existing products. The industry has commented that this conversion to protected electrode lead wires and patient cables could occur over a maximum of 2 years. FDA's proposal, if implemented, would be phased in over a 3-year period. This proposed phase-in would further minimize the costs associated with such a conversion. For these reasons, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

X. Request for Comments

Interested persons may, on or before September 21, 1995, submit to the Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

FDA is soliciting comments on all aspects of this proposal, and specifically requests comments on the following issues:

(1) Cost of converting or adapting unsafe electrode lead wire configurations to safe electrode lead wire configurations that meet the proposed requirements in this document. Please provide the source of your estimates.

(2) The list of devices subject to the proposed performance standard and ban, and their respective effective dates for compliance.

(3) The potential for cutaneous electrodes to be interchanged with various medical equipment.

(4) Test methods, if any, that should be included in the proposed mandatory standard.

XI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Letter to FDA Commissioner David A. Kessler from Ron Wyden, then Chairman, U.S. House of Representatives, Committee on Small Business, Subcommittee on Regulation, Business Opportunities, and Technology, dated August 2, 1994.

2. Information from FDA's medical device reporting (MDR) data base, Rockville, MD.

3. Information from FDA's medical device reporting (MDR) data base, Rockville, MD.

4. ''FDA Safety Alert: Unsafe Patient Lead Wires and Cables,'' FDA's September 3, 1993, Safety Alert.

5. Section 518(a) notification letter to apnea monitor manufacturers, September 3, 1993.

6. Section 518(a) notification letter to patient cable and lead wire manufacturers, September 20, 1993.

7. FDA Public Health Advisory: Unsafe Electrode Lead Wires and Patient Cables Used With Medical Devices, December 28, 1993.

List of Subjects

21 CFR Part 895

Administrative practice and procedure, Labeling, Medical devices.

21 CFR Part 897

Administrative practice and procedure, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and the Public Health Service Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that Title 21, Chapter I of the Code of Federal Regulations be amended as follows:

PART 895—BANNED DEVICES

1. The authority citation for 21 CFR part 895 continues to read as follows:

Authority: Secs. 502, 516, 518, 519, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 360f, 360h, 360i, 371).

2. Section 895.105 is added to subpart B to read as follows:

§ 895.105 Unprotected electrode lead wire.

(a) *Definition.* A lead wire that is intended to provide electrical contact between a patient and any medical device and that has a connector that is not protected at the end distal to the patient, i.e., the connector at the lead wire end that is distal to the patient is capable of making conductive contact with an alternating current electrical power source (e.g., wall receptacle, power cord plug).

(b) *Applicability.* Devices utilizing unprotected patient connected electrode lead wires shall be banned as of the date set forth in paragraph (c) of this section.

(c) *Effective date.* The effective date for the ban of devices utilizing unprotected patient-connected electrode lead wires as defined in paragraph (a) of this section shall be as follows:

(1) For the following devices, the effective date for which compliance is required is (insert date 1 year after date of publication of the final rule):

LISTING OF DEVICES FOR WHICH COMPLIANCE IS REQUIRED EFFECTIVE

[Insert date 1 year after date of publication of the final rule]

Phase	Product code	CFR section	Class	Device name
1	73 BZQ	868.2375	II	Monitor, Breathing Frequency.
1	73 FLS	868.2375	II	Monitor (Apnea Detector), Ventilatory Effort.
1	74 DPS	870.2340	II	Electrocardiograph.
1	74 DRG	870.2910	II	Transmitters and Receivers, Physiological Signal, Radiofrequency.
1	74 DRK	870.5300	III	DC-Defibrillator, High Energy, (Including Paddles).
1	74 DRO	870.5550	III	Pacemaker, Cardiac, External Transcutaneous (Noninvasive).
1	74 DRQ	870.2060	II	Amplifier and Signal Conditioner, Transducer Signal.
1	74 DRR	870.2050	II	Amplifier and Signal Conditioner, Biopotential.
1	74 DRT	870.2300	II	Monitor, Cardiac (Including Cardiotachometer and Rate Alarm).
1	74 DRW	870.2350	II	Adaptor, Lead Switching, Electrocardiograph.
1	74 DRX	870.2360	II	Electrode, Electrocardiograph.
1	74 DSA	870.2900	II	Cable, Transducer and Electrode, Patient, (Including Connector).
1	74 DSB	870.2770	II	Plethysmography, Impedance.
1	74 DSH	870.2800	II	Recorder, Magnetic Tape, Medical.
1	74 DSI	870.1025	III	Detector and Alarm, Arrhythmia.
1	74 DSJ	870.1100	II	Alarm, Blood Pressure.
1	74 DSK	870.1110	II	Computer, Blood Pressure.