

## ANNUAL BURDEN ESTIMATES

| Instrument                      | Number of respondents | Number of responses per respondent | Average burden hours per response (minutes) | Total burden hours |
|---------------------------------|-----------------------|------------------------------------|---|--------------------|
| 2009 .....<br>Follow-up Survey. | 464                   | 1                                  | 45  | 348                |
| 2010 Follow-up Survey .....     | 143                   | 1                                  | 45  | 107.25             |

*Estimated Total Annual Burden Hours: 455.25*

In compliance with the requirements of Section 3506(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 Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: [OPREinfocollection@acf.hhs.gov](mailto:OPREinfocollection@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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: September 4, 2008.

Brendan C. Kelly,

*OPRE Reports Clearance Officer.*

[FR Doc. E8-21007 Filed 9-10-08; 8:45 am]

BILLING CODE 4184-01-M

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2008-N-0132]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; State Petitions for Exemption from Preemption**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "State Petitions for Exemption from Preemption" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3794.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of June 16, 2008 (73 FR 34024), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0277. The approval expires on August 31, 2011. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: September 4, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E8-21020 Filed 9-9-08; 8:45 am]

BILLING CODE 4160-01-S

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2006-N-0178] (formerly Docket No. 2006N-0362)

**Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Absorbable Hemostatic Device; Availability; Reopening of Comment Period**

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

**ACTION:** Notice; reopening of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is reopening until October 14, 2008, the comment period for a draft guidance entitled "Class II Special Controls Guidance Document: Absorbable Hemostatic Device." The draft guidance describes a means by which the absorbable hemostatic device may comply with the requirements of special controls if it is reclassified. FDA is reopening the comment period to update comments and to receive any new information. Elsewhere in this issue of the **Federal Register**, FDA is reopening the comment period on a proposed rule to reclassify the absorbable hemostatic device from class III (premarket approval) into class II (special controls).

**DATES** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance October 14, 2008.

**ADDRESS:** Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:**

David Krause, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-3638.

**SUPPLEMENTARY INFORMATION:****I. Background**

In the **Federal Register** of October 31, 2006 (71 FR 63728), FDA published a proposed rule to reclassify the absorbable hemostatic device intended to produce hemostasis from class III (premarket) into class II (special controls). In the same issue of the **Federal Register** (71 FR 63774), FDA published a notice of availability of a draft guidance document entitled "Class II Special Controls Guidance Document: Absorbable Hemostatic Device." FDA invited interested persons to comment on the draft guidance document by January 29, 2007. In the **Federal Register** of May 8, 2007 (72 FR 26134), FDA published a notice reopening the comment period for 30 days.

On July 2, 2007, FDA received a petition under 21 CFR 10.30 and 10.35 requesting that the agency refrain from issuing a final regulation for the proposed reclassification and the draft special controls guidance for the absorbable hemostatic device until an updated and complete administrative record is made available to the public. The petitioner also requested that FDA reopen the rulemaking for the proposed reclassification to allow submission of comments based on the administrative record. Elsewhere in this issue of the **Federal Register**, FDA is reopening the comment period on the proposed rule for 30 days. Because the issues presented by the guidance document are intertwined with those presented by the proposed rule, FDA is reopening the comment period on the guidance document for the same period.

**II. Electronic Access**

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive the draft guidance document entitled "Class II Specials Controls Document: Absorbable Hemostatic Device," you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document, or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number 1558 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated

on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer" assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available at <http://www.regulations.gov>.

**III. Request for Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments submissions will be accepted by FDA through FDMS only.

Dated: September 4, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E8-21197 Filed 9-10-08; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2008-N-0475]

**Request for Notification From Industry Organizations Interested in Participating in Selection Process for Nonvoting Industry Representatives on Public Advisory Panels or Committees and Request for Nonvoting Industry Representatives on Public Advisory Panels or Committees**

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

**ACTION: Notice.**

**SUMMARY:** The Food and Drug Administration (FDA) is requesting that any industry organization interested in participating in the selection of nonvoting industry representatives to serve on the Devices Good Manufacturing Practice Advisory Committee (DGMPAC) and certain device panels of the Medical Devices Advisory Committee in the Center for Devices and Radiological Health notify FDA in writing. A nominee may either be self nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current vacancies effective with this notice.

**DATES:** Any industry organizations interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to FDA by October 14, 2008, for the vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA by October 14, 2008.

**ADDRESSES:** All letters of interest and nominations should be sent to Kathleen L. Walker (see **FOR FURTHER INFORMATION CONTACT**).

**FOR FURTHER INFORMATION CONTACT:**

Kathleen L. Walker, Center for Devices and Radiological Health (HFZ-17), Food and Drug Administration, 7520 Standish Pl. (MPN1), Rockville, MD 20855, 240-276-8938, e-mail: *kathleen.walker@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** The agency intends to add nonvoting industry representatives to the following advisory committees:

**I. CDRH—Various Committees and Panels****A. Devices Good Manufacturing Practice Advisory Committee (DGMPAC)**

Section 520 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(j)), as amended, provides that the DGMPAC shall be composed of two representatives of interests of the device manufacturing industry.

**B. Medical Devices Advisory Committee**

Section 520(f)(3) of the act, as amended by the Medical Device Amendments of 1976, provides that each medical device panel include one nonvoting member to represent the interests of the medical device manufacturing industry.