request should be submitted to the Dockets Management Branch (address above) and not to the address provided in § 860.123(b)(1). If a timely request for a change in the classification is submitted, FDA will, by August 21, 1995, and after consultation with the appropriate FDA advisory committee and by an order published in the **Federal Register**, either deny the request or initiate a change in the classification of the device in accordance with section 513(e) of the act and 21 CFR 860.130.

In accordance with section 515(c)(1)(D) of the act (21 U.S.C. 350e(c)(1)(D)) any class III device for which a PMA is filed would be required to include information showing that the device is in compliance with the standard.

D. The Proposed Effective Date

Section 861.36 (21 CFR 861.36) states that:

> A regulation establishing * * * a performance standard will set forth the date upon which it will take effect. To the extent practical, consistent with the public health and safety, such effective date will be established so as to minimize economic loss to, and disruption or dislocation of, domestic and international trade. (See also section 514(b)(3)(B) of the act.)

FDA has determined that the cost of converting or adapting unsafe electrode lead wire configurations in order to comply with the proposed standard is manageable because the standard will be phased in over a 1- or 3-year period. Furthermore, FDA believes that this cost is justifiable given the severity of the adverse events that have occurred and those that may reasonably be anticipated.

V. Banning Action

The SMDA amended section 516 of the act (21 U.S.C. 360f), which authorizes FDA to ban any device intended for human use if FDA finds, based on all available data and information, that such device presents a ''substantial deception'' or an ''unreasonable and substantial risk of illness or injury'' that FDA finds cannot be, or has not been, corrected or eliminated by labeling or a change in labeling.

The Report by the Committee on Interstate and Foreign Commerce on the amendments (House Report) stated that:

> By using the term substantial, the Committee intends that the Secretary make a determination that the deception or risk incurred through the continued marketing of such a device is important, material, or significant. In determining that the device is deceptive, it is not necessary that the Secretary find that there was intent to mislead users of the device. Nor is actual proof of deception of or injury to an individual required.

(H. Rept. 853, 94th Cong., 2d sess. 19 (1976).)

The legislative history of the amendments further stated that:

> A finding that a device presents the requisite degree of deception or risk is made 'on the basis of all available data and information', including information which the Secretary may obtain under other provisions of the proposed legislation, and information which may be supplied by the manufacturer in response to the proceeding relating to the safety, effectiveness, or labeling of the device.

(Id. at 19.)

Under the SMDA, FDA may initiate a proceeding to ban a device, based upon available data and information, without first consulting with a device panel. In addition, the SMDA no longer requires that the agency afford interested persons an opportunity for an informal hearing before proposing a regulation to ban a device. (See Section 18(d) of the SMDA; and also 21 CFR 895.20.) FDA believes, that the conference held on July 15, 1994, was an appropriate forum for interested parties to express their views on the agency's options for a proposed course of action. Further, the ANPRM solicited comments on alternative solutions to the removal of all unprotected electrode lead wires from the market, such as banning them under part 895 (21 CFR part 895). FDA considered the conference transcript, as well as the written comments submitted in response to the ANPRM, before determining that a banning action is warranted. For all these reasons, the agency has decided that an informal hearing is not necessary before proceeding with the proposal. Moreover, this document provides interested persons with an additional opportunity to provide comments on the agency's proposed actions.

FDA is aware that in response to the section 518(a) letters it issued last year, many firms conducted voluntary recalls of unprotected electrode lead wires to correct the labeling on these devices. However, FDA has determined that the continued marketing of unprotected electrode lead wires and patient cables, no matter how they are labeled, presents an unreasonable and substantial risk of illness or injury to individuals, and provides no benefit to the public health that is not provided by protected electrode lead wires and patient cables. Use of unprotected electrode lead wires has resulted in, and can be expected to continue to result in, serious adverse consequences or death because the devices are inherently dangerous when used in a reasonably foreseeable, albeit inappropriate, manner. There are no labeling requirements that can reliably prevent inappropriate connections of unprotected electrode lead wires and, thus, unprotected electrode lead wires cannot be safely marketed for the device's intended purposes. Accordingly, FDA has not proposed a change in device labeling. Indeed, labeling warnings are meaningless when unprotected electrode wires are available to preschool children or individuals with limitations such as vision problems, mental retardation, or other cognitive impairments. Further, labeling is often an inadequate solution in certain hospital settings where health care professionals find themselves in busy, stressful situations in which they may not be provided with, or could inadvertently overlook, instructions.

Therefore, FDA is proposing to ban unprotected electrode lead wires in order to prohibit their further introduction into commerce and to expedite the removal of these devices from commercial distribution and use, thereby preventing any further or unreasonable and substantial risk of illness or injury. Based on the public comments received to date, FDA believes that the proposed 1- or 3-year effective dates would provide a reasonable transition time with minimal economic disruption.

FDA notes that, even though current law requires that hospitals and other users of medical devices report problems such as serious injuries and deaths, that law did not become effective until late 1991. Therefore, there has probably been an underreporting of the deaths and serious injuries attributable to unprotected patient electrode lead wires and cables.

VI. Summary and Analysis of Comments and FDA'S Response

The agency received 19 written comments from manufacturers, distributors, user facilities, trade associations, and a consultant in response to the ANPRM. A summary of the written comments and oral testimony from the conference is provided below:

1. In general, several comments expressed their appreciation to FDA for allowing them to express their views to the agency on this important public health issue. A few comments noted that the July conference was an excellent forum for the exchange of ideas on a subject that is of concern to all manufacturers and users of medical instrumentation. One comment encouraged FDA to increase its use of