this matter when it establishes a performance standard for these devices.

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 I by adding new § 864.8625, to read as follows:

§ 864.8625 Hematology quality control mixture.

(a) *Identification.* A hematology quality control mixture is a device used to ascertain the accuracy and precision of manual, semiautomated, and automated determinations of cell parameters such as white cell count (WBC), red cell count (RBC), platelet count (PLT), hemoglobin, hematocrit (HCT), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), and mean corpuscular hemoglobin concentration (MCHC).

(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.

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21 CFR Part 864

[Docket No. 78N-1917]

Classification of Russell Viper Venom Reagents

AGENCY: Food and Drug Administration.
ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying Russell viper venom reagents 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 53039) a proposed regulation to classify Russell viper venom reagents into class I (general controls). 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 I by adding new § 864.8950, to read as follows:

§ 864.8950 Russell viper venom reagent.

(a) *Identification.* Russell viper venom reagent is a device used to determine the cause of an increase in the prothrombin time.

(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)))