

Trans #	Acquiring	Acquired	Entities
20060182 .....	ValueAct Capital Master Fund, L.P ...	The Reynolds and Reynolds Company.	The Reynolds and Reynolds Company.
20060201 .....	MediaNews Group, Inc. ....	Gannett Co., Inc .....	Texas-New Mexico Newspapers Partnership.
20060221 .....	Autonomy Corporation plc .....	Verity, Inc .....	Verity, Inc.
<b>Transactions Granted Early Termination—12/01/2005</b>			
20060196 .....	Johnson & Johnson .....	Biovail Corporation .....	Biovail Laboratories International SRL.

**FOR FURTHER INFORMATION CONTACT:**

Sandra M. Peay, Contact Representative or Renee Hallman, Contact Representative, Federal Trade Commission, Premerger Notification Office, Bureau of Competition, Room H-303, Washington, DC 20580, (202) 326-3100.

By Direction of the Commission.

**Donald S. Clark,**

*Secretary.*

[FR Doc. 05-24357 Filed 12-21-05; 8:45 am]

**BILLING CODE 6750-01-M**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration on Aging

#### Agency Information Collection Activities; Proposed Collection; Comment Request; State Annual Long-Term Care Ombudsman Report and Instructions for Older Americans Act Title VII

**AGENCY:** Administration on Aging, HHS.

**ACTION:** Notice

**SUMMARY:** The Administration on Aging (AoA) 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 information collection requirements relating to State Annual Long-Term Care Ombudsman Report and instructions for Older Americans Act Title VII.

**DATES:** Submit written or electronic comments on the collection of information by February 21, 2006.

**ADDRESSES:** Submit electronic comments on the collection of information to: [sue.wheaton@aoa.gov](mailto:sue.wheaton@aoa.gov).

Submit written comments on the collection of information to: Administration on Aging, Washington, DC 20201. Attention: Sue Wheaton

**FOR FURTHER INFORMATION CONTACT:** Sue Wheaton, by telephone: (202) 357-3587 or by e-mail: [sue.wheaton@aoa.gov](mailto:sue.wheaton@aoa.gov).

**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 request 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, AoA is publishing notice of the proposed collection of information set forth in this document. With respect to the following collection of information, AoA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of AoA's functions, including whether the information will have practical utility; (2) the accuracy of AoA'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.

Under section 712(c), section 712(h)(1) and section 712(h)(B) of the Older Americans Act, as amended, states are required to provide information on ombudsmen activities to

AoA, which AoA is then required to present to Congress. The reporting system, the National Ombudsman Reporting System (NORS), was developed in response to these directives and other needs pertaining to the Long Term Care Ombudsman Program and approved by the Office of Management and Budget for use for the first time in FY 1995-96; it was extended a second time with slight modifications for use in FY 1997-2001 and extended for the third time with no change for use from FY 2002-2006. This current (fourth) request is to extend, with modifications, use of the existing State Annual Long-Term Care Ombudsman Report (and Instructions) from Older Americans Act Title VII grantees. The details of these proposed changes are contained on the AoA Web site at: [http://www.aoa.gov/prof/aoaprog/elder\\_rights/LTCombudsman/NORS/nors\\_form\\_instructions.asp](http://www.aoa.gov/prof/aoaprog/elder_rights/LTCombudsman/NORS/nors_form_instructions.asp). AoA estimates the burden of this collection of information as follows: Approximately one and one-half hour per respondent with 52 State Agencies on Aging responding annually.

Dated: December 19, 2005.

**Josefina G. Carbonell,**

*Assistant Secretary for Aging.*

[FR Doc. 05-24356 Filed 12-21-05; 8:45 am]

**BILLING CODE 4154-01-P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005N-0486]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Drug Administration Public Health Notification (formerly known as Safety Alert/Public Health Advisory) Readership Survey

**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 FDA Public Health Notification (formerly known as Safety Alert/Public Health Advisory) Readership Survey.

**DATES:** Submit written or electronic comments on the collection of information by February 21, 2006.

**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, Room 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:** Denver Presley, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

**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 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.

**FDA Public Health Notification (formerly known as Safety Alert/Public Health Advisory) Readership Survey (OMB Control Number 0910-0341)—Extension**

Section 705(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 375(b)) authorizes FDA to disseminate information concerning imminent danger to public health by any regulated product. The Center for Devices and Radiological Health (CDRH) communicates these risks to user communities through two publications: (1) The Public Health Notification (PHN) and (2) the Preliminary Public Health Notification (PPHN). The PHN is published when CDRH has information or a message to convey to health care practitioners that they would want to know in order to make informed clinical decisions about the use of a device or device type, and that information may not be readily available to the affected target audience in the health care community, and CDRH can make recommendations that will help the health care practitioner mitigate or avoid the risk.

