

assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### **Adoption of the FDA Food Code by Local, State, and Tribal Governments (OMB Control Number 0910-0448)—Extension**

FDA has developed its model Food Code to assist and promote consistent implementation of national food safety regulatory policy among the local, State, and tribal governmental agencies that have primary responsibility for the regulation or oversight of retail level food operations. The FDA Food Code provides a scientifically sound technical and legal basis for regulating the retail segment of the food industry. Authority for providing such assistance is derived

from section 311(a) of the Public Health Service Act (42 U.S.C. 243(a)). Under 31 U.S.C. 1535, FDA provides assistance to other Federal agencies such as the Indian Health Service.

Nationwide adoption of the model FDA Food Code is an important step toward the agency's goal for consistent, scientifically sound, and risk-based food safety standards and practices. A current, comprehensive, and accurate inventory of food code adoptions by States and U.S. territories, local, and tribal governments is necessary to determine the status of up-to-date protection of the U.S. population and to identify areas where assistance to these governments may promote the adoption of regulations based on the FDA Food Code.

This collection effort, which began in 2001, has had remarkable success with 97 percent participation from State and territorial governmental agencies. FDA contracted with the Association of Food and Drug Officials (AFDO) to conduct

the initial survey using the OMB approved survey form. The rulemaking process that local, State, territorial, and tribal governmental agencies must follow to adopt the model FDA Food Code is often a long and complicated process that can extend for several years. For this reason, many agencies have reported that they are still in the rulemaking process to adopt or update their food codes. Thus, FDA believes that extension of OMB approval of the survey is needed in order to keep the current database accurate and up-to-date. AFDO will collect the information electronically and/or telephonically and will be able to provide respondents with previous survey responses already in the database.

Description of Respondents: States and U.S. territories, local, and tribal governmental agencies.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Food Code Survey	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Respondents	75	4	300	1	300

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

This estimate is based on FDA's experience and the number of updates received in the past 3 years. FDA has reduced the estimated number of annual respondents from 150 to 75. FDA estimates that 75 respondents will provide four quarterly updates each, resulting in an estimated 300 total annual responses. The agency estimates that each quarterly update will take about 1 hour. Of the 75 respondents, those who amend their regulations with changes unrelated to the risk factors and interventions, and those who are not adopting model FDA Food Code provisions, but are incorporating certain Conference for Food Protection recommendations only, will likely need only annual contact.

Dated: January 17, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-S**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket Nos. 2006M-0339, 2006M-0338, 2006M-0340, 2006M-0323, 2006M-0324, 2006M-0321, 2006M-0389, 2006M-0293, 2006M-0294, 2006M-0295, 2006M-0325, 2006M-0322, 2006M-0367, 2006M-0374, 2006M-0342, 2006M-0341, 2006M-0343, 2006M-0368]**

### **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, 240-276-4010, ext. 152.

#### **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 July 1, 2006, through September 30, 2006. 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 JULY 1, 2006, THROUGH SEPTEMBER 30, 2006

