Respondents	Number of respondents	Number of responses	Avg. burden/response (in hrs.)
Initial Application	5	1	3.5
Annual Letter	53	1	45/60
Report of Course Changes	12	1	45/60

Dated: October 10, 2001.

Nancy E. Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 01–25951 Filed 10–15–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Statement of Organization, Functions, and Delegations of Authority

This notice amends Part K of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (DHHS), Administration for Children and Families (ACF) as follows: Chapter KA, Office of the Assistant Secretary for Children and Families (OAS) as last amended January 2, 1998 (63 FR 81–87) and Chapter KP, Office of the Deputy Assistant Secretary for Administration (ODASA) as last amended February 27, 2001 (66 FR 12525–28) and April 9, 2001 (66 FR 18487). This notice realigns the Executive Secretariat Office from the Office of the Deputy Assistant Secretary for Administration to the Office of the Assistant Secretary for Children and Families.

These Chapters are amended as follows:

I. Chapter KA, Office of the Assistant Secretary for Children and Families.

A. Delete KA.10 Organization in its entirety and replace with the following:

KA.10 Organization. The Office of the Assistant Secretary for Children and Families is headed by the Assistant Secretary who reports directly to the Secretary and consists of:

—The Office of the Assistant Secretary (KA).
—President's Committee on Mental Retardation Staff (KAD).
—The Executive Secretariat Office (KAF).

B. Amend KA.20 Functions to add the following new paragraph:

C. The Executive Secretariat Office (ExecSec) ensures that issues requiring the attention of the Assistant Secretary, Deputy Assistant Secretaries and/or executive staff are addressed on a timely and coordinated basis and facilitates decisions on matters requiring immediate action including White House, Congressional and Secretarial assignments. The Office serves as the ACF liaison with the HHS Executive Secretariat. It receives, assesses and controls incoming correspondence and assignments to the appropriate ACF component(s) for response and action and provides assistance and advice to ACF staff on the development of responses to correspondence. The Office provides assistance to ACF staff on the use of the controlled correspondence system. The Office coordinates and/or prepares congressional correspondence; and tracks development of periodic reports and facilitates departmental clearances. The Director of the Executive Secretariat Office serves as the Freedom of Information Act Officer for ACF and coordinates hot line calls received by the Office of Inspector General and the General Accounting Office relating to ACF operations and personnel.

II. Chapter KP, Office of the Deputy Assistant Secretary for Administration.

A. Delete KP.00 Mission in its entirety and replace with the following:

KP.00 Mission. The Deputy Assistant Secretary for Administration serves as principal advisor and counsel to the Assistant Secretary for Children and Families on all aspects of personnel administration and management, information resource management, financial, grants policy and procurement issues, staff development and training activities, organizational development and organizational analysis, administrative services and facilities management and state systems policy. Oversees the ACF Equal Employment Opportunity and Civil Rights program and all special initiatives activities for ACF.

B. Amend KP.10 Organization to delete ''Executive Secretariat Office (KPG).''

C. Amend KP.20 Functions to delete paragraph G, in its entirety.

Dated: September 28, 2001.

Wade F. Horn,

Assistant Secretary for Children and Families.

[FR Doc. 01–25995 Filed 10–15–01; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0437]

Agency Information Collection Activities; Proposed Collection; Comment Request; New Animal Drugs for Investigational Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting and recordkeeping requirements for new animal drugs for investigational use.

DATES: Submit written or electronic comments on the collection of information by December 17, 2001.

ADDRESSES: Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor.

Collection of information is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 (c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and 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.

New Animal Drugs for Investigational Use—21 CFR Part 511 (OMB Control Number 0910– 0117)—Extension

FDA has the responsibility under the Federal Food, Drug, and Cosmetic Act (the act), for approval of new animal drugs. Section 512(j) of the act (21 U.S.C. 360b(j)), authorizes FDA to issue regulations relating to the investigational use of new animal drugs. The regulations setting forth the conditions for investigational use of new animal drugs have been codified at part 511 (21 CFR part 511). A sponsor must submit to FDA a notice of claimed investigational exemption (INAD), before shipping the new animal drug for clinical tests in animals. The INAD must contain, among other things, the following specific information: (1) Identity of the new animal drug, (2) labeling, (3) statement of compliance of any nonclinical laboratory studies with good laboratory practices, (4) name and address of each clinical investigator, (5) the approximate number of animals to be treated or amount of new animal drug(s) to be shipped, and (6) information regarding the use of edible tissues from investigational animals. Part 511 also requires that records be established and maintained to document the distribution and use of the investigational drug to assure that its use is safe, and that distribution is controlled to prevent potential abuse. The agency utilizes these required records under its Bio-Research Monitoring Program to monitor the validity of the studies submitted to FDA to support new animal drug approval and to assure that proper use of the drug is maintained by the investigator.

