studies, the experimental design, how the data were collected and analyzed, and a brief description of the results of the studies, whether positive, negative, or inconclusive. The summary of the clinical study(ies) should also include a discussion of the subject inclusion and exclusion criteria, the study population, reasons for patient discontinuations, and results of statistical analyses.

7. *Bibliography*. A copy of the key references, a brief summary of the salient features of each key reference, and a brief discussion of why the reference is relevant to an evaluation of the safety and effectiveness evaluation of the device.

Manufacturers who are aware of information that would support the reclassification of their device into class I or class II may either submit information using the format described below or may submit a formal reclassification petition, which should include the information described below in addition to the information required under 21 CFR 860.123.

1. *Identification*. A brief narrative identification of the device. This identification should be specific enough to distinguish a particular device from a generic type of device. Where appropriate, this identification should include a listing of the materials, and the component parts, and a description of the intended use of the device.

2. *Risks to Health*. An identification of the risks to health should be provided. This section should summarize all adverse safety and effectiveness information, which have not been submitted under section 519 of the act, particularly the most significant. The mechanisms or procedures which will control the risk should be described. A list of the general hazards associated with the device and a bibliography with copies of the referenced material should be provided.

3. *Recommendation*. A statement whether the manufacturer believes the device should be reclassified into class I or class II.

4. *Summary of Reasons for Recommendation*. Each manufacturer should include a summary of the reasons for requesting reclassification of its device and an explanation of why it believes the device meets the statutory criteria for reclassification into class I or class II. Each manufacturer should also identify the special controls that it believes would be sufficient to provide reasonable assurance of the safety and effectiveness of its device if it believes the device should be reclassified into class II.

5. *Summary of Valid Scientific Evidence on Which the Recommendation Is Based*. Manufacturers are advised that, when considering a formal reclassification petition, FDA will rely only upon valid scientific evidence to determine that there is a reasonable assurance of the safety and effectiveness of the device, if regulated by general controls alone (class I) or by general controls and special controls (class II). Valid scientific evidence consists of evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use. The evidence required may vary according to the characteristics of the device, its conditions of use, the existence and adequacy of warnings and other restrictions, and the extent of experience with its use. Isolated case reports, random experience, reports lacking sufficient details to permit scientific evaluation, and unsubstantiated opinions are not regarded as valid scientific evidence to show safety or effectiveness (see § 860.7(c)(2)).

According to § 860.7(d)(1), there is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions for use. Moreover, under § 860.7(e)(1), there is reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.

Manufacturers submitting a formal reclassification petition may wish to request two petitions as examples of successful reclassification petitions. Magnetic Resonance Imaging devices, docket Nos. 87P–0214/CP–1 through CP–13, and Nd:YAG Laser for posterior capsulotomy devices, docket no. 86P–0083, were both reclassified from class III to class II subsequent to the submission of reclassification petitions. Both petitions are available upon submission of a Freedom of Information request to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20850.

IV. Submission of Required Information

The summary of, and citation to, any information required by the act must be submitted by the dates listed above to the Document Mail Center (address above).

Dated: May 30, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–15449 Filed 6–12–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 94N–0417]

Order for Certain Class III Devices; Submission of Safety and Effectiveness Information; Group 2

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is revising the schedule for submission of summaries and citations for 3 devices included in the order requiring manufacturers of 31 class III devices (Group 2) to submit to FDA a summary of, and a citation to, all information known or otherwise available to them respecting such devices, including adverse safety or effectiveness information concerning the devices that have not been submitted under the Federal Food, Drug, and Cosmetic Act (the act). In response to comments received on the August 14, 1995, order and in order to facilitate the review process, FDA is grouping three cardiovascular devices with related uses together and is changing the date by which summaries and citations are to be submitted for them to February 14, 1998. As a reminder to device manufacturers, FDA is also reprinting the due dates for all other devices listed in the August 14, 1995, order.

DATES: Summaries and citations must be submitted by the dates listed below.

ADDRESSES: Submit summaries and citations to the Document Mail Center (HFZ–401), Food and Drug Administration, Center for Devices and Radiological Health, 9200 Corporate Blvd., Rockville, MD 20850.

