

and Treatment Act passed by Congress in 2000.

CDC proposes to collect one year of cost data from all 68 NBCCEDP grantees in order to conduct the first systematic, activity-based analysis of the costs and cost-effectiveness of the NBCCEDP. The information required to perform an activity-based cost analysis includes: Staff and consultant salaries, screening costs, contracts and material costs, provider payments, in-kind contributions, administrative costs, allocation of funds, and staff time

devoted to specific program activities. Data will be collected electronically via a Web-based Cost Assessment Tool (CAT).

CDC will use information collected through the CAT to assess the costs of various program components, identify factors that impact average cost, perform cost-effectiveness analysis, and to develop a resource allocation tool for ensuring the most appropriate use of limited program resources.

NBCCEDP grantees currently report information on screening and diagnosis

volumes (the effectiveness measures for the program) as part of the Minimum Data Elements (MDE)/System for Technical Assistance Reporting (STAR) (OMB 0920-0571, exp. 1/31/2010). Information to be collected through the CAT will complement information currently collected through the MDE/STAR.

There are no costs to respondents other than their time. The total estimated annualized burden hours are 1,496.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
NBCCEDP Grantees .....	68	1	22

Dated: November 26, 2007.

**Maryam I. Daneshvar,**

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

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2007N-0306]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practice Regulations for Type A Medicated Articles**

**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 January 2, 2008.

**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: 202-395-6974, or e-mailed to [baguilar@omb.eop.gov](mailto:baguilar@omb.eop.gov). All comments should be identified with the OMB control number 0910-0154. Also

include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

Denver Presley Jr., Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

**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.

**Current Good Manufacturing Practice Regulations for Type A Medicated Articles—21 CFR Part 226 (OMB Control Number 0910-0154)—Extension**

Under section 501 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351), FDA has the statutory authority to issue current good manufacturing practice (cGMP) regulations for drugs, including Type A medicated articles. A Type A medicated article is a feed product containing a concentrated drug diluted with a feed carrier substance. A Type A medicated article is intended solely for use in the manufacture of another Type A medicated article or a Type B or Type C medicated feed. Medicated feeds are administered to animals for the prevention, cure, mitigation, or treatment of disease or for growth promotion and feed efficiency.

Statutory requirements for cGMPs for Type A medicated articles have been codified under part 226 (21 CFR part 226). Type A medicated articles which are not manufactured in accordance with these regulations are considered adulterated under section 501(a)(2)(B) of

the act. Under part 226, a manufacturer is required to establish, maintain, and retain records for Type A medicated articles, including records to document procedures required under the manufacturing process to assure that proper quality control is maintained. Such records would, for example, contain information concerning receipt and inventory of drug components, batch production, laboratory assay results (i.e., batch and stability testing) and product distribution.

This information is needed so that FDA can monitor drug usage and possible misformulation of Type A medicated articles. The information could also prove useful to FDA in investigating product defects when a drug is recalled. In addition, FDA will use the cGMP criteria under part 226 to determine whether or not the systems used by manufacturers of Type A medicated articles are adequate to assure that their medicated articles meet the requirements of the act as to safety and also meet the article's claimed identity, strength, quality, and purity, as required by section 501(a)(2)(B) of the act.

In the **Federal Register** of August 16, 2007 (72 FR 46087), FDA published a 60-day notice soliciting public comment on the proposed collection of information provisions. In response to that notice, no comments were received.

The respondents for Type A medicated articles are pharmaceutical firms that manufacture both human and veterinary drugs, those firms that produce only veterinary drugs, and commercial feed mills.

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

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

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total
226.42	115	260	29,000	0.75	22,425
226.58	115	260	29,000	1.75	52,325
226.80	115	260	29,000	0.75	22,425
226.102	115	260	24,000	1.75	52,325
226.110	115	260	29,000	0.25	7,475
226.115	115	10	1,150	0.5	575
Total					157,550

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

The estimate of the time required for record preparation and maintenance is based on agency communications with industry. Other information needed to calculate the total burden hours (i.e., manufacturing sites, number of Type A medicated articles being manufactured, etc.) are derived from agency records and experience.

Dated: November 27, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2007N-0279]

#### 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 January 2, 2008.

**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:

202-395-6974, or e-mailed to [baguilar@omb.eop.gov](mailto:baguilar@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:** Jonna Capezzuto, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**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—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 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