The PPHN is also published when CDRH has information to convey to health care practitioners that they would want to know in order to make informed clinical decisions about the

use of a device or device type. However, two additional conditions exist that make the use of this type of notification preferable. First, CDRH's understanding of the problem, its cause(s), and the scope of the risk is still evolving, and in order to minimize the risk, the center believes that health care practitioners need the information they have, however incomplete, as soon as possible. Second, the problem is being actively investigated by the center, the industry, another agency or some other reliable entity, so that the center expects to be able to update the PPHN when definitive new information becomes available.

Notifications are sent to organizations affected by the risks discussed in the notification such as hospitals, nursing homes, hospices, home health care agencies, retail pharmacies, and other health care providers. Through a process for identifying and addressing postmarket safety issues related to regulated products, CDRH determines when to publish notifications.

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. FDA seeks to evaluate the clarity, timeliness, and impact of safety alerts and public health advisories by surveying a sample of recipients. Subjects will receive a questionnaire to be completed and returned to FDA. The information to be collected will address how clearly notifications for reducing risk are explained, the timeliness of the information, and whether the reader has taken any action to eliminate or reduce risk as a result of information in the alert. Subjects will also be asked whether they wish to receive future notifications electronically, as well as how the PHN program might be improved.

The information collected will be used to shape FDA's editorial policy for the PHN and PPHN. Understanding how target audiences view these publications will aid in deciding what changes should be considered in their content, format, and method of dissemination.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

No. of respondents	Annual Frequency per response	Total Annual responses	Hours per response	Total hours
308	3	924	.17	157

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on the history of the PHN program, it is estimated that an average of three collections will be conducted a year. The total burden of response time is estimated at 10 minutes per survey. This was derived by CDRH staff completing the survey and through discussions with the contacts in trade organizations.

Dated: December 8, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E5-7642 Filed 12-21-05; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005D-0274]

#### **Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Voluntary Hazard Analysis and Critical Control Point Manuals for Operators and Regulators of Retail and Food Service Establishments**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by January 23, 2006.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of Management Programs (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.

#### **Voluntary Hazard Analysis and Critical Control Point (HACCP) Manuals for Operators and Regulators of Retail and Food Service Establishments**

The draft Operator's Manual contains information and recommendations for operators of retail and foodservice establishments who wish to develop and implement a voluntary food safety management system based on HACCP principles. Operators may decide to incorporate some or all of the principles presented in the draft manual into their existing food safety management systems. The recordkeeping practices discussed in the draft manual are voluntary and may include documenting certain activities, such as monitoring and verification, which the operator may or may not deem necessary to ensure food safety. The draft manual includes optional worksheets to assist operators in developing and validating a voluntary food safety management system.

The draft Regulator's Manual contains recommendations for State, local, and tribal regulators on conducting risk-based inspections of retail and foodservice establishments, including recommendations about recordkeeping practices that can assist operators in preventing foodborne illness. These recommendations may lead to voluntary actions by operators based on consultation with regulators. For example, an operator may develop a risk control plan as an intervention strategy for controlling specific out-of-control foodborne illness risk factors identified during an inspection. Further, the draft manual contains recommendations to assist regulators when evaluating voluntary food safety management systems in retail and foodservice establishments. Such evaluations typically consist of the following two components: Validation (assessing whether the establishment's voluntary food safety management system is adequate to control food safety hazards) and verification (assessing whether the establishment is following its voluntary food safety management system). The draft manual includes a sample "Verification Inspection Checklist" to assist regulators when conducting verification inspections of establishments with voluntary food safety management systems.

Types of operator records discussed in the manuals and listed in the following burden estimates include: Food safety management systems (plans that delineate the formal procedures to follow to control all food safety hazards in an operation); risk control plans (HACCP-based, goal-oriented plans for achieving active managerial control over specific out-of-control foodborne illness risk factors); hazard analysis (written assessment of the significant food safety hazards associated with foods prepared in the establishment); prerequisite programs (written policies or procedures, including but not limited to, standard operating procedures, training protocols, and buyer specifications that address maintenance of basic operational and sanitation conditions); monitoring (records showing the observations or measurements that are made to help determine if critical limits are being met and maintained); corrective action (records indicating the activities that are completed whenever a critical limit is not met); ongoing verification (records showing the procedures that are followed to ensure that monitoring and other functions of the food safety management system are being implemented properly); and validation (records indicating that scientific and technical information is collected and evaluated to determine if the food safety management system, when properly implemented, effectively controls the hazards).

All recommendations in both manuals are voluntary. For simplicity and to avoid duplicate estimates for operator recordkeeping practices that are discussed in both manuals, the burden for all collection of information recommendations for retail and foodservice operators are estimated together in table 1 of this document, regardless of the manual in which they appear. Collection of information recommendations for regulators in the Regulator's Manual are listed separately in table 2 of this document.

The likely respondents to this collection of information are operators and regulators of retail and foodservice establishments.

In the **Federal Register** of July 21, 2005 (70 FR 42072), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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