FOR FURTHER INFORMATION CONTACT: Doreen M. Melling, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION:

I. Background

Section 513 of the act (21 U.S.C. 360c) requires the classification of medical devices into one of three classes: Class I (general controls), class II (special controls), and class III (premarket approval). Generally, devices that were on the market before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments) (Pub. L. 94–295), and devices marketed on or after that date that are substantially equivalent to such devices, have been classified by FDA. This notice refers to both the class III devices that were on the market before May 28, 1976, and the substantially equivalent devices that were marketed on or after that date, as ''preamendment devices''.

Section 515(b) of the act (21 U.S.C. 360e(b)) establishes the requirement that a preamendments device that FDA has classified into class III is subject to premarket approval. However the submission of a premarket approval application (PMA), or a notice of completion of a product development protocol (PDP), is not required until 90 days after FDA issues a final rule requiring premarket approval for the device, or 30 months after final classification of the device, whichever is later. Also, such a device is exempt from the investigational device exemption (IDE) regulations (21 CFR part 812) until the date stipulated by FDA in the final rule requiring premarket approval for that device. If a PMA or a notice of completion of a PDP is not filed by the later of the two dates, commercial distribution of the device is required to cease. The device may, however, be distributed only for investigational use if the manufacturer, importer, or other sponsor of the device complies with the IDE regulations.

To date, FDA has issued final rules requiring the submission of PMA's for 52 preamendment class III devices. Additionally, FDA has issued proposed rules for 12 other devices. There are 68 remaining preamendment class III devices for which FDA has not yet initiated any action requiring the submission of PMA's. The original number of approximately 140 preamendments class III devices can be accounted for by past reclassification actions.

The Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101–629) changed the definition of class II devices from those for which a performance standard is necessary to provide reasonable assurance of safety and effectiveness to those for which there is sufficient information to establish special controls to provide such assurance. Special controls include performance standards, postmarket surveillance, patient registries, guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 510(k) of the act (21 U.S.C. 360(k)), recommendations, and other appropriate actions the agency deems necessary to provide such assurance. Thus, the SMDA modified the definition of class II devices to permit reliance on special controls, rather than performance standards alone, to provide reasonable assurance of safety and effectiveness.

The SMDA also added new section 515(i) to the act. This section requires FDA to order manufacturers of preamendment class III devices for which no final regulation requiring the submission of PMA's has been issued to submit to the agency a summary of, and a citation to, any information known or otherwise available to them respecting such devices, including adverse safety and effectiveness information which has not been submitted under section 519 of the act (21 U.S.C. 360i). Section 519 of the act requires manufacturers, importers, or distributors to maintain records and to report information that reasonably suggests that one of its marketed devices may have caused or contributed to a death or serious injury or that a malfunction of the device is likely to cause death or serious injury on recurrence. Section 515(i) of the act also directs FDA to publish a regulation before December 1, 1995, for each device subject to section 515(i), either revising the classification of the device into class I or class II or requiring the device to remain in class III. Finally, section 515(i) of the act requires that, within 12 months after publication of a regulation retaining a device in class III, FDA is to establish a schedule for the promulgation of a rule requiring the submission of PMA's for the device.

In the **Federal Register** of May 6, 1994 (59 FR 23731), FDA announced its strategy for addressing the 116 remaining preamendment class III devices. In this notice, FDA made available a document setting forth its strategy for implementing the provisions of the SMDA that require FDA to review the classification of certain class III devices, and either reclassify the devices into class I or class II or retain them in class III. Under this plan, the agency divided the universe of preamendment class III devices into three groups: Group 1 devices are devices that FDA believes raise significant questions of safety and/or effectiveness, but are no longer used or are very limited in use; Group 2 devices are devices that FDA believes have a high potential for being reclassified into class II; and Group 3 devices are devices that FDA believes are currently in commercial distribution and are not likely candidates for reclassification. There are a total of 43, 31, and 42 (15 high priority) devices in Groups 1, 2, and 3, respectively.

