Use Device Classification Panel, and the Anesthesiology Device Classification Panel, FDA advisory committees, made the following recommendations with respect to the classification of blood pressure computers:

1. Identification: A blood pressure computer is a device that accepts the electrical signal from a blood pressure transducer amplifier and indicates the systolic, diastolic, or mean pressure based on the input signal.

2. Recommended classification: Class II (performance standards). The Panels recommend that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panels recommend that the blood pressure computer be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. This device is attached to the body through a blood pressure transducer amplifier and a catheter and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's measurement of blood pressure, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panels believe that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panels believe that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health : (a) Misdiagnosis: if the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (b) Cardiac arrhythmias or electrical shock; Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panels' recommendations and is proposing that the blood pressure computer be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Because blood pressure measurement is an indication of cardiovascular function, this device will be listed in the Code of Federal Regulations under cardiovascular devices. Although blood pressure computers are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

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 proposes to amend Part 870 in subpart B by adding new § 870.1110 as follows:

§ 870.1110 Blood pressure computer.

(a) *Identification.* A blood pressure computer is a device that accepts the electrical signal from a blood pressure transducer amplifier and indicates the systolic, diastolic, or mean pressure based on the input signal.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6106 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1410]

MEDICAL DEVICES

Classification of Blood Pressure Cuffs

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying blood pressure cuffs into class II (performance standards). The FDA is also publishing the recommendations of the Cardiovascular Device Classification Panel, the General Hospital and Personal Use Device Classification Panel, and the General and Plastic Surgery Device Classification Panel that the device be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, the General Hospital and Personal Use Device Classification Panel, and the General and Plastic

Surgery Device Classification Panel, FDA advisory committees, made the following recommendation with respect to the classification of blood pressure cuffs:

1. Identification: A blood pressure cuff is a device that has an inflatable bladder in an inelastic sleeve (cuff) with a mechanism for inflating and deflating the bladder. The cuff is used in conjunction with another device to determine a subject's blood pressure.

2. Recommended classification: Class II (performance standards). The Panels recommend that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panels recommend that blood pressure cuffs be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the design of the device is inadequate for accurate and precise measurement of blood pressure, the resulting misdiagnosis could have a significant negative effect on the patient's health. The mechanical design and performance characteristics of the device should be maintained at a generally accepted satisfactory level. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panels believe that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panels believe that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Tissue trauma: Overinflation, or use of an improper size cuff, can cause unnecessary tissue trauma. (b) Misdiagnosis: Inadequate design of cuff size can lead to generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendations and is proposing that the blood pressure cuff be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Because blood pressure measurement is an indication of cardiovascular function, this device will be listed in the Code of Federal Regulations under cardiovascular devices. Although blood pressure cuffs are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

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 proposes to amend Part 870 in Subpart B by adding § 870.1120 as follows:

§ 870.1120 Blood pressure cuff.

(a) *Identification.* A blood pressure cuff is a device that has an inflatable bladder in an inelastic sleeve (cuff) with a mechanism for inflating and deflating the bladder. The cuff is used in conjunction with another device to determine a subject's blood pressure.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6107 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1411]

MEDICAL DEVICES

Classification of Noninvasive Blood Pressure Measurement Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying noninvasive blood pressure measurement systems into class II (performance standards). The FDA is also publishing the recommendations of the Cardiovascular Device Classification Panel the Anesthesiology Device Classification Panel, the General Hospital and Personal Use Device Classification Panel, and the General and Plastic Surgery Device Classification Panel that the device be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, the Anesthesiology Device Classification Panel, the General Hospital and Personal Use Device Classification Panel, and the General and Plastic Surgery Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of nonin-

vasive blood pressure measurement systems:

1. Identification: A noninvasive blood pressure measurement system is a device that provides a signal from which systolic, diastolic, mean, or any combination of the three can be derived through the use of transducers placed on the surface of the body.

2. Recommended classification: Class II (performance standards). The Panels recommend that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panels recommend that noninvasive blood pressure measurement systems be classified into class II because this device is neither life-supportng nor life-sustaining, but is potentially hazardous to life or health even when properly used. This device is attached to the body through surface transducers and can be electrically powered. It is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. If the design of the device is inadequate for accurate and precise measurement of blood pressure, the resulting misdiagnosis could have a significant negative effect on the patient's health. When functioning properly, the device emits an acceptable energy level into the body. Malfunction of the ultrasonic types of the device, however, may result in unsafe energy levels. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's measurement of blood pressure, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panels believe that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panels believe that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device. In addition, the Cardiovascular Device Classification Panel cited three standards proposed by the medical community for blood pressure measurement equipment (Refs. 1 through 3).

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Tissue damage: In devices that use an ultrasonic detection method, excessive ultrasonic energy output can cause tissue damage. (c) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (d) Tissue ischemia: Any system that allows prolonged cuff inflation can cause tissue ischemia (deficiency of blood supply to a portion of the body).

Proposed Classification

The Commissioner agrees with the Panels' recommendations and is proposing that the noninvasive blood pressure measurement system be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Because blood pressure measurement is an indication of cardiovascular function, this device will be listed in the Code of Federal Regulations under cardiovascular devices. Although noninvasive blood pressure measurement systems are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. "Standardization of Blood Pressure Readings. Joint Recommendations of the American Heart Association and the Cardiac Society of Great Britain and Ireland," *American Heart Journal* 18:95-101, 1939.

2. Bordley, J., et al., "Recommendations for Human Blood Pressure Determinations by Sphygmomanometers," *Circulation*, 4:503-509, 1951.

3. Kirkendall, W. M., et al., "Recommendations for Human Blood Pressure Determinations by Sphygmomanometers," *Circulation*, 36:980-988, 1967.

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 proposes to amend Part 870 in Subpart B by adding new § 870.1130 as follows:

§ 870.1130 Noninvasive blood pressure measurement system.

(a) *Identification.* A noninvasive blood pressure measurement system is a device that provides a signal from which systolic, diastolic, mean, or any combination of the three can be derived through the use of tranducers placed on the surface of the body.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6108 Filed 3-8-79 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1412]

MEDICAL DEVICES

Classification of Venous Blood Pressure Manometers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying venous blood pressure manometers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II and the recommendation of the General and Plastic Surgery Device Classification Panel that the device be classified into class I. 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification and the General and Plastic Surgery Device Classification Panels, FDA advisory committees, made the following recommendations with respect to the classification of venous blood pressure manometers:

1. Identification: A venous blood pressure manometer is a device attached to a venous catheter to indicate manometrically the central or peripheral venous pressure.

2. Recommended classification: The Cardiovascular Device Classification Panel recommends class II (performance standards) and recommends that establishing a performance standard for this device be a low priority. The General and Plastic Surgery Device Classification Panel recommends class I (general controls) with no exemptions.

3. Summary of reasons for recommendation: The Cardiovascular Device Classification Panel recommends that venous blood pressure manometers be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device is inadequate for accurate and precise measurement of blood pressure, the resulting misdiagnosis could have a significant negative effect on the patient's health. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's measurement of blood pressure, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Cardiovascular Device Classification Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Cardiovascular Device Classification Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance. The General and Plastic Surgery Device Classification Panel believes that general controls would provide sufficient control over the performance characteristics of the device and listed no risks to health for the device.

4. Summary of data on which the recommendation is based: The Panel members based their recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: Misdiagnosis: Inadequate design of calibration characteristics of the manometer can lead to generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Cardiovascular Device Classification Panel recommendation and is proposing that the venous blood pressure manometer be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control misdiagnosis listed as a risk to health by the Cardiovascular Device Classification Panel. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Because blood pressure measurement is an indication of cardiovascular function, this device will be listed in the Code of Federal Regulations under cardiovascular devices. Although venous blood pressure manometers are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

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 proposes to amend Part 870 in Subpart B by adding new § 870.1140 as follows:

§ 870.1140 Venous blood pressure manometer.

(a) *Identification.* A venous blood pressure manometer is a device attached to a venous catheter to indicate manometrically the central or peripheral venous pressure.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6109 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1413]

MEDICAL DEVICES

Classification of diagnostic intravascular Catheters

AGENCY: Food and Drug Administration

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying diagnostic intravascular catheters into class II (performance standards). The FDA is also publishing the recommendations of the Cardiovascular Device Classification Panel, the General and Plastic Surgery Device Classification Panel, the Neurological Device Classification Panel, and the Radiological Device Classification Panel that the device be classified into class II. 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