Investigational new animal drugs are used primarily by drug industry firms, academic institutions, and the government. Investigators may include individuals from these entities as well as research firms and members of the medical profession. Respondents to this collection of information are the persons who use new animal drugs investigationally.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
511.1(b)(4)	190	6	1,147	8	9,176
511.1(b)(5)	190	1.5	287	140	40,180
511.1(b)(6)	190	.005	1	250	250
511.1(b)(8)(ii)	190	.005	1	20	20
511.1(b)(9)	190	.16	30	8	240
Total					49,866

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
511.1(a)(3)	190	7.5	1,434	9	12,906
511.1(b)(3)	190	10	1,912	1	1,912
511.1(b)(7)(ii)	190	2	956	3.5	3,346
511.1(b)(8)(i)	190	4	956	3.5	3,346
Total					21,510

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

The estimate of the time required for reporting requirements, record preparation, and maintenance for this collection of information is based on agency communication with industry. Additional information needed to make a final calculation of the total burden hours (i.e. the number of respondents, the number of recordkeepers, the number of INAD applications received, etc.) is derived from agency records.

Dated: October 9, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–25918 Filed 10–15–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0266]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Medical Device Registration and Listing

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 November 14, 2001.

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: Wendy Taylor, 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.

Medical Device Registration and Listing—21 CFR 807.22 and 807.31 (OMB Control No. 0910–0387)—Extension

Section 510 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360) requires that manufacturers and initial importers engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of medical devices intended for human use and in commercial distribution register their establishments and list the devices they manufacture with FDA. This is accomplished by completing FDA Form 2891 entitled ''Initial Registration of Device Establishment'' and FDA Form 2892 entitled ''Medical Device Listing.'' In addition, each year active, registered establishments must notify FDA of changes to the current registration and device listing for the establishment. Annual changes to current registration information are preprinted on FDA Form 2891a and sent to registered establishments. The form must be sent back to FDA's Center for Devices and Radiological Health, even if no changes have occurred. Changes to listing information are submitted on Form 2892. On August 14, 2001, all hospitals who reprocess single-use devices will be required to register and list their activities. Under the Food and Drug Administration Modernization Act of 1997, foreign manufacturers are now required to register their establishments and list their devices, but foreign registration and listing will be covered under a separate information requirement. FDA will also accept voluntary registration and listings from firms not covered above that wish to be registered with FDA.

In addition, under § 807.31 (21 CFR 807.31), each owner or operator is required to maintain a historical file containing the labeling and advertisements in use on the date of initial listing, and in use after October 10, 1978, but before the date of initial listing. The owner or operator must maintain in the historical file any labeling or advertisements in which a material change has been made anytime after initial listing, but may discard labeling and advertisements from the file 3 years after the date of the last shipment of a discontinued device by an owner or operator. Along with the recordkeeping requirements above, the owner or operator must be prepared to submit to FDA all labeling and advertising mentioned above (§ 807.31(e)).

The information collected through these provisions is used by FDA to identify firms subject to FDA's regulations and is used to identify geographic distribution in order to effectively allocate FDA's field resources for these inspections and to identify the class of the device that determines the inspection frequency. When complications occur with a particular device or component, manufacturers of similar or related devices can be easily identified.

The likely respondents to this information collection will be domestic establishments engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of medical devices intended for human use and commercial distribution.

In the **Federal Register** of July 6, 2001 (66 FR 35642), the agency requested comments on the proposed collection of information. No comments were received.

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

TABLE 1.—ESTIMATED YEAR 1 ANNUAL REPORTING BURDEN[1]

21 CFR Section	FDA Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
807.22(a)	Form 2891 Initial Establishment Registration	2,045	1	2,045	0.25	511
807.22(a) (hospital reuse manufacturers)	Form 2891 Initial Establishment Registration	2,000	1	2,000	0.25	500
807.22(b)	Form 2892 Device Listing—initial and updates	3,450	1	3,450	0.50	1,725
807.22(b) (hospital reuse manufacturers)	Form 2892 Device Listing—initial and updates	2,000	10	20,000	0.50	10,000
807.22(a)	Form 2891(a)—Registration Update	16,500	1	16,500	0.25	4,125
807.31(e)		200	1	200	0.50	100
Total year 1 burden hours						16,961

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