TABLE 5—ESTIMATED ANNUAL REPORTING BURDEN [1]

Form FDA No.	Number of respondents	Number of responses per respondent	Total annual respondents	Average burden per response (in Hours) [2]	Total hours
3519	500	1	500	1/60	50
3520	500	1	500	1/60	50
CFP Training Plan and Log	500	3	1,500	1/60	150
Total					250

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format "[number of minutes per response]/60".

FDA bases its estimates of the number of respondents and the hours per response on its experience with the Program Standards over the past 3 years. As explained previously in this document, FDA estimates that 500 regulatory jurisdictions will enroll in the Program Standards. FDA estimates a total of 12 minutes annually for each enrolled jurisdiction to complete both forms. FDA bases its estimate on the small number of data elements on the two forms and the ease of availability of the information. FDA estimates that, annually, 500 regulatory jurisdictions will submit one Form FDA 3519 for a total of 500 annual responses. Each submission is estimated to take 0.1 hour per response for a total of 50 hours. FDA estimates that, annually, 500 regulatory jurisdictions will submit one Form FDA 3520 for a total of 500 annual responses. Each of these submissions is estimated to take 0.1 hour per response for a total of 50 hours. FDA estimates that, annually, 500 regulatory jurisdictions will submit three requests for documentation of successful completion of staff training using the *CFP Training Plan and Log* for a total of 1,500 annual responses. Each submission is estimated to take 0.1 hour per response for a total of 150 hours. Thus, the total reporting burden for this information collection is 250 hours.

Dated: *March 23, 2011.*

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2011–7191 Filed 3–25–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0148]

Clarifying Edits to Existing Special Controls Guidance Documents; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of updated special controls guidance documents for class II devices, which contain edits that reflect the Agency's effort to clarify questions and confusion regarding its position on the binding nature of special controls guidance documents. The revised language does not change the Agency's position or view, but rather is intended to clarify its position and remedy any possible confusion or misunderstanding.

DATES: Submit either electronic or written comments on this document at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for electronic access to affected documents.

Submit electronic comments on this document to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Philip Desjardins, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5452, Silver Spring, MD 20993–0002, 301–796–5678; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

In December 2008, FDA revised the cover sheet and standard language in newly issued special controls guidance documents to clarify the effect of a guidance that has been established as a special control ("special controls guidance"). In order to comply with the special controls guidance, manufacturers must address each identified risk to health presented in the guidance for the class II device by either meeting the recommendations of the guidance or by some other means that provides equivalent assurances of safety and effectiveness.

FDA is now updating all pre-December 2008 special controls guidance documents with the revised standard language. Revisions to the special controls guidance documents include clarifying the statement of the special controls guidance document's effect by replacing the standard language with the following statement: "The firm must show that its device addresses the issues of safety and effectiveness identified in this guidance, either by meeting the recommendations of this guidance or by some other means that provides equivalent assurances of safety and effectiveness."

Special controls guidance documents on the following topics have been affected: [1]

1. Acute Upper Airway Obstruction Devices,
2. Clitoral Engorgement Devices,
3. Anti-*Saccharomyces cerevisiae* (*S. cerevisiae*) Antibody (ASCA) Premarket Notifications,
4. Shoulder Joint Metal/Polymer/Metal Nonconstrained or Semi-Constrained Porous-Coated Uncemented Prosthesis,
5. B-Type Natriuretic Peptide Premarket Notifications,
6. Home Uterine Activity Monitors,
7. Pharmacy Compounding Systems,
8. Tissue Culture Media for Human ex vivo Tissue and Cell Culture Processing Applications,
9. Indwelling Blood Gas Analyzers,
10. Ingestible Telemetric Gastrointestinal Capsule Imaging System,
11. Premarket Notifications for Automated Differential Cell Counter for Immature or Abnormal Blood Cells,
12. Medical Washers and Medical Washer-Disinfectors,

[1] All guidance titles throughout this document reflect the style of the published versions.

