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
179.21(b)(1) and 179.21(b)(2)(i)	4	1	4	5	20

[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 of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
179.25(e)	3	120	360	1	360

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

The number of firms who process food using irradiation is extremely limited. FDA estimates that there is a single irradiation plant whose business is devoted primarily (i.e., approximately 100 percent) to irradiation of food and other agricultural products. Two other firms also irradiate small quantities of food (mainly spices). FDA estimates that this irradiation accounts for no more than 10 percent of the business for each of these firms. Although recent FDA rulemaking has authorized the irradiation of red meat, United States Department of Agriculture/Food Safety and Inspection Service (USDA/FSIS) has yet to issue a rule regarding meat irradiation. Actual implementation of meat irradiation cannot take place until USDA/FSIS final regulations are in place, which may not take place until later this fiscal year. At this time, FDA has no basis for estimating the extent of changes in the food irradiation business as a result of future USDA/FSIS actions. Therefore, the average estimated burden is based on: (1) Facility devoting 100 percent of its business (or 300 hours for recordkeeping annually) to food irradiation; (2) facilities devoting 10 percent of their business or 60 hours (2 x 30 hours) for recordkeeping annually, to food irradiation or (300 + 60)/3 = 120 x 3 firms x 1 hour = 360 hours annually.

No burden has been estimated for the labeling requirements in §§ 179.21(b)(2)(i) and (b)(2)(ii) and 179.26(c) because the information to be disclosed is information that has been supplied by FDA. Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not a collection of information.

Dated: December 22, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 99–33761 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–0240]

Agency Information Collection Activities; Announcement of OMB Approval; Veterinary Feed Directive

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Veterinary Feed Directive'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

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 a proposed rule entitled ''Animal Drug Availability Act; Veterinary Feed Directive'' that appeared in the **Federal Register** of July 2, 1999 (64 FR 35966 at 35970), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. 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 information collection and has assigned OMB control number 0910–0325. The approval expires on September 30, 2002. 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. 99–33758 Filed 12–28–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0529]

Agency Information Collection Activities; Announcement of OMB Approval; Guidance for Industry: Changes to an Approved New Drug Application (NDA) or Abbreviated New Drug Application (ANDA)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance for Industry: Changes to an ''Approved NDA or ANDA'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

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 the **Federal Register** of November 23, 1999 (64 FR 65716), the agency announced that the proposed information collection had been submitted to OMB for review

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