Respondents	Number of respondents	Responses/ respondent	Average burden response (hrs)
Interview Booklet	4800	1	30/60
Medical History Questionnaire (male)	2400	1	1
Medical Records Release Telephone Script	240	1	5/60
Medical History Questionnaire (female)	2400	1	1
Travel Form	480	1	20/60
Residence History	2400	1	5/60
Refusal Questionnaire	48	1	5/60

This comparison will determine if the risk of mortality in Washington County (the exposed group) is significantly greater than Cache County (the control group). CDC/NCEH is requesting a three-year clearance. The annual burden hours are estimated to be 13,607.

Dated: December 15, 2000.

Nancy Cheal,

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

[FR Doc. 00–32548 Filed 12–20–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY–10–01]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Project

The Incidence of Breast and Other Cancers among Female Flight Attendants—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC)—Flight attendants experience exposures which may affect breast cancer risk including exposure to elevated levels of cosmic radiation and circadian rhythm disruption. This study will evaluate the incidence of breast and other cancers among a cohort of approximately 10,000 women who were employed as flight attendants.

The occurrence of breast and other cancers will be obtained from death certificates and from telephone interviews with living women and next-of-kin of deceased women. Each interview will take approximately 60 minutes to complete. Medical records will be requested to confirm cancer diagnoses. The primary analysis will evaluate the risk of breast and other cancers associated with occupational exposure within the cohort. The secondary analysis will compare the incidence of breast and other cancers in the cohort to that in the general population, with adjustment for factors which might increase cancer risk in the cohort independent of occupational exposure to cosmic radiation and circadian rhythm disruption. The annualized total burden is 10,525 hours.

Respondents	Number of respondents	Number of responses/ respondent	Avg. burden per response (in hrs.)
Flight attendants/proxies	10,000	1	60/60
Flight attendants/proxies whose eligibility for the study is unknown	300	1	5/60
Medical providers	1,000	1	30/60

Dated: December 15, 2000.

Nancy Cheal,

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

[FR Doc. 00–32549 Filed 12–20–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1637]

Agency Information Collection Activities; Proposed Collection; Comment Request; Transmittal of Advertising and Promotional Labeling for Drugs and Biologics for Human 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 the collection of information regarding the promotion of prescription human drugs and biologics—specifically advertising and promotional labeling.

DATES: Submit written or electronic comments on the collection of information by February 20, 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: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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.

Transmittal of Advertising and Promotional Labeling for Drugs and Biologics for Human Use (OMB Control Number 0910–0376) (Form FDA 2253)

Under § 314.81(b)(3)(i) (21 CFR 314.81(b)(3)(i)), sponsors of approved applications for marketed prescription drugs and antibiotic drugs for human use are required to submit specimens of promotional labeling and advertisements at the time of initial dissemination of the labeling and at the time of initial publication of the advertisements. Each submission is required to be accompanied by a completed transmittal Form FDA 2253 (Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use). Statutory authority for the collection of this information is provided by sections 505(a), (b), (j), and (k) and 701(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a), (b), (j), and (k) and 371(a)). Similarly, under 21 CFR 601.12(f)(4) (62 FR 39890, July 24, 1997; effective October 7, 1997), manufacturers of licensed biological products are required to submit specimens of advertising and promotional labeling to FDA in accordance with § 314.81(b)(3)(i). Statutory authority for the collection of this information is provided by section 351 of the Public Health Service Act (42 U.S.C. 262), which gives FDA the responsibility to prescribe standards designed to ensure the safety, purity, potency, and effectiveness of biological products. In furtherance of this responsibility, FDA regulates advertising and labeling for biological products. Currently, specimens of advertising and promotional labeling are submitted to FDA's Center for Biologics Evaluation and Research (CBER) with either Form FDA 2253 or Form FDA 2567, which is a two-part transmittal form that is also used to transmit other forms of labeling (e.g., circulars, package labels, and container labels) for CBER review when a sponsor is requesting premarket approval of a product or proposing changes to a product carton or container labeling.

The many types of promotional materials are described on Form FDA 2253 for easy reference. For example, possible submitted promotional materials could be a consumer advertisement, a professional sales aid, or a consumer broadcast advertisement. A single submission would include two copies each of the promotional materials, Form FDA 2253, and the approved product labeling. Submissions of multiple applications are handled in a similar manner as described in the form.