13. Endolymphatic Shunt Tube with Valve,
14. Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis,
15. Apnea Monitors,
16. Polymethylmethacrylate (PMMA) Bone Cement,
17. Cyclosporine and Tacrolimus Assays,
18. Transcutaneous Air Conduction Hearing Aid System (TACHAS),
19. Intraoral Devices for Snoring and/or Obstructive Sleep Apnea,
20. Cutaneous Carbon Dioxide and Oxygen Monitors,
21. Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses,
22. Optical Impression Systems for Computer Assisted Design and Manufacturing (CAD/CAM) of Dental Restorations,
23. Resorbable Calcium Salt Bone Void Filler Device,
24. Surgical Sutures,
25. Breath Nitric Oxide Test,
26. Breast Lesion Documentation System,
27. Arrhythmia Detector and Alarm,
28. Serological Reagents for the Laboratory Diagnosis of West Nile Virus,
29. Endotoxin Assay,
30. Dental Sonography and Jaw Tracking Devices,
31. Human Dura Mater (applicable to dura mater recovered before May 25, 2005),
32. Hepatitis A Virus Serological Assays,
33. Factor V Leiden DNA Mutation Detection Systems,
34. Immunomagnetic Circulating Cancer Cell Selection and Enumeration System,
35. Root-form Dental Implants and Endosseous Dental Implant Abutments,
36. Dental Base Metal Alloys,
37. Dental Noble Metal Alloys,
38. Serological Assays for the Detection of Beta-Glucan,
39. Sirolimus Test Systems,
40. Newborn Screening Test Systems for Amino Acids, Free Carnitine, and Acylcarnitines Using Tandem Mass Spectrometry,
41. Implantable Radiofrequency Transponder System for Patient Identification and Health Information,
42. External Penile Rigidity Devices,
43. Assisted Reproduction Laser Systems,
44. Vascular and Neurovascular Embolization Devices,
45. Drug Metabolizing Enzyme Genotyping System,
46. Instrumentation for Clinical Multiplex Test Systems,
47. Automated Fluorescence in situ Hybridization (FISH) Enumeration Systems,
48. Dental Bone Grafting Material Devices,
49. RNA Preanalytical Systems (RNA Collection, Stabilization and Purification Systems for RT–PCR used in Molecular Diagnostic Testing),
50. Oral Rinse to Reduce the Adhesion of Dental Plaque,
51. AFP–L3% Immunological Test Systems,
52. CFTR Gene Mutation Detection System,
53. Low Energy Ultrasound Wound Cleaner,
54. Tinnitus Masker Devices,
55. Labeling for Male Condoms Made of Natural Rubber Latex,
56. Implantable Intra-Aneurysm Pressure Measurement System,
57. Reagents for Detection of Specific Novel Influenza A Viruses,
58. Topical Oxygen Chamber for Extremities,
59. Olfactory Test Device,
60. Fecal Calprotectin Immunological Test Systems,
61. Absorbable Hemostatic Device,
62. Quality Control Material for Cystic Fibrosis Nucleic Acid Assays,
63. Oxygen Pressure Regulators and Oxygen Conserving Devices,
64. Herpes Simplex Virus Types 1 and 2 Serological Assays,
65. Computerized Labor Monitoring Systems,
66. Gene Expression Profiling Test System for Breast Cancer Prognosis,
67. Intervertebral Body Fusion Device,
68. Filtering Facepiece Respirator for Use by the General Public in Public Health Medical Emergencies,
69. Absorbable Poly(hydroxybutyrate) Surgical Suture Produced by Recombinant DNA Technology,
70. In Vitro Human Immunodeficiency Virus (HIV) Drug Resistance Genotype Assay,
71. Electrocardiograph Electrodes,
72. Remote Medication Management System,
73. Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle,
74. Plasmodium Species Antigen Detection Assays,
75. Full Field Digital Mammography System,
76. Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters,
77. Tissue Adhesive for the Topical Approximation of Skin,
78. Bone Sonometers,
79. Tissue Expander,
80. Cord Blood Processing System and Storage Container.

II. Electronic Access

Persons interested in obtaining a copy of any revised special controls guidance document may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. To receive any affected CDRH guidance you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy.

For CBER guidances, you may send a request to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. In addition, CBER guidance documents are available at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm*.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Authority: 21 U.S.C. 371(h).

Dated: March 23, 2011.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2011–7211 Filed 3–25–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2010–M–0519, FDA–2010–M–0556, FDA–2010–M–0558, FDA–2010–M–0557, and FDA–2010–M–0591]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications