

CWHSP will soon be accepting digital images as well as the traditional analog x-ray films, the number of x-ray

facilities participating will increase over the next several years. This increase is reflected in this submission. The forms

associated with this approval process require approximately 30 minutes for completion.

ESTIMATED ANNUALIZED BURDEN

Respondents	Number of respondents	Number of responses per respondent	Average burden/response (in hrs)	Total burden (in hrs)
Invoice-Pathologist .....	50	1	5/60	4
Report-Pathologist .....	50	1	5/60	4
Consent, Release and History Form—Next-of-Kin (Form 2.6) .....	50	1	15/60	13
Roentgenographic Interpretation Form—Physicians (Form 2.8) .....	10,000	1	3/60	500
Interpreting Physician Certification Document—Physicians (Form 2.12) .....	300	1	10/60	50
Miner Identification Document—Coal Miners (Form 2.9) .....	5,000	1	20/60	1,666
Spirometry Test—Coal Miners .....	2,500	1	20/60	833
X-ray—Coal Miners .....	5000	1	15/60	750
Coal Mine Operators Plan—Mine Operators (Form 2.10) .....	200	1	30/60	100
Facility Certification Document—X-ray Facilities (Form 2.11) .....	100	1	30/60	200
Total .....				4,120

Dated: February 16, 2011.

**Carol E. Walker,**

*Acting Reports Clearance Officer, Centers for Disease Control and Prevention.*

[FR Doc. 2011-4165 Filed 2-23-11; 8:45 am]

**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**Disease, Disability, and Injury Prevention and Control**

Special Emphasis Panel: Occupational Safety and Health Training Project Grant, Program Announcement PAR 10-288, initial review.

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting:

*Times and Dates:* 8:30 a.m.–5 p.m., March 17, 2011 (Closed).

*Place:* Courtyard Marriott, 2700 Eisenhower Avenue, Alexandria, Virginia 22314-4553, Telephone (703) 329-2323.

*Status:* The meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

*Matters to be Discussed:* The meeting will include the initial review, discussion, and evaluation of “Occupational Safety and Health Training Project Grant, PAR 10-288.”

*Contact Person for More Information:* M. Chris Langub, PhD, Scientific Review Officer,

CDC, 1600 Clifton Road NE., Mailstop E74, Atlanta, Georgia 30333, Telephone (404) 498-2543.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: February 14, 2011.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office Centers for Disease Control and Prevention.*

[FR Doc. 2011-4197 Filed 2-23-11; 8:45 am]

**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2010-N-0622]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Color Additive Certification Requests and Recordkeeping**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget

(OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by March 28, 2011.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0216. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3793.

**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. Color Additive Certification Requests and Recordkeeping—21 CFR part 80 (OMB Control Number 0910-0216)—Extension.

FDA has regulatory oversight for color additives used in foods, drugs, cosmetics, and medical devices. Section 721(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379e(a)) provides that a color additive shall be deemed to be unsafe unless it

meets the requirements of a listing regulation, including any requirement for batch certification, and is used in accordance with the regulation. FDA lists color additives that have been shown to be safe for their intended uses in Title 21 of the Code of Federal Regulations (CFR). FDA requires batch certification for all color additives listed in 21 CFR part 74 and for all color additives provisionally listed in 21 CFR part 82. Color additives listed in 21 CFR part 73 are exempted from certification.

The requirements for color additive certification are described in part 80 (21 CFR part 80). In the certification procedure, a representative sample of a new batch of color additive, accompanied by a "request for certification" that provides information about the batch, must be submitted to FDA's Office of Cosmetics and Colors. FDA personnel perform chemical and other analyses of the representative sample and, providing the sample satisfies all certification requirements, issue a certification lot number for the batch. FDA charges a fee for certification based on the batch weight and requires manufacturers to keep records of the batch pending and after certification.

Under § 80.21, a request for certification must include: Name of color additive, manufacturer's batch number and weight in pounds, name and address of manufacturer, storage conditions, statement of use(s), certification fee, and signature of person

requesting certification. Under § 80.22, a request for certification must include a sample of the batch of color additive that is the subject of the request. The sample must be labeled to show: Name of color additive, manufacturer's batch number and quantity, and name and address of person requesting certification. Under § 80.39, the person to whom a certificate is issued must keep complete records showing the disposal of all the color additive covered by the certificate. Such records are to be made available upon request to any accredited representative of FDA until at least 2 years after disposal of all of the color additive.

The purpose for collecting this information is to help FDA assure that only safe color additives will be used in foods, drugs, cosmetics, and medical devices sold in the United States. The required information is unique to the batch of color additive that is the subject of a request for certification. The manufacturer's batch number is used for temporarily identifying a batch of color additive until FDA issues a certification lot number and for identifying a certified batch during inspections. The manufacturer's batch number also aids in tracing the disposal of a certified batch or a batch that has been denied certification for noncompliance with the color additive regulations. The manufacturer's batch weight is used for assessing the certification fee. The batch weight also is used to account for the

disposal of a batch of certified or certification-denied color additive. The batch weight can be used in a recall to determine whether all unused color additive in the batch has been recalled. The manufacturer's name and address and the name and address of the person requesting certification are used to contact the person responsible should a question arise concerning compliance with the color additive regulations. Information on storage conditions pending certification is used to evaluate whether a batch of certified color additive is inadvertently or intentionally altered in a manner that would make the sample submitted for certification analysis unrepresentative of the batch. FDA checks storage information during inspections. Information on intended uses for a batch of color additive is used to assure that a batch of certified color additive will be used in accordance with the requirements of its listing regulation. The statement of the fee on a certification request is used for accounting purposes so that a person requesting certification can be notified promptly of any discrepancies.

