

presentation on early warning from representatives of the Advisory Council on Governmental Audit Standards.

Any interested person may attend the meeting as an observer. Board discussions and reviews are open to the public.

FOR FURTHER INFORMATION CONTACT:

Wendy Comes, Executive Director, 441 G St., NW., Room 3B18, Washington, DC 20548, or call (202) 512-7350.

Authority: Federal Advisory Committee Act, Pub. L. No. 92-463, Section 10(a)(2), 86 Stat. 770, 774 (1972) (current version at 5 U.S.C. app. section 10(a)(2) (1988); 41 CFR 101-6.1015 (1990).

Dated: July 16, 1998.

Wendy M. Comes,
Executive Director.

[FR Doc. 98-19417 Filed 7-20-98; 8:45 am]

BILLING CODE 1610-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy Sites: Notice of Charter Renewal

This gives notice under the Federal Advisory Committee Act (Public Law 92-463) of October 6, 1972, that the Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy Sites of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services, has been renewed for a 2-year period beginning July 7, 1998 through July 7, 2000.

For further information, contact the Management Analysis and Services Office, Committee Management and Program Panels Activity, CDC, Mailstop E-72, 1600 Clifton Road, NE, Atlanta, Georgia 30333, telephone 404-639-6389 or fax 404-639-6290.

Dated: July 13, 1998.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98-19326 Filed 7-20-98; 8:45 am]

BILLING CODE 4861-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0515]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

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 (the PRA).

DATES: Submit written comments on the collection of information by August 20, 1998.

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: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (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—Reinstatement)

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 CGMP's for Type A medicated articles have been codified under part 226 (21 CFR part 226). Type A medicated articles that 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 ensure 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 in part 226 to determine whether or not the systems used by manufacturers of Type A medicated articles are adequate to ensure that their medicated articles meet the requirements of the act pertaining to safety and also meet the articles, claimed identity, strength, quality and purity, as required by section 501(a)(2)(B) of the act.

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

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
226.42	200	120	24,000	0.75	18,000
226.58	200	120	24,000	1.75	42,000
226.80	200	120	24,000	0.75	18,000
226.102	200	120	24,000	1.75	42,000

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹—Continued

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
226.110	200	120	24,000	0.25	6,000
226.115	200	120	24,000	1.00	24,000
Total burden hours					150,000

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

The estimate of the times 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: July 13, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98-19312 Filed 7-20-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N-0546]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

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 (the PRA).

DATES: Submit written comments on the collection of information by August 20, 1998.

ADDRESSES: Submit written comments on the proposed 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: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Margaret R. 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 section 3507 of the

PRA (44 U.S.C. 3507), FDA has submitted the following collection of information to OMB for review and clearance.

Food Labeling Regulations (21 CFR Parts 101, 102, 104, and 105)

FDA regulations in parts 101, 102, 104, and 105 (21 CFR parts 101, 102, 104, and 105) require food producers to disclose to consumers and others specific information about themselves or their products on the label or labeling of their products. Certain of these regulations also require that food producers retain records establishing the basis for the information contained in the label or labeling of their products and provide those records to regulatory officials. Finally, certain regulations provide for submissions of information to FDA in the form of petitions or notices. These regulations were issued under the authority of sections 4, 5, and 6 of the Fair Packaging and Labeling Act (FPLA) (15 U.S.C. 1453, 1454, and 1455) and of sections 201, 301, 402, 403, 409, 411, 701, and 721 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321, 331, 342, 343, 348, 350, 371, and 379e). Most of these regulations derive from section 403 of the act, which provides that a food product shall be misbranded if, among other things, its label or labeling fails to bear certain required information concerning the food product, is false or misleading in any particular, or bears certain types of unauthorized claims. The disclosure requirements and other collections of information in the regulations in parts 101, 102, 104, and 105 are necessary to ensure that food products sold in the United States are in compliance with the labeling provisions of the act and the FPLA. One purpose of this submission to OMB under the PRA is to consolidate all of the information collection provisions in these regulations into one submission to OMB for its review and approval.

Section 101.3 of FDA's food labeling regulations requires that the label of a food product in packaged form bear a statement of identity (i.e., the name of the product), including, as appropriate, the form of the food or the name of the

food imitated. Section 101.4 prescribes the requirements for the declaration of ingredients on the label or labeling of food products in packaged form. Section 101.5 requires that the label of a food product in packaged form specify the name and place of business of the manufacturer, packer, or distributor and, if the food producer is not the manufacturer of the food product, its connection with the food product. Section 101.9 requires that nutrition information be provided for all food products intended for human consumption and offered for sale, unless an exemption in § 101.9(j) applies to the product. Section 101.9(g)(9) provides for the submission to FDA of requests for alternative approaches to nutrition labeling. Finally, § 101.9(j)(18) provides for the submission to FDA of notices from firms claiming the small business exemption from nutrition labeling. Section 101.10 requires that restaurants provide nutrition information, upon request, for any food or meal for which a nutrient content claim or health claim is made. Section 101.12(e) provides that a manufacturer that adjusts the reference amount customarily consumed (RACC) of an aerated food for the difference in density of the aerated food relative to the density of the appropriate nonaerated reference food must be prepared to show FDA detailed protocols and records of all data that were used to determine the density-adjusted RACC. Section 101.12(g) requires that the label or labeling of a food product disclose the serving size that is the basis for a claim made for the product if the serving size on which the claim is based differs from the RACC. Section 101.12(h) provides for the submission of petitions to FDA to request changes in the reference amounts defined by regulation.

Section 101.13 requires that nutrition information be provided in accordance with the provisions of § 101.9 for any food product for which a nutrient content claim is made. Under some circumstances, § 101.13 also requires the disclosure of other types of information as a condition for the use of a nutrient content claim. For example, under § 101.13(j), if the claim compares