In the May 6, 1994, notice, FDA announced its intention to call for the submission of PMA's for the 15 highest priority devices in Group 3, and for all Group 1 devices. In the **Federal Register** of September 27, 1996 (61 FR 50704), was published a final rule requiring the filing of a PMA or a notice of completion of a PDP for 41 class III devices (Group 1 device). In the **Federal Register** of May 6, 1994, notice, the agency also announced its intention to issue an order under section 515(i) of the act for the remaining Group 3 devices and all of the Group 2 devices.

In the **Federal Register** of August 14, 1995 (60 FR 41986), FDA issued an order requiring manufacturers of the 31 devices in Group 2 to submit a summary of, and citation to, all safety and effectiveness information known or otherwise available to them respecting such devices, including adverse safety and effectiveness information concerning the devices which had not been submitted under section 519 of the act. Under section 515(i) of the act, FDA is authorized to require the submission of the adverse safety and effectiveness information identified in the summary and citation submitted in response to this order, if such information is available. In this notice, FDA is grouping three devices with related uses together and is revising the date by which summaries and citations are to be submitted. The summaries for the cardiopulmonary bypass arterial line blood filter (originally due by August 14, 1997), the cardiopulmonary bypass pulsatile flow generator (originally due by August 14, 1998), and the cardiopulmonary bypass oxygenator (originally due by August 14, 1997) are now due by February 14, 1998. Based upon the information submitted in

response to this order, FDA will issue a proposed regulation for each device either proposing its reclassification into class I or class II, or retaining the device in class III. The due dates for summaries and citations for the other Group 2 devices remain the same and are listed below.

II. Statutory Authority and Enforcement

In addition to the provisions of section 515(i) of the SMDA described in section I of this document, this order is issued under section 519 of the act, as implemented by § 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 comply with this order is a prohibited act under section 301(q) of the act (21 U.S.C. 331(q)), and the agency will use its enforcement powers to deter noncompliance. Violations under section 301 of the act may be subject to seizure or injunction under sections 302(a) and 304(a) of the act (21 U.S.C. 332(a) and 334(a)). 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.

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. The three devices listed with a February 14, 1998, due date are the devices whose due date is being revised. The remaining due dates are reprinted here from the August 14, 1995, order as a reminder to device manufacturers.

A. Deadlines for Submission of Information

For the following eight devices, the required information was to be submitted by August 14, 1996:

1. § 864.7250 *Erythropoietin assay.*
2. § 864.7300 *Fibrin monomer paracoagulation test.*
3. § 876.3630 *Penile rigidity implant.*
4. § 878.5360 *Tweezer-type epilator.*
5. § 884.1060 *Endometrial aspirator.*
6. § 884.1100 *Endometrial brush.*
7. § 884.1185 *Endometrial washer.*
8. § 886.3920 *Eye valve implants.*

For the following nine devices, the required information was to be submitted by February 14, 1997:

9. § 866.3305 *Herpes simplex virus serological reagents.*
10. § 866.3510 *Rubella virus serological reagents.*
11. § 870.3620 *Pacemaker lead adaptor.*
12. § 872.6080 *Airbrush.*
13. § 876.4480 *Electrohydraulic lithotriptor.*
14. § 878.3610 *Esophageal prosthesis.*
15. § 878.3720 *Tracheal prosthesis.*
16. § 884.4100 *Endoscopic electrocautery and accessories.*
17. § 884.4150 *Bipolar endoscopic coagulator-cutter and accessories.*

For the following eight devices, the required information shall be submitted by August 14, 1997:

18. § 868.1150 *Indwelling blood carbon dioxide partial pressure analyzer.*
19. § 868.1170 *Indwelling blood hydrogen ion concentration.* analyzer.
20. § 868.1200 *Indwelling blood oxygen partial pressure analyzer.*
21. § 870.3680 *Cardiovascular permanent pacemaker electrodes.*
22. § 876.5860 *High permeability hemodialysis system.*
23. § 878.5650 *Topical 02 chamber.*
24. § 882.5940 *Electroconvulsive therapy device.*
25. § 888.3660 *Shoulder semi-constrained.*

For the following three devices, the required information shall be submitted by February 14, 1998:

