TRANSACTIONS GRANTED EARLY TERMINATION BETWEEN: 112596 AND 120696—Continued

Name of acquiring person, name of acquired person, name of acquired entity	PMN No.	Date terminated
The Gordon Gray 1956 Living Trust, InterMedia Partners, L.P., Kauai CableVision, L.P	97–0510	12/05/96
Mercury General Corporation, William M. Cameron, American Fidelity Insurance Company	97–0511	12/05/96
Mercury General Corporation, Lynda L. Cameron, American Fidelity Insurance Company	97–0512	12/05/96
Ronald W. Burkle, The Starkman Family Trust, Jerry's Famous Deli, Inc.	97–0517	12/05/96
Unitrin, Inc., Gregory M. Shepard and Tracy M. Shepard, Union Automobile Indemnity Company	97–0518	12/05/96
Bemis Company, Inc., Paramount Packaging, L.L.C., Paramount Packaging, L.L.C	97–0520	12/05/96
American Financial Group, Inc., American Eagle Group, Inc., American Eagle Group, Inc	97–0523	12/05/96
Bemis Company, Inc., Paramount Packaging Corporation, Paramount Packaging Corporation	97–0526	12/05/96
Ryder System, Inc., Leland E.G. Larson, School Bus Services, Inc	97–0507	12/06/96
MEI Holdings, L.P., Mountasia Entertainment International, Inc., Mountasia Entertainment International, Inc	97–0625	12/06/96

FOR FURTHER INFORMATION CONTACT: Sandra M. Peay or Parcellena P. Fielding, contact representatives—Federal Trade Commission, Premerger Notification Office, Bureau of Competition, room 303, Washington, D.C. 20580, (202) 326–3100.

By Direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 96–32665 Filed 12–23–96; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N–0458]

Agency Information Collection Activities: Proposed Collection; Comment Request; Extension

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, 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 relating to the affirmation of generally recognized as safe (GRAS) substances.

DATES: Submit written comments on the collection of information by February 24, 1997.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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 listed below.

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.

Affirmation of Generally Recognized As Safe (GRAS) Status (21 CFR 170.35(c)(1))—(OMB Control Number 0910–0132)—Extension

Under authority of sections 201, 402, 409, and 701 of the act (21 U.S.C. 321, 342, 348, and 371), FDA reviews petitions for affirmation as GRAS which are submitted on a voluntary basis by the food industry and other interested parties. Under section 409 of the act (21 U.S.C. 348), the agency has the authority to regulate food additives. Section 201(s) of the act (21 U.S.C. 321(s)), defines ''food additive'' and expressly excludes from the definition substances generally recognized as safe for use in food.

Specifically under section 201(s) of the act, a substance is GRAS if it is generally recognized among experts qualified by scientific training and experience to evaluate its safety, to be safe through either scientific procedures or common use in food. The act has historically been interpreted to permit food manufacturers to make their own determination that use of a substance in food is GRAS. To implement the GRAS provisions of the act, FDA has issued procedural regulations under § 170.35(c)(1). These regulations establish a process by which a person may obtain FDA concurrence with a GRAS determination; this concurrence is referred to as ''GRAS affirmation.'' These regulations set forth the information to be submitted to FDA to obtain agency concurrence that a substance is GRAS (§ 170.35(c)(1)).

GRAS petitions are reviewed by FDA to ascertain whether the available data establish that the intended use of the substance is GRAS based upon either a history of the safe use of the substance, or upon widely available safety data (scientific procedures). The GRAS affirmation process is a voluntary one, and there is some risk that FDA may not

agree with the petitioner's GRAS determination. The GRAS petition process does provide a public procedure for coordinating GRAS determinations. The process reduces the potential for public health problems when substances are marketed based upon unwarranted safety determinations and allows a food manufacturer to rely on the lawful status of a substance that has been affirmed by FDA as GRAS.

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

ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
170.35(c)(1)	5	1	5	2614 (avg.)	13,070

There are no capital costs or operating and maintenance costs associated with this collection.

This estimate is based on the number of GRAS affirmation petitions received in 1995. Although the burden varies with the type, size, and complexity of the petition submitted, GRAS petitions may involve analytical work and analysis of appropriate toxicological studies, as well as the work of drafting the petition itself.

Since 1980, FDA has not received any petitions for affirmation of GRAS status under 21
CFR part 186—Indirect Food Substances Affirmed As Generally Recognized As Safe. Section 184.1(a) (21 CFR 184.1(a)) affirms the use of those substances affirmed as GRAS in 21 CFR part 184—Direct Food Substances Affirmed As Generally Recognized As Safe, for use as indirect food ingredients.

Dated: December 13, 1996.

William K. Hubbard.

Associate Commissioner for Policy Coordination.

[FR Doc. 96–32551 Filed 12–23–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0467]

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

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 23, 1997.

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: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Geraldine M. Hogan, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1481.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Gender Differences in Perception of Risks Communicated by Prescription and Over-the-Counter (OTC) Drug Labels

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. The Marketing Practices and Communications Branch of FDA's Division of Drug Marketing, Advertising, and Communications is studying the effectiveness of various formats for the presentation of risk and benefit information for OTC and prescription drugs to male and female patients through patient labeling. To gain information about the value and utility of benefit and risk information presented in several formats, three studies will be undertaken. In each study subjects will examine materials varied by one or more risk formatting variables for one prescription and one OTC drug. Subjects will be recruited at large shopping malls. They will be brought to a private interview room where they will examine the materials, and a structured interview will be conducted. Equal numbers of subjects of each gender will be included in each study. In addition, there will be a control group for each study that receives ''no-risk'' information labels for the drugs. The original study design was to use male-oriented and female-oriented drugs with 2,700 respondents. Based on focus group responses, the design was refined. It was determined that more accurate information would be obtained by assessing males' and females' responses to gender-neutral drugs. Accordingly, the sample size has been reduced to 960. The annual estimated hour burden for respondents is 480 hours.

ESTIMATED ANNUAL REPORTING BURDEN

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
960	1	1	0.5	480

There are no capital costs or operating and maintenance costs associated with this collection.