Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Optional Submission of Data on Child Poverty from an Independent Source	54	1	8	432
Assessment of the Impact of TANF on the Increase in Child Poverty	54	1	120	6,480
Corrective Action Plan	54	1	160	8,640

Estimated Total Burden Hours: 15,552.

In compliance with the requirements of Section 3506(c)(2) 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 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: *grjohnson@acf.hhs.gov*.

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: July 11, 2005.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 05–13919 Filed 7–14–05; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0565]

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: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,301–827–1223.

SUPPLEMENTARY INFORMATION: In the Federal Register of April 8, 2005 (70 FR 18029), 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 July 31, 2008. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: July 8, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–13899 Filed 7–14–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0032]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Food Canning Establishment Registration, Process Filing, and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Food Canning Establishment Registration, Process Filing, and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 8, 2005 (70 FR 18034), 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 0910–0037. The approval expires on June 30, 2008. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: July 8, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–13900 Filed 7–14–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2005M–0024, 2005M–0025, 2005M–0026, 2005M–0092, 2005M–0087, 2005M–0055, 2005M–0089, 2005M–0027, 2005M–0109, 2005M–0028, 2005M–0088, 2005M–0110, 2005M–0132]

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 (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Thinh Nguyen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**. Instead, the agency now posts this information on the Internet on FDA's home page at *http://www.fda.gov*. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from January 1, 2005, through March 31, 2005. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JANUARY 1, 2005, THROUGH MARCH 31, 2005

PMA No./Docket No.	Applicant	TRADE NAME	Approval Date
P010058/2005M–0024	Medilink	OSTEOSPACE	March 15, 2004
P030029/2005M–0025	Bayer HealthCare, LLC	ADVIA CENTAUR ANTI HBs READYPACK REAGENTS & ADVIA CENTAUR ANTI HBs READYPACK CALIBRATORS	May 14, 2005
P030028/2005M–0026	Ophtec USA, Inc.; Ophtec BV	ARTISAN (MODEL 206 & 204) PHAKIC INTRAOCULAR LENS (PIOL) VERISYSE (VRSM5US & VRMA6US) PHAKIC INTRAOCULAR LENS	September 10, 2004
P040006/2005M–0092	DePuy Spine, Inc.	CHARITE ARTIFICIAL DISC	October 26, 2004
P030007/2005M–0087	Eastman Kodak Co.	KODAK MAMMAGRAPHY CAD ENGINE	November 23, 2004
P930016 (S17)/2005M–0055	VISX, Inc.	STAR S4 EXCIMER LASER SYSTEM WITH VARIABLE SPOT SCANNING (VSS) & WAVESCAN WAVEFRONT SYSTEM	December 14, 2004
P030030/2005M–0089	Genyx Medical	URYX URETHRAL BULKING AGENT	December 16, 2004
P030022/2005M–0027	Smith & Nephew, Inc.	REFLECTION CERAMIC ACETABULAR SYSTEM	December 17, 2004
P040004/2005M–0109	Bayer Healthcare LLC	ADVIA CENTAUR HBC TOTAL READY PAK REAGENTS & ADVIA CENTAUR HBC TOTAL QUALITY CONTROL MATERIALS	December 22, 2004
P030034/2005M–0028	Orthofix, Inc.	CERVICAL–STIM MODEL 505L CERVICAL FUSION SYSTEM	December 23, 2004
P040014/2005M–0088	Irvine Biomedical, Inc.	IBI THERAPY CARDIAC ABLATION SYSTEM	January 14, 2005

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JANUARY 1, 2005, THROUGH MARCH 31, 2005—Continued

PMA No./Docket No.	Applicant	TRADE NAME	Approval Date
P040017/2005M–0110	Bayer Healthcare, LLC	ADVIA CENTAUR ANTI–HAV TOTAL ASSAY & ADVIA CENTAUR TOTAL QUALITY CONTROL MATERIALS	March 7, 2005
H030005/2005M–0132	CoAxia, Inc.	COAXIA NEUROFLO CATHETER	March 30, 2005

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cdrh/pmapage.html*.

Dated: July 6, 2005.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 05–13901 Filed 7–14–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0195]

Draft Guidance for Industry and Food and Drug Administration Staff; The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #9; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #9.'' The draft guidance document is intended to assist facilities and their personnel in meeting the Mammography Quality Standards Act (MQSA) final regulations.

DATES: Submit written or electronic comments on this draft guidance by October 13, 2005.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #9'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance and the information collection provisions 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.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Charles Finder, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3332.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance is intended to provide guidance to mammography facilities and their personnel. It represents the FDA's current thinking on various aspects of the final regulations implementing the MQSA (Public Law 102–539). Once finalized, this draft guidance document will add to and update material in the Policy Guidance Help System (PGHS) in order to address recurring inquiries to the Center for Devices and Radiological Health (CDRH) about these issues. The PGHS is a computerized system accessible through FDA's Web site that is intended to provide useful information to mammography facilities and their personnel on issues relating to MQSA. The guidance only addresses those portions of the PGHS that are being revised.

This draft guidance addresses the following issues:

1. Definitions of final interpretation and lossless and lossy digital compression;
2. Use of Small Field Digital Mammography image receptors;
3. Clarification relating to reestablishing processor operating levels;
4. Impact of the Health Insurance Portability and Accountability Act requirements on certain MQSA activities;
5. Retention of medical outcomes audit records;
6. Steps to take when patients do not wish to receive their lay summaries;
7. Combining medical reports;
8. The effect of film digitization and compression of Full Field Digital Mammography (FFDM) digital data on retention, transfer, and interpretation of mammographic images;
9. Clarification of continuing education requirements;
10. Use of foreign-trained physicians;
11. Use of the American Registry of Radiologic Technologists ARRT(M) certificate to meet certain radiologic technologist requirements;
12. Quality Control testing when using cushion pads on compression devices;
13. Medical physicist involvement in certain FFDM repairs;
14. Use of printers and monitors that were not specifically approved as part of an FFDM unit; and
15. Digitization of paper records and personnel documents.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the issues described in the previous paragraphs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

To receive ''The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #9'' by fax, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to