TABLE1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
610.2	86	82.72	7,114	3	21,342
640.101(f)(2)	5	4.40	22	5	110
660.6(b)	6	11.33	68	5	340
660.36(a)(2) and (b)	1	1	1	6	6
660.46(b)	2	8	16	5	80
Total					21,878

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

Dated: March 15, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–7012 Filed 3–21–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–5325]

Agency Information Collection Activities; Submission for OMB Review; Irradiation in the Production, Processing, and Handling of Food

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 April 21, 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: 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.

Irradiation in the Production, Processing, and Handling of Food—21CFR Part 179 (OMB Control Number 0910–0186—Extension)

Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(s) and 348), food irradiation is subject to regulation as a food additive. The regulations providing for uses of irradiation in the production, processing, and handling of food are found in part 179 (21 CFR part 179).

To assure safe use of radiation source, § 179.21(b)(1) requires that the label of sources bear appropriate and accurate information identifying the source of radiation and the maximum energy of radiation emitted by X-ray tube sources. Section 179.21(b)(2)(i) requires that the label or accompanying labeling bear adequate directions for installation and use.

Section 179.25(e) requires that food processors who treat food with radiation make and retain, for 1 year past the expected shelf life of the products up to a maximum of 3 years, specified records relating to the irradiation process (e.g., the food treated, lot identification, scheduled process, etc.).

The records required by § 179.25(e) are used by FDA inspectors to assess compliance with the regulation that establishes limits within which radiation may be safely used to treat food. The agency cannot ensure safe use without a method to assess compliance with the dose limits, and there are no practicable methods for analyzing most foods to determine whether they have been treated with ionizing radiation and are within the limitations set forth in part 179. Records inspection is the only way to determine whether firms are complying with the regulations for treatment of foods with ionizing radiation.

In the **Federal Register** of December 29, 1999 (64 FR 73054), the agency requested comments on the proposed collections of information (hereinafter referred to as the 60-day notice). No significant comments were received.

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

TABLE1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per 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, the 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 the following: (1) A facility devoting 100 percent of its business (or 300 hours for recordkeeping annually) to food irradiation; and (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.

As stated in the 60-day notice, no burden was 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. Therefore in this notice, table 1 from the 60-day notice (64 FR 73054 at 73055) estimated annual reporting burden is not included.

Dated: March 16, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–7008 Filed 3–21–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Arthritis Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed.

Name of Committee: Arthritis Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 11, 2000, 8 a.m. to 5 p.m.

Location: Holiday Inn, Walker and Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Kathleen R. Reedy or LaNise S. Giles, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, or e-mail: reedyk@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12532. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss biologics license application 99–0884, Enbrel™ (etanercept, Immunex), for an indication in patients with early rheumatoid arthritis.

Procedure: The meeting is open to the public from 8 a.m. to 2:30 p.m. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by April 3, 2000. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11:30 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 3, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: The meeting will be closed from 2:30 p.m. to 5 p.m. to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)).

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 15, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–7006 Filed 3–21–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Orally Inhaled and Nasal Drug Products Subcommittee of the Advisory Committee for Pharmaceutical Science; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Orally Inhaled and Nasal Drug Products Subcommittee of the Advisory Committee for Pharmaceutical Science.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 26, 2000, 8:30 a.m. to 5:30 p.m.

Location: 5630 Fishers Lane, Center for Drug Evaluation and Research Advisory Committee conference room 1066, Rockville, MD.

Contact Person: Kimberly Littleton Topper, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, e-mail: TOPPERK@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12539. Please call the Information Line for up-to-date information on this meeting.

Agenda: The subcommittee will discuss specific scientific issues where the additional expertise of the subcommittee is needed to aid the agency in refining draft guidances for orally inhaled and nasal drug products in the areas of: (1) Chemistry, manufacturing, and controls; and (2) in vitro and in vivo bioavailability/bioequivalence.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by April 19, 2000. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 19, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 14, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–7007 Filed 3–21–00; 8:45 am]

BILLING CODE 4160–01–F