

## ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF-196TR .....	3	4	8	96

*Estimated Total Annual Burden Hours: 96.*

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the

proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: April 06, 2009.

**Janean Chambers,**

*Reports Clearance Officer.*

[FR Doc. E9-8058 Filed 4-8-09; 8:45 am]

**BILLING CODE 4184-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Submission for OMB Review; Comment Request

*Title:* Financial Status Reporting Form for State Councils on Developmental Disabilities Program.

OMB No.: 0980-0212.

*Description:* For the program of the State Councils on Developmental Disabilities, funds are awarded to State agencies contingent on fiscal requirements in subtitle B of the Developmental Disabilities Assistance and Bill of Rights Act. The SF-269, ordinarily mandated in the revised OMB Circular A-102, provides no accounting breakouts necessary for proper stewardship. Consequently, the proposed streamlined form will substitute for the SF-269 and will allow compliance monitoring and proactive compliance maintenance and technical assistance.

*Respondents:* State Councils and Designated State Agencies.

## ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Financial Status Reporting Form for State Councils on Developmental Disabilities Program .....	55	3	5.10	841.50

*Estimated Total Annual Burden Hours: 841.50.*

*Additional Information:* Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

*OMB Comment:* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it

within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202-395-6974, Attn: Desk Officer for the Administration for Children and Families.

Dated: April 6, 2009.

**Janean Chambers,**

*Reports Clearance Officer.*

[FR Doc. E9-8123 Filed 4-8-09; 8:45 am]

**BILLING CODE 4184-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-M-0101]

#### Medical Devices; Order for Certain Class III Devices; Submission of Safety and Effectiveness Information

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing an order requiring manufacturers of remaining preamendments class III devices for which regulations requiring submission of premarket approval applications (PMAs) have not been issued to submit to FDA a summary of,

and a citation to, any information known or otherwise available to them respecting such devices, including adverse safety or effectiveness information concerning the devices which has not been submitted under the Federal Food, Drug, and Cosmetic Act (the act). FDA is requiring the submission of this information in order to determine, for each device, whether the classification of the device should be revised to require the submission of a PMA or a notice of completion of a Product Development Protocol (PDP), or whether the device should be reclassified into class I or II.

**DATES:** Summaries and citations must be submitted by August 7, 2009.

**ADDRESSES:** Submit paper copies of summaries and citations to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic copies of summaries and citations to <http://www.regulations.gov>. Identify summaries and citations with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Sarah K. Morabito, Center for Devices and Radiological Health (HFZ-402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-3975.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background—Regulatory Authorities**

The act (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94-295), the Safe Medical Devices Act (SMDA) (Public Law 101-629), the Food and Drug Administration Modernization Act of 1997 (Public Law 105-115), the Medical Device User Fee and Modernization Act of 2002 (Public Law 107-250), the Medical Devices Technical Corrections Act (Public Law 108-214), and the Food and Drug Administration Amendments Act of 2007 (Public Law 110-85), establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) requires the classification of medical devices into one of three regulatory classes: Class I (general controls), class II (special controls), or class III (premarket approval). Generally, devices that were on the market before May 28, 1976, the date of enactment of the 1976 amendments, and devices marketed on or after that date that are substantially equivalent to such devices, have been classified by FDA. This order refers to both the class III

devices that were on the market before May 28, 1976, and the devices found to be substantially equivalent to them that were marketed on or after that date, as “preamendments devices.”

Section 515(b)(1) of the act (21 U.S.C. 360e(b)(1)) establishes the requirement that a preamendments device that FDA has classified into class III is subject to premarket approval. However, submission of a PMA (or a notice of completion of a PDP) is not required until 90 days after FDA promulgates a final rule requiring premarket approval for the device, or 30 months after final classification of the device, whichever is later. See section 501(f)(2)(B) of the act (21 U.S.C. 351(f)(2)(B)). The device may, however, be distributed only for investigational use if the manufacturer, importer, or other sponsor of the device complies with the investigational device exemption (IDE) requirements.

The SMDA 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 section 515(i) (21 U.S.C. 360e(i)) to the act. This section requires FDA to order manufacturers of preamendments class III devices for which no final regulation has been issued requiring the submission of PMAs 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 that has not been submitted under section 519 of the act (21 U.S.C. 360i). Section 519 of the act requires manufacturers, importers, and 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 either revise the classification of the device into class I or class II or require the device to remain in class III; and for devices remaining in class III, to establish a schedule for the promulgation of a rule requiring the submission of PMAs for the device.

In the **Federal Register** of May 6, 1994 (59 FR 23731), FDA announced the availability of a notice setting forth its strategy for addressing the remaining class III preamendments devices. Of the approximately 149 preamendments devices FDA initially classified or proposed to classify into class III (48 FR 40272, September 6, 1983), FDA has either reclassified into class I or II, or issued regulations requiring the submission of PMAs for, all but 27 devices. Of the 27 devices, 25 are the subject of this notice. The two remaining devices, Herpes simplex virus serological assays (21 CFR 866.3305) and Topical oxygen chamber for extremities (21 CFR 878.5650), will be addressed in separate orders.

##### **II. Statutory Authority and Enforcement**

In addition to the provisions of section 515(i) of the act 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)). Section 860.7(g)(2) 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 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 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 (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 must be submitted by the date set forth in this document (see **DATES**) so that FDA may begin the process established by section 515(i) of

the act to either reclassify these devices into class I or II or initiate rulemaking to require submission of PMAs or PDPs for them. FDA does not anticipate extending the time for submitting the required information.

For the following 25 devices, the required information must be submitted by August 7, 2009.

