

• *Mail*: NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34, 4676 Columbia Parkway, Cincinnati, OH 45226.

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All information received in response to this notice will be available for public examination and copying at the NIOSH Docket Office, Room 111, 4676 Columbia Parkway, Cincinnati, Ohio 45226. A complete electronic docket containing all comments submitted will be available on the NIOSH Web page at <http://www.cdc.gov/niosh/docket>, and comments will be available in writing by request. NIOSH includes all comments received without change in the docket, including any personal information provided.

#### FOR FURTHER INFORMATION CONTACT:

Lauralynn Taylor McKernan, NIOSH, Robert A Taft Laboratories, MS-C32, 4676 Columbia Parkway, Cincinnati, OH 45226, telephone: (513) 533-8542.

#### SUPPLEMENTARY INFORMATION: 2,3-

pentanedione is an alpha-diketone that has received attention as a substitute for diacetyl. 2,3-pentanedione is structurally very similar to diacetyl since 2,3-pentanedione is a 5-carbon alpha-diketone and diacetyl is a 4-carbon alpha-diketone. Published reports on the toxicity of 2,3-pentanedione are currently only in abstract form but suggest that in rats 2,3-pentanedione causes airway epithelial damage similar to that produced by diacetyl (Hubbs *et al.* 2010b; Morgan *et al.* 2010). Preliminary data also suggest that, under certain conditions, both diacetyl and 2,3-pentanedione can cause changes in the central nervous system (Hubbs *et al.* 2010a). Additional alpha-diketones of interest include, but are not limited to, those used in food manufacturing such as 2,3-hexanedione and 2,3-heptanedione (Kreiss *et al.* 2010).

NIOSH seeks to obtain materials, including published and unpublished reports and research findings, to evaluate the possible health risks of occupational exposure to 2,3-pentanedione and other alpha-diketones used as diacetyl substitutes. Examples of requested information include, but are not limited to, the following:

(1) Identification of industries or occupations in which exposures to 2,3-pentanedione, and other alpha-diketones used as diacetyl substitutes may occur;

(2) Trends in the production and use of 2,3-pentanedione, and other alpha-diketones;

(3) Description of work tasks and scenarios with a potential for exposure

to 2,3-pentanedione, and other alpha-diketones used as diacetyl substitutes;

(4) Workplace exposure measurement data in various types of industries and jobs where 2,3-pentanedione, and other alpha-diketones are used;

(5) Case reports or other health information demonstrating potential health effects in workers exposed to 2,3-pentanedione, and other alpha-diketones;

(6) Research findings from *in vitro* and *in vivo* toxicity studies;

(7) Information on control measures (e.g., engineering controls, work practices, personal protective equipment) being taken to minimize worker exposure to 2,3-pentanedione, and other alpha-diketones used as diacetyl substitutes;

(8) Educational materials for worker safety and training on the safe handling of 2,3-pentanedione and other alpha-diketones; and

(9) Data pertaining to the feasibility of establishing a REL for 2,3-pentanedione, and other alpha-diketones.

#### References

- Hubbs, A. F., Cumpston, A., Goldsmith, W. T., Battelli, L. A., Kashon, M. L., Jackson, M. C., Frazer, D. G., Fedan, J. S., Goravanahally, M. P., and Sriram, K. (2010a). Acute central neurotoxicity of inhaled alpha-diketone butter flavoring compounds in the rat brain. *Vet Path* 47(6), 57S.
- Hubbs, A. F., Moseley, A. E., Goldsmith, W. T., Jackson, M. C., Kashon, M. L., Battelli, L. A., Schwegler-Berry, D., Goravanahally, M. P., Frazer, D., Fedan, J. S., Kreiss, K., and Castranova, V. (2010b). Airway epithelial toxicity of the flavoring agent, 2,3-pentanedione. *The Toxicologist: Supplement to Toxicological Sciences* 114(1), 319.
- Kreiss, K., Day, G. A., Cummings, K. J., and Kullman, G. (2010). Diacetyl substitutes in bakery product manufacture *Am J Respir Crit Care Med* 181(1), A4650.
- Morgan, D. L., Kirby, P. J., Price, H. C., Bosquet, R. W., Taylor, G. J., Gage, N., and Flake, G. P. (2010). Inhalation toxicity of acetyl propionyl in rats and mice. *The Toxicologist: Supplement to Toxicological Sciences* 114(1), 316.

#### John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10142 and CMS-R-262]

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

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

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 2012 Bid Pricing Tool (BPT) for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP); *Use:* Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), and implementing regulations at 42 CFR, Medicare Advantage organizations (MAO) and Prescription Drug Plans are required to submit an actuarial pricing "bid" for each plan offered to Medicare beneficiaries for approval by CMS.

MAOs and PDPs use the Bid Pricing Tool (BPT) software to develop their actuarial pricing bid. The information provided in the BPT is the basis for the plan's enrollee premiums and CMS payments for each contract year. The tool collects data such as medical expense development (from claims data and/or manual rating), administrative expenses, profit levels, and projected plan enrollment information. By statute, completed BPTs are due to CMS by the first Monday of June each year. CMS reviews and analyzes the information provided on the Bid Pricing Tool.

Ultimately, CMS decides whether to approve the plan pricing (*i.e.*, payment and premium) proposed by each organization. *Form Number:* CMS-10142 (OMB#: 0938-0944); *Frequency:* Yearly; *Affected Public:* Business or other for-profits and not-for-profit institutions; *Number of Respondents:* 550; *Total Annual Responses:* 4,950; *Total Annual Hours:* 148,500. (For policy questions regarding this collection contact Diane Spitalnic at 410-786-5745. For all other issues call 410-786-1326.)

**2. Type of Information Collection**  
*Request:* Revision of a currently approved collection; *Title of Information Collection:* CY 2012 Plan Benefit Package (PBP) Software and Formulary Submission; 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 Plan Benefit Package (PBP) software, formulary file, and supporting documentation, as necessary. MA and PDP organizations use the PBP software to describe their organization's plan benefit packages, including information on premiums, cost sharing, authorization rules, and supplemental benefits. They also generate a formulary to describe their list of drugs, including information on prior authorization, step therapy, tiering, and quantity limits. Additionally, CMS uses the PBP and formulary 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 PBP and formulary 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. Refer to the

supporting document "Appendix B" for a list of changes. *Form Number:* CMS-R-262 (OMB#: 0938-0763); *Frequency:* Yearly; *Affected Public:* Business or other for-profits and not-for-profit institutions; *Number of Respondents:* 651; *Total Annual Responses:* 6,159; *Total Annual Hours:* 45,407. (For policy questions regarding this collection contact Kristy Holtje at 410-786-2209. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on February 9, 2011, OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer. *Fax Number:* (202) 395-6974. *E-mail:* [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov).

**Martique Jones,**

*Director, Regulations Development Division-B, Office of Strategic Operations and Regulatory Affairs.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for OMB Review; Comment Request**

*Title:* Tracking of Participants in the Early Head Start Research and Evaluation Project.

*OMB No.:* New Collection.

*Billing Accounting Code (BAC):* 418422 (G994426).

*Description:* The Administration for Children and Families (ACE) within the Department of Health and Human Services (HHS) will conduct tracking of children/families who participated in the Early Head Start Research and Evaluation Project (EHSREP). The purpose of tracking these participants is to maintain up-to-date contact information for the children/families in the event that the Administration for Children and Families (ACE) determines that a future follow-up to the EHSREP will take place.

The EHSREP is a longitudinal study originally designed to meet 1994 requirement for a national evaluation of the Early Head Start program. 3001 children and families in 17 sites were randomly assigned either to the program group (allowed to enroll in EHS), or to the control group (precluded from enrolling in EHS, although they could receive other services in the community). Child and family assessments were conducted when children were 14 months old, 24 months old, 36 months old, in the spring prior to kindergarten entry, and again in the spring of the sixth year of formal schooling (5th grade for most children).

If the decision is made to follow the sample through high school, it is important to maintain contact with the participants so that response rates at follow-up points will be maximized. Telephone interviews will be conducted in order to update the respondent's location and contact information. This information will be collected from parents or guardians in the spring of 2011.

*Respondents:* Treatment and control group members in the Early Head Start Research and Evaluation Project.

**ANNUAL BURDEN ESTIMATES**

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Tracking Interview .....	2700	1	.25	675
3rd Party Contacts .....	200	1	.05	10

*Estimated Total Annual Burden Hours:* 685.

**Additional Information**

Copies of the proposed collection may be obtained by writing to the

Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. All requests should be

identified by the title of the information collection. E-mail address: [OPREinfocollection@acf.hhs.gov](mailto:OPREinfocollection@acf.hhs.gov).