The secondary peer review will be conducted by the NIOSH Secondary Review Committee which evaluates how the applications will contribute to the purpose for this program as stated at the beginning of this announcement.

V.3. Anticipated Announcement and Award Dates

Award notification dates are expected to be June 1, 2005 with award start dates of July 1, 2005.

VI. Award Administration Information

VI.1. Award Notices

Successful applicants will receive a Notice of Grant Award (NGA) from the CDC Procurement and Grants Office. The NGA shall be the only binding, authorizing document between the recipient and CDC. The NGA will be signed by an authorized Grants Management Officer, and mailed to the recipient fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review by mail.

VI.2. Administrative and National Policy Requirements

45 CFR Part 74 and Part 92

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: *http://www.access.gpo.gov/nara/cfr/cfr-table-search.html.*

The following additional requirements apply to this project:

- AR–1* Human Subjects Requirements
- AR–2* Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
- AR–3* Animal Subjects Requirements
- AR–10 Smoke-Free Workplace Requirements
- AR–11 Healthy People 2010
- AR–12 Lobbying Restrictions

*Applies only to ERC Pilot Project Research Training Program.

Additional information on these requirements can be found on the CDC Web site at the following Internet address: *http://www.cdc.gov/od/pgo/funding/ARs.htm.*

VI.3. Reporting Requirements

You must provide CDC with an original, plus two hard copies of the following reports:

1. Initial interim progress report is due December 1, 2004. This report is required on December 1, on an annual basis. The progress report will serve as your non-competing continuation application, and must contain the following elements:

a. Current Budget Period Activities Objectives.

b. Current Budget Period Financial Progress.

c. New Budget Period Program Proposed Activity Objectives.

d. Budget and justification.

e. Additional Requested Information.

f. Measures of Effectiveness.

2. Financial status report, no more than 90 days after the end of each budget period. The initial report is due September 30, 2006.

3. Final financial and performance reports, no more than 90 days after the end of the project period. These reports must be mailed to the Grants Management or Contract Specialist listed in the ''Agency Contacts'' section of this announcement.

VII. Agency Contacts

For general questions about this announcement, contact:

Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770–488–2700.

For program technical assistance, contact:

John T. Talty, Program Officer, Office of Extramural Programs, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 4676 Columbia Parkway, Mailstop C–7, Cincinnati, OH 45226–1998, Telephone: (513) 533–8241, E-mail: *jtt2@cdc.gov.*

For financial, grants management, or budget assistance, contact: Cynthia Y. Mitchell, Grants Management Specialist, CDC Procurement and Grants Office, 626 Cochrans Mill Rd., Mailstop P05, Pittsburgh, PA 15236, Telephone: (412) 386–6434, E-mail: *CMitchell@cdc.gov.*

VIII. Other Information

A pre-application technical assistance conference call will be held from 2 to 3 p.m. (eastern time) on May 13, 2004, to allow potential applicants the opportunity to ask questions about this announcement. The call in number is 1–866–524–1250, and the participant passcode is 469181.

Dated: April 2, 2004.

William P. Nichols,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 04–7936 Filed 4–7–04; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0093]

Agency Information Collection Activities; Proposed Collection; Comment Request; Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution

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 requirements governing the registration of producers of drugs and listing of drugs in commercial distribution.

DATES: Submit written or electronic comments on the collection of information by June 7, 2004.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments.* Submit written comments on the collection of information to the Division of Dockets Management (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 Management Programs (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 1320.39(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 these topics: (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.

Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution—(21 CFR Part 207)—(OMB Control Number 0910–0045—Extension)

Under section 510 of the Federal Food, Drug, and Cosmetic Act (the act), (21 U.S.C. 360), FDA is authorized to establish a system for registration of producers of drugs and for listing of drugs in commercial distribution. To implement section 510 of the act, FDA issued part 207 (21 CFR part 207). Under § 207.20, manufacturers, repackers, and relabelers that engage in the manufacture, preparation, propagation, compounding, or processing of human or veterinary drugs and biological products, including bulk drug substances and bulk drug substances for prescription compounding, and drug premixes as well as finished dosage forms, whether prescription or over-the-counter, are required to register their establishment. In addition, manufacturers, repackers, and relabelers are required to submit a listing of every drug or biological product in commercial distribution. Owners or operators of establishments that distribute, under their own label or trade name, a drug product manufactured by a registered establishment are not required to either register or list. However, distributors may elect to submit drug listing information in lieu of the registered establishment that manufactures the drug product. Foreign drug establishments must also comply with the establishment registration and product listing requirements if they import or offer for import their products into the United States.