26. § 870.4260 *Cardiopulmonary bypass arterial line blood filter.* (Originally due August 14, 1997.)[1]
27. § 870.4320 *Cardiopulmonary bypass pulsatile flow generator.* (Originally due on August 14, 1998.)[1]
28. § 870.4350 *Cardiopulmonary bypass oxygenator.* (Originally due on August 14, 1997.)[1]

For the following three devices, the required information shall be submitted by August 14, 1998:

29. § 870.3710 *Pacemaker repair or replacement material.*
30. § 870.5200 *External cardiac compressor.*
31. § 876.5540 *Implanted blood access device.*

B. Required Contents of Submissions

By the dates listed in section III. A of this document, all manufactures 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 that would support the reclassification of the device into class I (general controls) or class II (special controls). Information that 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 are not aware of any information that 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 the adverse effects of the device on health. The summary should include a

[1] Revised due date.

brief description of the objective of the studies, the experimental design, how the data were collected and analyzed, and a brief description of the results of the studies, whether positive, negative, or inconclusive. The summary of the clinical study(ies) should also include a discussion of the subject inclusion and exclusion criteria, the study population, reasons for patient discontinuations, and results of statistical analyses.

7. *Bibliography*. A copy of the key references, a brief summary of the salient features of each key reference, and a brief discussion of why the reference is relevant to an evaluation of the safety and effectiveness evaluation of the device.

Manufacturers who are aware of information that would support the reclassification of their device into class I or class II may either submit information using the format described below or may submit a formal reclassification petition, which should include the information described below in addition to the information required under 21 CFR 860.123:

1. *Identification*. A brief narrative identification of the device. This identification should be specific enough to distinguish a particular device from a generic type of device. Where appropriate, this identification should include a listing of the materials, and the component parts, and a description of the intended use of the device.

2. *Risks to health*. An identification of the risks to health should be provided. This section should summarize all adverse safety and effectiveness information that has not been submitted under section 519 of the act, particularly the most significant. The mechanisms or procedures which will control the risk should be described. A list of the general hazards associated with the device and a bibliography with copies of the referenced material should be provided.

3. *Recommendation*. A statement whether the manufacturer believes the device should be reclassified into class I or class II.

4. *Summary of reasons for recommendation*. Each manufacturer should include a summary of the reasons for requesting reclassification of its device and an explanation of why it believes the device meets the statutory criteria for reclassification into class I or class II. Each manufacturer should also identify the special controls that it believes would be sufficient to provide reasonable assurance of the safety and effectiveness of its device if it believes the device should be reclassified into class II.

5. *Summary of valid scientific evidence on which the recommendation is based*. Manufacturers are advised that, when considering a formal reclassification petition, FDA will rely only upon valid scientific evidence to determine that there is reasonable assurance of the safety and effectiveness of the device, if regulated by general controls alone (class I) or by general controls and special controls (class II). Valid scientific evidence consists of evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use. The evidence required may vary according to the characteristics of the device, its conditions of use, the existence and adequacy of warnings and other restrictions, and the extent of experience with its use. Isolated case reports, random experience, reports lacking sufficient details to permit scientific evaluation, and unsubstantiated opinions are not regarded as valid scientific evidence to show safety or effectiveness (see § 860.7(c)(2)).

According to § 860.7(d)(1), there is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions for use. Moreover, under § 860.7(e)(1), there is reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.

Manufacturers submitting a formal reclassification petition may wish to request two petitions as examples of successful reclassification petitions. Magnetic resonance imaging devices, Docket Nos. 87P–0214/CP–1 through CP–13, and Nd:YAG Laser for posterior capsulotomy devices, Docket No. 86P–0083, were both reclassified from class III to class II subsequent to the submission of reclassification petitions. Both petitions are available upon submission of a Freedom of Information request to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20850.

IV. Submission of Required Information

The summary of, and citation to, any information required by the act must be submitted by the dates listed above to the Document Mail Center (address above).

Dated: June 4, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–15450 Filed 6–12–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–255]

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collection for public comment. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Municipal Health Services Cost Report Form, and supporting regulations 42 CFR 405.427; *Form No.:* HCFA–255; *Use:* The Municipal Health Services Program (MHSP) Cost Report (HCFA–255) is