In 1998, FDA revised Form FDA 2253 to enable it to be used to transmit specimens of promotional labeling and advertisements for biological products as well as for prescription drugs and antibiotics. The revised form had the following major changes:

1. The revised, harmonized form is now used by sponsors of approved applications for marketed prescription drugs and antibiotic drugs regulated by the Center for Drug Evaluation and Research (CDER) who must submit specimens of advertisements and promotional labeling to the agency, and it may be used by manufacturers of licensed biological products regulated by the Center for Biologics and Research (CBER) who submit draft and/or final copies of promotional labeling and advertisements to the agency. The revised and harmonized Form FDA 2253 eliminated the need for sponsors to use two different forms to transmit similar materials for submission to the two centers. Although manufacturers of biological products had the option to continue to use Form FDA 2567 to transmit advertisements and promotional labeling if they wished, the other uses of Form FDA 2567 remained unchanged.

2. The revised, harmonized form updated the information about the types of promotional materials and the codes that are used to clarify the type of advertisement or promotional labeling (e.g., consumers, professionals, news services); and it helped ensure that the submission is complete.

3. The revised form provides for sponsors to submit specimens of multiproduct promotional labeling and advertisements to only two files; to the approved product application of the sponsor's choice (generally the most frequently promoted product), and to a company name file. This revision in the form has saved sponsors time and money by eliminating the need for making multiple submissions of the same promotional materials. In addition, because the form was revised, sponsors no longer need to maintain dual inventories of both forms, and they now have multiple processing capabilities.

From October 1, 1999, through September 30, 2000, 386 sponsors submitted 12,235 postmarketing reports via Form FDA 2253 to CDER; this included 2,343 multiple submissions. In the same time period, 134 sponsors submitted 4,243 postmarketing reports via Forms FDA 2253 and 2567 to CBER.

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 [2]	Total Annual Responses [3]	Hours per Response	Total Hours
CBER (none)	134 [4]	32	4,243	2	8,486
CDER § 314.81(b)(3)(i)	386 [5]	32	12,395	2	24,790
Total					33,276

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Average number (rounded to the nearest whole number) of submissions submitted annually per sponsor. We note that some sponsors submit only once per year, whereas one sponsor had 893 submissions in 1999.
[3] Total number of Form FDA 2253 submissions to CDER and Form FDA 2253 plus Form FDA 2567 to CBER in fiscal year (FY) 1999.
[4] Number of sponsors that submitted establishment license applications and product license applications to CBER in FY 1999.
[5] Number of sponsors that submitted new drug applications (including applications for new antibiotics), abbreviated new drug applications, and abbreviated antibiotic applications in FY 1999.

In FY 1999, CDER received a total of 12,395 submissions and CBER received 4,353 submissions that would require the use of this form. FDA estimates that 2 hours would be required for an industry regulatory affairs specialist to fill out the form, collate the documentation, and send the submissions to CDER or CBER.

Electronic Submission of Promotional Materials Regarding Prescription Drugs and Biologics for Human Use

CDER and CBER are currently piloting with approximately 20 sponsors, different methods to submit postmarketing submissions of advertising and promotional labeling. FDA anticipates publishing in the **Federal Register** a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Prescription Drug Advertising and Promotional Labeling.'' By using this suggested format for electronically submitting promotional materials, we anticipate that by January 2002, sponsors will submit about 20 percent of all materials electronically via Form FDA 2253. Further, we anticipate posting a fillable electronic Form FDA 2253 on FDA's Internet site. Applicants may then have the option to fill out the form on their computer, and with additional software, they can maintain records regarding submitted promotional materials.

Dated: December 14, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–32617 Filed 12–20–00 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1395]

Agency Information Collection Activities; Announcement of OMB Approval; Medicated Feed Mill License

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

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 October 6, 2000 (65 FR 59852), 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 0910–0337. The approval expires on November 30, 2003. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: December 14, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–32615 Filed 12–20–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1316]

Agency Information Collection Activities; Announcement of OMB Approval; Guidance for Industry on How to Use E–Mail to Submit a Request for a Meeting or Teleconference to the Office of New Animal Drug Evaluation

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 on How to Use E–Mail to Submit a Request for a Meeting or Teleconference to the Office of New Animal Drug Evaluation'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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 September 21, 2000 (65 FR 57194), 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 0910–0452. The approval expires on November 30, 2003. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.