• Serves as liaison with the Department of Health and Human Services and White House press offices.
• Serves as focal point for all Agency interactions with Native American and Alaskan Native tribes.
• Coordinates State program issues/concerns (i.e., waiver reviews, Medigap, Medicare-Select, survey and certification, Clinical Laboratory Improvement Act (CLIA), tribal affairs) with program staff and regional offices.
• Serves as coordinator of State health care policy and as liaison between CMS and State and local officials, and individual lobbyists representing State and local officials and advocate groups.
• Serves as coordinator of tribal affairs issues and liaison between CMS and State and local officials representing tribal affairs groups.
• Responsible for handling highly sensitive and complex correspondence from and to State and local elected officials. Reviews proposed regulations affecting States.
• Coordinates roll-out of waivers or other significant announcements relating to States.

10. Center for Medicaid and State Operations (FAS)

• Serves as the focal point for all Agency interactions with States and local governments (including the Territories).
• Develops national Medicaid policies and procedures which support and assure effective State program administration and beneficiary protection. In partnership with the States, evaluates the success of State agencies in carrying out their responsibilities and, as necessary, assists the States in correcting problems and improving the quality of their operations.
• Develops, interprets, and applies specific laws, regulations, and policies that directly govern the financial operation and management of the Medicaid program and the related interactions with the States and regional offices.
• Develops national policies and procedures to support and assure appropriate State implementation of the rules and processes governing group and individual health insurance markets and the sale of health insurance policies that supplement Medicare coverage.
• In coordination with other components, develops, implements, evaluates and refines standardized provider performance measures used within provider certification programs. Supports States in their use of standardized measures for provider feedback and quality improvement activities. Develops, implements and supports the data collection and analysis systems needed by States to administer the certification program.
• Reviews, approves and conducts oversight of Medicaid managed care waiver programs. Provides assistance to States and external customers on all Medicaid managed care issues.
• Develops national policies and procedures on Medicaid automated claims/encounter processing and information retrieval systems such as the Medicaid Management Information System (MMIS) and integrated eligibility determination systems.
• In coordination with the Office of Financial Management, directs, coordinates, and monitors program integrity efforts and activities by States and regions. Works with the Office of Financial Management to provide input in the development of program integrity policy.
• Through administration of the home and community based services program and policy collaboration with other Agency components and the States, promotes he appropriate choice and continuity of quality services available to frail elderly, disabled and chronically ill beneficiaries.
• Develops and tests new and innovative methods to improve the Medicaid program through demonstrations and best practices including managing review, approval, and oversight of the Section 1115 demonstrations.
• Directs the planning, coordination, and implementation of the survey, certification, and enforcement programs for all Medicare and Medicaid providers and suppliers, and for laboratories under the auspices of the Clinical Laboratory Improvement Act (CLIA). Reviews and approves applications by States for ''exemption'' from CLIA and applications from private accreditation organizations for deeming authority. Develops assessment techniques and protocols for periodically evaluating the performance of these entities. Monitors the performance of proficiency testing programs under the auspices of CLIA.

Dated: January 2, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 02–1064 Filed 1–24–02; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0399]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Rapid Response Surveys

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by February 25, 2002.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

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

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Rapid Response Surveys (OMB Control No. 0910–0457)—Extension

Under section 519 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i), FDA is authorized to require manufacturers to report medical device related deaths, serious injuries, and malfunctions, and user facilities to report device-related deaths directly to FDA and to manufacturers, and to report serious injuries to the manufacturer. Section 522 of the act (21 U.S.C. 360l) authorizes FDA to require manufacturers to conduct postmarket surveillance of medical devices. Section 705(b) of the act (21 U.S.C. 375(b)) authorizes FDA to collect and disseminate information regarding medical products or cosmetics in situations involving imminent danger to health, or gross deception of the consumer. Section 903(d)(2) of the act (21 U.S.C. 393(d)(2)) authorizes the

Commissioner of Food and Drugs (the Commissioner) to implement general powers (including conducting research) to effectively carry out the mission of FDA. These sections of the act enable FDA to enhance consumer protection from risks associated with medical device usage that are not foreseen or apparent during the premarket notification and review process. FDA monitors medical product related postmarket adverse events via both the mandatory and voluntary MedWatch Reporting Systems using FDA Forms 3500 and 3500A (OMB Control No. 0910–0281).

FDA received a 1-year OMB approval on February 5, 2001, to implement Emergency Health Surveys (since that time, renamed ''Rapid Response Surveys''), via a series of surveys, thus implementing section 705(b) of the act and the Commissioner's authority as specified in section 903(d)(2) of the act. To date, FDA has initiated one Rapid Response Survey (66 FR 49391, September 27, 2001), with two more in development. FDA is now seeking OMB clearance to continue collecting this information. Participation in these surveys has been, and will continue to be, voluntary. This request covers Rapid Response Surveys for general type medical facilities and specialized medical facilities (those known for cardiac surgery, obstetric/gynecological services, pediatric services, etc.), and health professionals, but more typically risk managers working in medical facilities.

FDA currently uses the information gathered from these surveys to quickly obtain vital information from the appropriate clinical sources so that FDA may take appropriate public health or regulatory action. FDA projects 10 rapid response surveys per year with a sample of between 50 and 200 respondents per survey.

In the **Federal Register** of September 27, 2001 (66 FR 49391), the agency requested comments on the proposed collection of information. No comments were received.

FDA originally estimated the burden of this collection to be 2 hours per survey. However, FDA is revising the estimated burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
200	10 (maximum)	2,000	.5	1,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates are based on the maximum sample size per questionnaire that FDA could analyze in a timely manner. The annual frequency per response was determined by the maximum number of questionnaires that will be sent to any individual respondent. Some respondents may be contacted only one time per year, while another respondent may be contacted several times—depending on the medical device under evaluation. Based on the questions developed for the one survey that has been conducted, and for the two under development, it is estimated, given the expected type of issues that will be addressed by the surveys, that at a maximum it will take 30 minutes for a respondent to gather the requested information and fill in the answers.

Dated: January 17, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–1928 Filed 1–24–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00E–1234]

Determination of Regulatory Review Period for Purposes of Patent Extension; SONATA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for SONATA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Office of Regulatory Policy (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5645.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted, as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all