upon the information submitted in response to this order, FDA will either propose reclassification of some or all of these devices into class I or class II, or propose retaining some or all of them in class III.

In this document, FDA is requiring manufacturers of 27 devices in Group 3 to submit a summary of, and citation to, all safety and effectiveness information known or otherwise available to them respecting such devices, including adverse information concerning the devices which has not been submitted under section 519 of the act. As noted above, based on information known to date by the agency, FDA believes these devices are not likely candidate for reclassification.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a similar notice covering the 31 Group 2 devices.

II. Statutory Authority and Enforcement

In addition to the provisions of section 515(i) of the SMDA described above, this order is issued under section 519 of the act, as implemented by $\S~860.7(g)(2)$ (21 CFR 860.7(g)(2)). This regulation authorizes FDA to require reports or other information bearing on the classification of a device. Section 519 of the act also requires the reporting of any death or serious injury caused by a device or by its malfunction.

Failure to furnish the information required by this order results in the device being misbranded under section 502(t) of the act (21 U.S.C. 352(t)) and is a prohibited act under sections 301(a) and (q) of the act (21 U.S.C. 331(a) and (q)). The agency will use its enforcement powers to deter noncompliance. Violations of section 301 of the act may be subject to seizure or injunction under sections 304(a) and 302(a) of the act (21 U.S.C. 334(a) and 332(a) respectively). In addition, violations under section 301 of the act may be subject to civil penalties under section 303(f) of the act (21 U.S.C. 333(f)), and criminal prosecution under section 303(a) of the act (21 U.S.C. 333(a)).

III. Order

The agency is hereby issuing this order under sections 515(i) and 519 of the act and § 860.7(g)(1) of the regulations. Under the order, the required information shall be submitted by the dates listed below so that FDA may begin promptly the process established by section 515(i) of the act to either revise or sustain the current classification of these devices.

A. Deadlines for Submission of Information

For the following nine devices, the required information shall be submitted by August 14, 1996.

- 1. § 868.2450 Lung water monitor.
- 2. § 868.2500 Cutaneous oxygen monitor.
- 3. § 868.5610 Membrane lung for longterm pulmonary support.
- 4. § 870.1025 Arrhythmia detector and alarm.
- 5. § 870.3300 Arterial embolization device.
- 6. § 870.3375 Cardiovascular intravascular filter.
 - 7. § 874.3400 Tinnitus masker.
- 8. § 884.5940 Powered vaginal muscle stimulator for therapeutic use.
- 9. § 890.3890 Stair-climbing wheelchair.

For the following nine devices, the required information shall be submitted by February 14, 1997.

- 10. § 870.3610 Implantable pacemaker pulse generator.
- 11. § 870.3700 Pacemaker programmers.
 - 12. § 870.3800 Annuloplasty ring.
- 13. § 870.4230 Cardiopulmonary bypass defoamer.
- 14. § 870.5225 External counterpulsating device.
- 15. § 870.5550 External transcutaneous cardiac pacemaker (noninvasive).
- 16. § 874.3930 Tympanostomy tube with semipermeable membrane.
- 17. § 874.5350 Suction antichoke device.
- 18. § 886.3400 *Keratoprosthesis*. For the following nine devices, the required information shall be submitted by August 14, 1997.
- 19. § 870.3450 Vascular graft prosthesis of less than 6 millimeters diameter.
- 20. § 870.3535 Intra-aortic balloon and control system.
- 21. § 870.3600 External pacemaker pulse generator.
- 22. § A874.5370 Tongs antichoke device.
- 23. § 876.5870 Sorbent hemoperfusion system.
- 24. § 876.5955 Peritoneo-venous shunt.
- 25. § 882.1790 Ocular plethysmograph.
- 26. § 882.5860 Implanted neuromuscular stimulator.
- 27. § 882.5950 Artificial embolization device.

B. Required Contents of Submissions

By the dates listed above, all manufacturers currently marketing preamendments class III devices subject to this order shall provide a summary of, and citation to, any information known or otherwise available to them respecting the devices, including adverse safety and effectiveness data which has not been submitted under section 519 of the act. FDA suggests that it may be in the best interest of submitters to summarize the information submitted under section 519 of the act to facilitate FDA's decisionmaking, even though such information is not required.

The information should be submitted in one of the two following formats depending on whether the applicant is aware of any information which would support the reclassification of the device into class I (general controls) or class II (special controls). Information which would support the reclassification of the device must consist of adequate, valid scientific evidence showing that general controls alone (class I), or general controls and special controls (class II) will provide a reasonable assurance of the safety and effectiveness of the device.

For manufacturers who do *not* believe that existing information would support the reclassification of their device into class I or class II, the information provided should be submitted in the following format:

- 1. *Indications for use.* A general description of the disease or condition to be diagnosed, treated, cured, mitigated, or prevented, including a description of the patient population for which the device is intended.
- 2. Device description. An explanation of how the device functions, significant physical and performance characteristics of the device, and basic scientific concepts that form the basis for the device.
- 3. Other device labeling. Other device labeling that includes contraindications, warnings and precautions and/or promotional materials.
- 4. *Risks*. A summary of all adverse safety and effectiveness information and identification of the risks presented by the device as well as any mechanisms or procedures which will control the risk.
- 5. Alternative practices and procedures. A description of alternative practices or procedures for diagnosing, treating, preventing, curing, or mitigating the disease or condition for which the device is intended.
- 6. Summary of preclinical and clinical data. The summary of preclinical and clinical data should include the conclusions drawn from the studies which support the safety and effectiveness of the device as well as special controls, if any, which address