and clearance under the emergency processing provisions of the PRA (44 U.S.C. 3507(j) and 5 CFR 1320.13). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the collection of information and has assigned OMB control number 0910–0431. The approval expires on May 31, 2000. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: December 22, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 99–33760 Filed 12–28–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–4068]

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

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 January 28, 2000.

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: JonnaLynn P. Capezzuto, Office of Information Resources Management (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.

Advisory Opinions—21 CFR 10.85 (OMB Control Number 0910–0193)—Extension

Section 10.85 (21 CFR 10.85), issued under section 701(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(a)), provides that an interested person may request an advisory opinion from the Commissioner of Food and Drugs (the Commissioner) on a matter of general applicability. Section 10.85 sets forth the format and instructions for making an advisory opinion request. When making a request, the petitioner must provide a concise statement of the issues and questions on which an opinion is requested and a full statement of the facts and legal points relevant to the request. An advisory opinion represents the formal position of FDA on a matter of general applicability. Respondents to this collection of information are parties seeking an advisory opinion from the Commissioner on the agency's formal position for matters of general applicability.

In the **Federal Register** of September 28, 1999 (64 FR 52329), the agency requested comments on the proposed collection of information. No significant comments were received.

FDA estimates the burden of 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
10.85	3	1	3	16	48

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

The burden estimate for this collection of information is based on an average for the period 1996 through 1998 with each advisory opinion requiring an estimated 16 hours of preparation time.

Dated: December 22, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 99–33757 Filed 12–28–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–4069]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Notice of Participation

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 January 28, 2000.

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: JonnaLynn P. Capezzuto, Office of Information Resources Management (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.

Notice of Participation—21 CFR 12.45 (OMB Control Number 0910–0191)—Extension

Under part 12 (21 CFR part 12) regulations issued under sections 201 to 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 to 393), any interested person may participate in a formal evidentiary hearing, either personally or through a representative by filing a notice of participation under § 12.45. Section 12.45 requires that any person filing a notice of participation state the person's specific interest in the proceedings, including the specific issues of fact about which the person desires to be heard. This section also requires that the notice include a statement that the person will present testimony at the hearing and will comply with specific requirements in § 12.85 or, in the case of a hearing before a public board of inquiry, in 21 CFR 13.25, concerning disclosure of data and information by participants. A participant's appearance can be struck by the presiding officer in accordance with § 12.45(e). The information obtained is used by the presiding officer and other participants in a hearing to identify specific interests to be presented. This preliminary information serves to expedite the prehearing conference and commits participation. The affected respondents are individuals or households, State or local governments, not-for-profit institutions and businesses or other for-profit groups and institutions.

In the **Federal Register** of September 28, 1999 (64 FR 52330), the agency requested comments on the proposed collections of information. No significant comments were received.

FDA estimates the burden of 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
12.45	30	1	30	3	90

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

The agency bases this estimate on an average for the period 1996 through 1998 in which each notice of participation filed took an estimated 3 hours to complete.

Dated: December 22, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 99–33759 Filed 12–28–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Office of Strategic Planning; Statement of Organization, Functions, and Delegations of Authority

Part F of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Health Care Financing Administration (HCFA), (**Federal Register**, Vol. 63, No. 45, p. 11448 dated Monday, March 9, 1998 is amended to reflect a functional realignment in the Office of Strategic Planning. The realignment moves the international communications function from the Office of Professional Relations, Center for Health Plans and Providers to the Office of Strategic Planning (OSP). The purpose of the realignment is to consolidate HCFA's international communications function within OSP to better serve the needs of the international community and intergovernmental agencies.

The specific amendments to part F are described below:

Section F.20., (Functions) is amended to read as follows:

4. Office of Strategic Planning (FAK)

- Develops and manages the long-term strategic planning process for the Agency; responsible for the Agency's conformance with the Strategic Plan requirements of the Government Performance and Results Act (GPRA).
- Provides analytic support and information to the Administrator and the Executive Council needed to establish Agency goals and directions.
- Performs environmental scanning, identifying, evaluating, and reporting emerging trends in health care delivery and financing and their interactions with Agency programs.
- Manages strategic, crosscutting initiatives.
- Designs and conducts research and evaluations of health care programs, studying their impacts on beneficiaries, providers, plans, States and other partners and customers, designing and assessing potential improvements, and developing new measurement tools.
- Coordinates all Agency demonstration activities, including development of the research and demonstration annual plan, evaluation of all Agency demonstrations, and assistance to other components in the design of demonstrations and studies.
- Manages assigned demonstrations, including Federal review, approval, and oversight; coordinates and participates with departmental components in experimental health care delivery projects.
- Develops research, demonstration, and other publications and papers related to health care issues.
- Serves as contact in HCFA for international visitors. Responds to requests from intergovernmental agencies and the international community for information related to the United States health care system.

Dated: November 23, 1999.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

[FR Doc. 99–33746 Filed 12–28–99; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Availability of a Draft Recovery Plan for the Bighorn Sheep in the Peninsular Ranges for Review and Comment

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of document availability.

SUMMARY: The U.S. Fish and Wildlife Service (Service) announces the availability for public review of a draft recovery plan for the bighorn sheep in the Peninsular Ranges of southern California. The Peninsular bighorn sheep represents a distinct vertebrate population that is restricted to east facing, lower elevation slopes typically