1. 21 CFR 868.5610 Membrane lung for long-term pulmonary support.
2. 21 CFR 870.3535 Intra-aortic balloon and control system.
3. 21 CFR 870.3545 Ventricular bypass (assist) device.
4. 21 CFR 870.3600 External pacemaker pulse generator.
5. 21 CFR 870.3610 Implantable pacemaker pulse generator.
6. 21 CFR 870.3680(b) Cardiovascular permanent pacemaker electrode.
7. 21 CFR 870.3700 Pacemaker programmers.
8. 21 CFR 870.3710 Pacemaker repair or replacement material.
9. 21 CFR 870.4360 Nonroller-type cardiopulmonary bypass blood pump.
10. 21 CFR 870.5200 External cardiac compressor.
11. 21 CFR 870.5225 External counter-pulsating device.
12. 21 CFR 870.5310 Automated external defibrillator.
13. 21 CFR 872.3640(b)(2) Endosseous dental implant (blade form).
14. 21 CFR 872.3960 Mandibular condyle prosthesis (temporary implant).
15. 21 CFR 876.5540(b)(1) Implanted blood access device.
16. 21 CFR 876.5870 Sorbent hemoperfusion system.
17. 21 CFR 882.5800 Cranial electrotherapy stimulator.
18. 21 CFR 882.5940 Electroconvulsive therapy device.
19. 21 CFR 884.5330 Female condom.
20. 21 CFR 888.3070(b)(2) Pedicle screw spinal system (certain uses).
21. 21 CFR 888.3320 Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis.
22. 21 CFR 888.3330 Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis.
23. 21 CFR 890.5290(b) Shortwave diathermy (certain uses).
24. 21 CFR 890.5525(b) Iontophoresis device (certain uses).
25. 892.1990 Transilluminator for breast evaluation.

#### *Required Contents of Submissions*

By the date listed in the **DATES** section of this document, all manufacturers currently marketing the 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 that 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.

The information should be submitted in one of the two following formats depending on whether the manufacturer is aware of 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, or general controls along with special controls, will provide a reasonable assurance of the safety and effectiveness of the device.

If a manufacturer is not aware of information that would support the reclassification of its device into class I or class II, the information 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 that support the safety and effectiveness of the device, and that address the adverse effects of the device on health. The summary should include a 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 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 each key reference, 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 of the device.

Any manufacturer who is aware of information that would support the reclassification of its device into class I or class II may either submit information using the format described below or may submit a formal reclassification petition, which as described in 21 CFR 860.123(a)(3) and (a)(4), should include:

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. 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 information. The mechanisms or procedures that 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 whether 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.

#### IV. Submission of Required Information

The summary of, and citation to, any information required by the act must be submitted by the dates listed in the **DATES** section of this document to the Division of Dockets Management (see **ADDRESSES**).

#### V. Paperwork Reduction Act of 1995

This order refers to collections of information necessary to comply with the requirements found in sections 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807, subpart E or the requirements of 515(b) of the act (21 U.S.C. 360e(b)), 21 CFR part 860, and 21 CFR part 814. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 860.123 have been approved under OMB control number 0910–0138; the collections of information in 21 CFR part 814, have been approved under OMB control number 0910–0231; and the collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120.

Dated: April 2, 2009.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E9–8022 Filed 4–8–09; 8:45 am]

**BILLING CODE 4160–01–S**

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. FDA–2009–N–0664]

##### The 12th Annual Food and Drug Administration-Orange County Regulatory Affairs Educational Conference; “Regulatory Affairs: The Challenges of Ensuring Product Safety”

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following conference: 12th Annual Educational Conference co-sponsored with the Orange County Regulatory Affairs Discussion Group (OCRA). The conference is intended to provide the Drug, Device, and Biologics industries with an opportunity to interact with FDA reviewers and compliance officers from the Centers and District Offices, as well as other industry experts. The main focus of this interactive conference will be product approval, compliance, and risk management in the three medical product areas. Industry speakers, interactive questions and answers, and workshop sessions will also be included to assure open exchange and dialogue on the relevant regulatory issues.

**Date and Time:** The conference will be held on June 9 and 10, 2009, from 7:30 a.m. to 5 p.m.

**Location:** The conference will be held at the Irvine Marriott Hotel, 18000 Von Karman Ave., Irvine, CA 92612.

**Contact:** Linda Hartley, Food and Drug Administration, 19701 Fairchild, Irvine, CA 92612, 949–608–4413, FAX: 949–608–4417, or OCRA, Attention to Detail, 5319 University Dr., suite 641, Irvine, CA 92612, 949–387–9046, FAX: 949–387–9047, Web site: <http://www.ocra-dg.org>.

**Registration and Meeting Information:** See OCRA Web site, <http://www.ocra-dg.org>. Contact Attention to Detail at 949–387–9046.

Before May 8, 2009, registration fees are as follows: \$675.00 for members, \$725.00 for nonmembers and \$475.00 for FDA/Govt/Students.<sup>1</sup> After May 8, 2009, \$725.00 for members, \$775.00 for nonmembers, and \$475.00 for FDA/Govt/Students.<sup>1</sup>

The registration fee will cover actual expenses including refreshments, lunch, materials, parking, and speaker expenses.

If you need special accommodations due to a disability, please contact Linda Hartley at least 10 days in advance.

Dated: April 6, 2009.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E9–8135 Filed 4–8–09; 8:45 am]

**BILLING CODE 4160–01–S**

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Health Resources and Services Administration

##### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, e-mail [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management

<sup>1</sup> OCRA Student Rate applies to those individuals enrolled in a Regulatory or Quality related academic program at an accredited institution. Proof of enrollment required.