Under §§ 207.21 and 207.22, establishments, both domestic and foreign, must register with FDA by submitting Form FDA–2656 (Registration of Drug Establishment) within 5 days after beginning the manufacture of drugs or biologicals, or within 5 days after the submission of a drug application or biological license application. In addition, establishments must register annually by returning, within 30 days of receipt from FDA, Form FDA–2656e (Annual Update of Drug Establishment). (Note: This form is no longer mailed to registrants by FDA; updating registration information is estimated in table 1 of this document by the information submitted annually on Form FDA–2656). Changes in individual ownership, corporate or partnership structure location, or drug-handling activity must be submitted as amendments to registration under § 207.26 within 5 days of such changes. Distributors that elect to submit drug listing information must submit Form FDA–2656 to FDA and a copy of the completed form to the registered establishment that manufactured the product to obtain a labeler code. Establishments must, within 5 days of beginning the manufacture of drugs or biologicals, submit to FDA a listing for every drug or biological product in commercial distribution at that time by using Form FDA–2657 (Drug Product Listing). Private label distributors may elect to submit to FDA a listing of every drug product they place in commercial distribution. Registered establishments must submit to FDA drug product listing for those private label distributors who do not elect to submit listing information by using Form FDA–2658 (Registered Establishments' Report of Private Label Distributors).

Under § 207.25, product listing information submitted to FDA by domestic and foreign manufacturers must, depending on the type of product being listed, include any new drug application number or biological establishment license number, copies of current labeling and a sampling of advertisements, a quantitative listing of the active ingredient for each drug or biological product not subject to an approved application or license, the National Drug Code number, and any drug imprinting information.

In addition to the product listing information required on Form FDA–2657, FDA may also require, under § 207.31, a copy of all advertisements and a quantitative listing of all ingredients for each listed drug or biological product not subject to an approved application or license; the basis for a determination, by the establishment, that a listed drug or biological product is not subject to marketing or licensing approval requirements; and a list of certain drugs or biological products containing a particular ingredient. FDA may also request, but not require, the submission of a qualitative listing of the inactive ingredients for all listed drugs or biological products, and a quantitative listing of the active ingredients for all listed drugs or biological products subject to an approved application or license.

Under § 207.30, establishments must update their product listing information by using Form FDA–2657 and/or Form FDA–2658 every June and December or, at the discretion of the establishment, when any change occurs. These updates must include the following information: (1) A listing of all drug or biological products introduced for commercial distribution that have not been included in any previously submitted list, (2) all drug or biological products formerly listed for which commercial distribution has been discontinued, (3) all drug or biological products for which a notice of discontinuance was submitted and for which commercial distribution has been resumed, and (4) any material change in any information previously submitted. No update is required if no changes have occurred since the previously submitted list.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section/Form No.	No. of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
FDA–2656 (Registration of Drug Establishment) 207.21 207.22 207.25 207.26 207.40	18,430	.36	6,700	2.50	16,750
FDA–2656 (Annual Update of Drug Establishment) 207.21 207.22 207.25 207.26 207.40	8,382	.82	6,859	2.50	17,147.50
FDA–2657 (Drug Product Listing) 207.21 207.22 207.25 207.30 207.31 207.40	15,530	3	46,713	2.50	116,782.50
FDA–2658 (Registered Establishments' Report of Private Label Distributors) 207.21 207.22 207.25 207.30 207.31	7,216	2.14	15,415	2.50	38,537.50
Total Reporting Burden					189,217.50

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

Dated: March 29, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–7907 Filed 4–7–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0463]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Infant Formula Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 13, 2004 (69 FR 1985), 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 0910–0256. The approval expires on March 31, 2007.

A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: April 2, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–8024 Filed 4–7–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0507]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Experimental Study of Trans Fat Claims on Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Experimental Study of Trans Fat Claims on Food'' has been approved by the Office of Management and Budget