Act, may be found in the FTC's privacy policy, at (*http://www.ftc.gov/ftc/privacy.shtm*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the proposed information requirements should be sent to Stephen Ecklund, Investigator, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Ave., N.W., Washington, D.C. 20580, (202) 326-2841.

SUPPLEMENTARY INFORMATION: Under the PRA, 44 U.S.C. 3501-3521, Federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. ''Collection of information'' means agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. 44 U.S.C. 3502(3); 5 CFR 1320.3(c). As required by the PRA, the FTC is providing this opportunity for public comment before requesting that OMB extend the existing paperwork clearance for the regulations noted herein. 44 U.S.C. 3506(c)(2)(A).

On October 10, 2008, the Commission sought public comments concerning the proposed collection of information. *See* 73 FR 60286. No comments were received. Pursuant to the OMB regulations that implement the PRA (5 CFR Part 1320), the Commission is providing this second opportunity for public comment while seeking OMB clearance for the FPLA regulations. All comments should be filed as prescribed in the **ADDRESSES** section above, and must be received on or before February 9, 2009.

The FPLA, 15 U.S.C. 1451-1461, was enacted to eliminate consumer deception concerning product size representations and package content information. The regulations that implement the FPLA, 16 CFR Parts 500 - 503, establish requirements for the manner and form of labeling applicable to manufacturers, packagers, and distributors of ''consumer commodities.''[2] Section 4 of the FPLA specifically requires packages or labels to be marked with: (1) A statement of identity; (2) a net quantity of contents disclosure; and (3) the name and place of business of a company that is responsible for the product.

Estimated annual hours burden: 7,570,740 total burden hours (solely relating to disclosure[3])

As in the past, Commission staff has used Census data[4] to estimate the number of companies subject to the FPLA. Staff conservatively estimates[5] that approximately 757,074 manufacturers, packagers, distributors, and retailers of consumer commodities make disclosures at an average burden of ten hours per entity, for a total disclosure burden of 7,570,740 hours.

Estimated annual cost burden: $158,985,540 (solely relating to labor costs)

The estimated annual labor cost burden associated with the FPLA disclosure requirements consists of an estimated hour of managerial and/or professional time per covered entity (at an estimated average hourly rate of $55), plus two hours of specialized clerical support[6] (at an estimated average hourly rate of $25), and seven hours of clerical time per covered entity (at an estimated average hourly rate of $15), for a total of $158,985,540 ($210 blended labor cost per covered entity x 757,074 entities).[7]

Total capital and start-up costs are de minimis. For many years, the packaging and labeling activities that require capital and start-up costs have been performed by covered entities in the ordinary course of business independent of the FPLA and implementing regulations. Similarly, firms provide in the ordinary course of business the information that the statute and regulations require be placed on packages and labels.

William Blumenthal

General Counsel

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[2] ''Consumer commodity'' means any article, product, or commodity of any kind or class which is customarily produced or distributed for sale through retail sales agencies or instrumentalities for consumption by individuals, or use by individuals for purposes of personal care or in the performance of services ordinarily rendered within the household, and which usually is consumed or expended in the course of such consumption or use.'' 16 CFR 500.2(c). For the precise scope of the term's coverage *see* 16 CFR 500.2(c); 503.2; 503.5. *See* also (*http://www.ftc.gov/os/statutes/fpla/outline.html*).

[3] To the extent that the FPLA-implementing regulations require sellers of consumer commodities to keep records that substantiate ''cents off,'' ''introductory offer,'' and/or ''economy size'' claims, staff believes that most, if not all, of the records that sellers maintain would be kept in the ordinary course of business, regardless of the legal mandates.

[4] Staff has drawn upon the U.S. Census Bureau's 2002 economic census, the most recent census available providing data for purposes of staff's instant estimates. *See* (*http://www.census.gov/econ/census02/guide/SUBSUMM.HTM*) and (*http://www.census.gov/prod/ec02/ec0231sg1.pdf*) (Table 2).

[5] Although the estimates are non-rounded figures, they remain estimates as they are the sum total of projected industry codes subject to the FPLA. But, even allowing for industries that may apply, the Census data do not separately break out non-household products from household use and, accordingly, overstate what is actually subject to the FPLA.

[6] ''Specialized clerical support'' consists of graphic design specialists, working by computer to design the appearance and layout of product packaging, including appropriate display of the disclosures required by the FPLA regulations.

[7] Based generally on the National Compensation Survey: Occupational Earnings in the United States, 2007, U.S. Department of Labor, Bureau of Labor Statistics (August 2008) (''BLS National Compensation Survey'') (citing the mean hourly earnings for management occupations, legal occupations/lawyers, and assorted clerical positions), available at (*http://www.bls.gov/ncs/ocs/sp/nctb0300.pdf*). Clerical estimates are derived from the above source data, applying roughly a mid-range of mean hourly rates for potentially applicable clerical types, *e.g.*, computer operators, data entry and information processing workers.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[ATSDR–249]

Announcement of Final Priority Data Needs for Two Priority Hazardous Substances

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), U.S. Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice announces the final priority data needs for two priority hazardous substances (see Table 1) as part of the continuing development and implementation of the ATSDR Substance-Specific Applied Research Program (SSARP). The notice also serves as a continuous call for voluntary research proposals.

The exposure and toxicity priority data needs in this notice were distilled from the data needs identified in ATSDR's toxicological profiles by the logical scientific approach described in a decision guide published in the **Federal Register** on September 11, 1989 (54 FR 37618). The priority data needs represent essential information to improve the database for conducting public health assessments. Research to address these priority data needs will help to determine the types or levels of exposure that may present significant risks of adverse health effects in people exposed to the hazardous substances.

The priority data needs announced in this notice reflect the opinion of ATSDR, in consultation with other federal programs, about the research needed pursuant to ATSDR's authority under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980

(Superfund), or CERCLA, as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA) [42 U.S.C. 9604(i)]. The needs identified here do not represent the priority data needs for any other agency or program.

Consistent with section 104(i)(12) of CERCLA as amended [42 U.S.C. 9604(i)(12)], nothing in this research program shall be construed to delay or otherwise affect or impair the President, the Administrator of ATSDR, or the Administrator of the Environmental Protection Agency (EPA) from exercising any authority regarding any other provision of law, including the Toxic Substances Control Act of 1976 (TSCA), the Federal Insecticide, Fungicide, and Rodenticide Act of 1972 (FIFRA), or the response and abatement authorities of CERCLA.

ATSDR worked with other federal programs to determine common substance-specific data needs and mechanisms to implement research that may include authorities under TSCA and FIFRA, private-sector voluntarism, or the direct use of CERCLA funds.

Table 1 presents the priority data needs for acrolein and barium, two priority substances included in the ATSDR Priority List of Hazardous Substances (73 FR 12178, March 6, 2008). These priority data needs were initially announced by ATSDR in the **Federal Register** on September 8, 2006 (71 FR 53102). The public was invited to comment on these data needs for these two substances during a 90-day period. No public comments were received. These priority data needs and accompanying documents were reviewed by EPA and the National Institute of Environmental Health Sciences (NIEHS), and will be addressed by the mechanisms described in the ''Implementation of Substance-Specific Applied Research Program'' section of this **Federal Register** Notice.

TABLE 1—SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS FOR TWO PRIORITY HAZARDOUS SUBSTANCES

Substance	Priority data needs
Acrolein	Exposure levels in humans living near hazardous waste sites and other populations.
	Exposure levels in children.
	Dose-response data for chronic duration [1] via inhalation exposure.
Barium	Dose-response data for acute duration [2] via oral exposure.

[1] 365 days or more.
[2] 14 days or less.

The substance-specific priority data needs were based on and determined from information in corresponding ATSDR toxicological profiles. Background technical information and justification for the priority data needs in this notice are in the priority data needs documents, available on ATSDR's Web site at *http://www.atsdr.cdc.gov/pdns/*. Printed copies are also available by written request from ATSDR (see **ADDRESSES** section of this notice).

Voluntary Research. This notice also serves as a continuous call for voluntary research proposals. Private-sector organizations may volunteer to conduct research to address specific priority data needs in this notice by submitting a letter of intent to ATSDR (see **ADDRESSES** section of this notice). A Tri-Agency Superfund Applied Research Committee (TASARC), comprised of scientists from ATSDR, the National Toxicology Program (NTP), and EPA will review all proposals.

DATES: The ATSDR voluntary research program is a continuous program, and private-sector organizations can volunteer to fill identified data needs from now until ATSDR announces that other research has been initiated for a specific data need.

ADDRESSES: The priority data needs are available on ATSDR's Web site at *http://www.atsdr.cdc.gov/pdns/*. Private-sector organizations interested in volunteering to conduct research to fill identified priority data needs should write to Nickolette Roney, Applied Toxicology Branch, Division of Toxicology and Environmental Medicine, ATSDR, 1600 Clifton Road, NE., Mailstop F–32, Atlanta, Georgia 30333; e-mail: *NRoney@cdc.gov*. Information about pertinent ongoing or completed research that may fill priority data needs cited in this notice should be similarly addressed. Also, use the same address to request printed copies of the priority data needs documents.

FOR FURTHER INFORMATION CONTACT: Nickolette Roney, Applied Toxicology Branch, Division of Toxicology and Environmental Medicine, ATSDR, 1600 Clifton Road, NE., Mailstop F–32, Atlanta, Georgia 30333; e-mail: *NRoney@cdc.gov*; telephone: (770) 488–3332; fax: (770) 488–4178.

SUPPLEMENTARY INFORMATION:

Background

CERCLA, as amended by SARA [42 U.S.C. 9604(i)], requires that ATSDR (1) develop jointly with EPA a list of hazardous substances found at National Priorities List (NPL) sites (in order of priority), (2) prepare toxicological profiles of these substances, and (3) ensure the initiation of a research program to address identified priority data needs associated with the substances.

The SSARP was initiated in 1991. A list of priority data needs for 38 priority hazardous substances was announced for public comment in the **Federal Register** on October 17, 1991 (56 FR 52178) and was published in final form on November 16, 1992 (57 FR 54150). In 1997, after releasing for public comment, ATSDR finalized the priority data needs for a second list of 12 substances and that priority data needs list was announced in the **Federal Register** on July 30, 1997 (62 FR 40820). ATSDR then identified priority data needs for a third list of 10 hazardous substances; this list was released as a draft for public comment and published in its final form on April 29, 2003 (68 FR 22704). On September 8, 2006 (71 FR 53102), ATSDR released for public comment the priority data needs for the two hazardous substances that are the subject of this final notice.

The ATSDR SSARP supplies the necessary information to improve the database to conduct public health assessments. The link between research and public health assessments and the process for distilling priority data needs from the data needs identified in associated ATSDR toxicological profiles are described in the ATSDR ''Decision Guide for Identifying Substance-Specific Data Needs Related to Toxicological Profiles'' (54 FR 37618, September 11, 1989).

Implementation of Substance-Specific Applied Research Program

In Section 104(i)(5)(D), CERCLA states that Congress believes the costs for conducting this research program should be borne by the manufacturers and processors of the hazardous substances found under the Toxic Substances Control Act of 1976 (TSCA); by registrants under the Federal Insecticide, Fungicide, and Rodenticide Act of 1972 (FIFRA); or by cost recovery from responsible parties under CERCLA. To execute this statutory intent, ATSDR developed a plan whereby parts of SSARP are being conducted through regulatory mechanisms (TSCA/FIFRA), private-sector voluntarism, and the direct use of CERCLA funds.

CERCLA also requires that ATSDR consider recommendations of the Interagency Testing Committee, established under section 4(e) of TSCA, for the types of research to be done. ATSDR actively participates on this committee. Federally funded projects that collect information from 10 or more respondents and that are funded by

cooperative agreements are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. If the proposed project involves research on human subjects, the applicants must comply with Department of Health and Human Services regulations (45 CFR part 46) regarding the protection of human subjects. The applicants must ensure that the project will be subject to initial and continuing review by the appropriate institutional review committees. Overall, by providing additional scientific information for the risk assessment process, data generated from this research will support other researchers who are conducting human health assessments involving these two substances.

The mechanisms for implementing SSARP are discussed next. The status of SSARP in addressing priority data needs of the first 60 priority hazardous substances through these mechanisms was described in a **Federal Register** Notice on December 13, 2005 (70 FR 73749).

A. TSCA/FIFRA

In developing and implementing SSARP, ATSDR and EPA established procedures to identify priority data needs of common interest to multiple federal programs. Where practicable, these data needs will be addressed through a program of toxicologic testing under TSCA or FIFRA. This part of the research will be conducted according to established TSCA/FIFRA procedures and guidelines.

B. Private-Sector Voluntarism

As part of SSARP, on February 7, 1992, ATSDR announced a set of proposed procedures for conducting voluntary research (57 FR 4758). Revisions based on public comments were published on November 16, 1992 (57 FR 54160). ATSDR strongly encourages private-sector organizations to propose research to address priority data needs at any time until ATSDR announces that research has already been initiated for a specific priority data need. Private-sector organizations may volunteer to conduct research to address specific priority data needs identified in this notice by submitting a letter of intent.

The letter of intent should be a brief statement (1–2 pages) that identifies the priority data need(s) to be filled and the methods to be used. TASARC will review these proposals and recommend to ATSDR the voluntary research projects that should be pursued—and how they should be conducted—with the volunteer organizations. ATSDR will enter into only those voluntary research projects that lead to high-quality, peer-reviewed scientific work. Additional details regarding the process for voluntary research are in the **Federal Register** Notices cited in this section.

C. CERCLA

Those priority data needs that are not addressed by TSCA/FIFRA or initial voluntarism will be considered for funding by ATSDR through its CERCLA budget. Much of this research program is envisioned to be unique to CERCLA—for example, research on substances not regulated by other programs or research needs specific to public health assessments. A current example of the direct use of CERCLA funds is a cooperative agreement with the Association of Minority Health Professions Schools (AMHPS) that supports the AMHPS Environmental Health, Health Services, and Toxicology Research programs.

Mechanisms to address these priority data needs may include a second call for voluntarism. Again, scientific peer review of study protocols and results would occur for all research conducted under this auspice.

ATSDR encourages private-sector organizations and other governmental programs to use ATSDR's priority data needs to plan their research activities.

Dated: January 6, 2009.

Ken Rose,

Director, Office of Policy, Planning, and Evaluation, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry.

[FR Doc. E9–189 Filed 1–8–09; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–R–262, CMS–10142 and CMS–R–137]

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

AGENCY: Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* CY 2010 Plan Benefit Package (PBP) and Formulary Submission for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP) *Use:* Under the Medicare Modernization Act (MMA), Medicare Advantage (MA) and Prescription Drug Plan (PDP) organizations are required to submit plan benefit packages for all Medicare beneficiaries residing in their service area. The plan benefit package submission consists of the formulary file, Plan Benefit Package (PBP) software, and supporting documentation as necessary. MA and PDP organizations will generate a formulary to illustrate their list of drugs, including information on prior authorization, step therapy, tiering, and quantity limits. Additionally, the PBP software will be used to describe their organization's plan benefit packages, including information on premiums, cost sharing, authorization rules, and supplemental benefits. CMS uses the formulary and PBP data to review and approve the plan benefit packages proposed by each MA and PDP organization.

CMS requires that MA and PDP organizations submit a completed formulary and PBP as part of the annual bidding process. During this process, organizations prepare their proposed plan benefit packages for the upcoming contract year and submit them to CMS for review and approval. Based on operational changes and policy clarifications to the Medicare program and continued input and feedback by the industry, CMS has made the necessary changes to the plan benefit package submission. *Form Number:* CMS–R–262 (OMB# 0938–0763); *Frequency:* Yearly; *Affected Public:* Business or other for-profits b. Not-for-profit institutions; *Number of Respondents:* 475; *Total Annual Responses:* 4987.5; *Total Annual Hours:* 12112.5.

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of*