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P030019/2006M-0339	Anika Therapeutics, Inc.	ORTHOVISC HIGH MOLECULAR WEIGHT HYALURONAN	February 4, 2004
P010029/2006M-0338	Ferring Pharmaceuticals, Inc./applicant at approval was Savient Pharmaceuticals, Inc.	NUFLEXXA (1% SODIUM HYALURONATE)	December 3, 2004
P030016/2006M-0340	Staar Surgical Co.	VISIAN ICL (IMPLANTABLE COLLAMER LENS)	December 22, 2005
P970043(S20)/2006M-0323	Alcon Laboratories, Inc.	LADARVISION 4000 EXCIMER LASER SYSTEM	May 1, 2006
P970043(S22)/2006M-0324	Alcon Laboratories, Inc.	LADARVISION 4000 EXCIMER LASER SYSTEM	May 2, 2006
P050051/2006M-0321	Abbott Laboratories, Inc.	ABBOTT ARCHITECT AUSA-B	June 1, 2006
P050042/2006M-0389	Abbott Laboratories, Inc.	ARCHITECT ANTI-HCV ASSAY; ARCHITECT ANTI-HCV CALIBRATOR; AND ARCHITECT ANTI-HCV CONTROL	June 7, 2006
P050044/2006M-0293	Orthovita, Inc.	VITAGEL SURGICAL HEMOSTAT	June 16, 2006
P050017/2006M-0294	Cook Incorporated	ZILVER VASCULAR STENT	June 26, 2006
P050014/2006M-0295	Fujifilm Medical System USA, Inc.	FUJI'S COMPUTED RADIOGRAPHY MAMMOGRAPHY SUITE (FCRMS)	July 10, 2006
P020050(S4)/2006M-0325	Wavelight AG/applicant at approval was SurgiVision Regulatory Consultants, Inc.	WAVELIGHT ALLEGRETTO WAVE EXCIMER LASER SYSTEM	July 26, 2006
P050011/2006M-0322	Baxter Healthcare Corp./applicant at approval was Innovata PLC	ADEPT (4% ICODextrin) ADHESION REDUCTION SOLUTION	July 28, 2006
P050023/2006M-0367	Biotronik, Inc.	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STERIOD PACING LEAD	August 10, 2006
P040036/2006M-0374	Biosense Webster, Inc.	NAVISTAR THERMOCOOL DEFLECTABLE DIAGNOSTIC ABLATION CATHETER	August 11, 2006
P060004/2006M-0342	Carl Zeiss, Inc./applicant at approval was Carl Zeiss Meditec, Inc.	MEL 80 EXCIMER LASER	August 11, 2006
P050006/2006M-0341	WL Gore & Associates, Inc.	GORE HELEX SEPTAL OCCLUDER	August 11, 2006
P050010/2006M-0343	Synthes Spine/applicant at approval was Synthes Spine Co., L.P.	PRODISC-L TOTAL DISC REPLACEMENT	August 14, 2006
H040006/2006M-0368	Abiomed, Inc.	ABICOR IMPLANTABLE REPLACEMENT HEART	September 5, 2006

**II. Electronic Access**

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

Dated: January 16, 2007.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

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**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, call the HRSA Reports Clearance Office on (301)-443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

**Proposed Project: Application for the  
National Health Service Corps (NHSC)  
Scholarship Program (OMB No. 0915-  
0146); Extension**

The National Health Service Corps (NHSC) Scholarship Program's mission is to ensure the geographic representation of physicians and other health practitioners in the United States. Under this program, health professions

students are offered scholarships in return for service in a federally designated Health Professional Shortage Area (HPSA). The Scholarship Program provides the NHSC with the health professionals it requires to carry out its mission of providing primary health care to HPSA populations in areas of greatest need. Students are supported who are well qualified to participate in the NHSC Scholarship Program and who want to assist the NHSC in its mission, both during and after their period of obligated service. Scholars are selected for these competitive awards based on the information provided in the application. Awards are made to applicants who demonstrate a high potential for providing quality primary health care services.

The estimated response burden is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Application .....	1800	1	1800	1	1800
Interview .....	600	1	600	.25	150
Total .....	1800	.....	2400	.....	1950

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Karen Matsuoka, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: January 19, 2007.

**Caroline Lewis,**

*Acting Associate Administrator for Administration and Financial Management.*

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**DEPARTMENT OF HEALTH AND  
HUMAN SERVICES**
**Health Resources and Services  
Administration**
**Agency Information Collection  
Activities: Proposed Collection:  
Comment Request**

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506 (c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries

of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443-1129.

*Comments are invited 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) ways to enhance 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.

**Proposed Project: National Bioterrorism  
Hospital Preparedness Program  
(NBHPR) Data Collection Instrument  
(DCI)—NEW**

The Healthcare Systems Bureau (HSB), Division of Healthcare Preparedness (DHP), is proposing a Data Collection Instrument (DCI) to gather critical information from the 62

Awardees participating in the National Bioterrorism Hospital Preparedness Program (NBHPR).

The DCI will capture information related to: Performance measures, critical benchmarks, minimal levels of readiness, program statistics, policies and procedures, surge capacity elements, surge capacity as measured by exercises, and other pertinent information for programmatic improvement and tracking performance. The data will be gathered from mid-year progress reports on annual activities, final reports on annual activities, and progress indicator reports submitted to HRSA's HSB, DHP.

Awardees will indicate the progress made toward each of the financial and programmatic objectives noted on their cooperative agreement application (CAA) on the mid-year progress report. The final report on annual activities will require Awardees to provide additional details on how objectives were achieved and how the program funds were spent. The progress indicator report will require Awardees to outline improvements made to date toward achieving the program's critical benchmarks.

Currently, there is no uniform reporting system in place to capture mid-year, final, and indicator reporting data. A uniform system for data