In the **Federal Register** of December 13, 2010 (75 FR 77645), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

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

21 CFR Section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
80.21 .....	32	185	5,920	0.17	1,006
80.22 .....	32	185	5,920	0.05	296
Total .....	.....	.....	.....	0.22	1,302

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

21 CFR Section	Number of recordkeepers	Annual frequency per record-keeping	Total annual records	Hours per record	Total hours
80.39 .....	32	185	5,920	0.25	1,480
Total .....	.....	.....	.....	.....	1,480

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

FDA bases its estimate on its review of the certification requests received over the past 3 fiscal years (FY). The annual burden estimate for this information collection is 2,782 hours. The estimated reporting burden for this information collection is 1,302 hours and the

estimated recordkeeping burden for this information collection is 1,480 hours. From FY 2008 to FY 2010, FDA processed an average of 5,932 responses (requests for certification of batches of color additives) per year. There were 32 different respondents, corresponding to

an average of approximately 185 responses from each respondent per year. Using information from industry personnel, FDA estimates that an average of 0.22 hour per response is required for reporting (preparing certification requests and accompanying

samples) and an average of 0.25 hour per response is required for recordkeeping.

FDA's Web-based color certification information system allows certifiers to request color certification online, follow their submissions through the process, and obtain information on account status. The system sends back the certification results electronically, allowing certifiers to sell their certified color before receiving hard copy certificates. Any delays in the system result only from shipment of color additive samples to FDA's Office of Cosmetics and Colors for analysis. FDA has estimated a reduction in the hour burden for reporting from use of the Web-based system.

Dated: February 17, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-4155 Filed 2-23-11; 8:45 am]

BILLING CODE 4160-01-P

**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, Pub. L. 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, e-mail [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Reports Clearance Officer at (301) 443-1129.

*Comments are invited on:* (a) The proposed collection of information for the proper performance of the functions of the agency; (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: Patient Navigator Outreach and Chronic Disease Prevention Demonstration Program (OMB No. 0915-NEW)—[NEW]**

The Patient Navigator Outreach and Chronic Disease Prevention

Demonstration Program (PNDP) authorizes funds for the development and operation of projects to provide patient navigator services to improve health outcomes for individuals with cancer and other chronic diseases, with a specific emphasis on health disparities populations. Award recipients are to use grant funds to recruit, assign, train, and employ patient navigators who have direct knowledge of the communities they serve to facilitate the care of those who are at risk for or who have cancer or other chronic diseases, including conducting outreach to health disparities populations.

As authorized by the statute, an evaluation of the outcomes of the program must be submitted to Congress. The purpose of these data collection instruments, including navigated patient data intake, VR-12 health status, patient navigator survey, patient navigator encounter/tracking log, patient medical record and clinic data, clinic rates (baseline measures), and quarterly reports is to provide data to inform and support the Report to Congress for: the quantitative analysis of baseline and benchmark measures; aggregate information about the patients served and program activities, and; recommendations on whether patient navigator programs could be used to improve patient outcomes in other public health areas.

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Navigated Patient Data Intake Form .....	6,327	1	6,327	0.5	3,163.5
VR-12 Health Status Form .....	6,327	2	12,654	.12	1,519
<i>SubTotal—Patient Burden .....</i>	<i>6,327</i>	<i>3</i>	<i>18,981</i>	<i>.62</i>	<i>4,682.5</i>

The annual estimate of burden is as follows:

Patient Navigator Survey .....	46	1	46	0.2	9.2
Patient Navigator Encounter/Tracking Log .....	46	825.3	37,962	0.2	7,592.4
<i>SubTotal—Patient Navigator Burden .....</i>	<i>46</i>	<i>826.3</i>	<i>38,008</i>	<i>0.4</i>	<i>7,601.6</i>
Patient Medical Record and Clinic Data .....	10	632.7	6,327	.17	2,151.2
Clinic Rates (Baseline Measures) .....	10	1	10	10	100
Quarterly Report .....	10	4	40	1	40
<i>SubTotal—Grantee Burden .....</i>	<i>30</i>	<i>637.7</i>	<i>6,377</i>	<i>11.17</i>	<i>2,291.2</i>
<i>Totals .....</i>	<i>6,403</i>	<i>.....</i>	<i>63,366</i>	<i>.....</i>	<i>14,575.3</i>
<i>Total Average Annual Burden .....</i>	<i>.....</i>	<i>.....</i>	<i>.....</i>	<i>.....</i>	<i>14,575.3</i>

Anticipated Number of Patients per Site:

	Over 3 years		Over 3 years
Clinica Sierra Vista .....	2,280	CMAP .....	1,000
		New River .....	7,200
		Project Concern .....	450
		Queens Medical Center .....	500
		South County .....	600
		Texas Tech .....	200
		University of Utah .....	1,350
		Vista .....	3,000