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 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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[Billing code: 6750–01–S]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Secretary's Advisory Committee on Human Research Protections; Notice of Meetings

AGENCY: Office of Public Health and Science, Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a) of the Federal Advisory Committee Act, U.S.C. Appendix 2, notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHRP) will hold its seventeenth meeting. The meeting will be open to the public.

DATES: The meeting will be held on Monday, October 27, 2008 from 8:30 a.m. until 4:30 p.m. and Tuesday, October 28, 2008 from 8:30 a.m. until 4:30 p.m.

ADDRESSES: The Sheraton National Hotel, 900 South Orme Street, Arlington, Virginia 22204. Phone: 703–521–1900.

FOR FURTHER INFORMATION CONTACT: Ivor Pritchard, PhD, Acting Director, Office for Human Research Protections (OHRP), or Julia Gorey, JD, Executive Director, Secretary's Advisory Committee on Human Research Protections (SACHRP); U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; 240–453–8141; fax: 240–453–6909; e-mail address: *sachrp@osophs.dhhs.gov.*

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services and the Assistant Secretary for Health on issues and topics pertaining to or associated with the protection of human research subjects.

On October 27, 2008, the morning session will begin with a SACHRP update. Members of OHRP and the Office of the General Counsel will make brief presentations on the status of SACHRP recommendations that have been approved to date, the OHRP guidance and Federal rulemaking process, and the status of OHRP budget and staffing. This will be followed by a period of discussion. In the afternoon, SACHRP will receive a report from the Subpart A Subcommittee. This subcommittee is charged with developing recommendations for consideration by SACHRP regarding the application of Subpart A of 45 CFR part 46 in the current research environment. This subcommittee was established by SACHRP at its October 4–5, 2006 meeting.

The following day, October 28, 2008, the Subcommittee on Inclusion of Individuals with Impaired Decision-Making in Research will present and discuss their current report. The Subcommittee on Inclusion of Individuals with Impaired Decision-Making in Research is charged with developing recommendations for consideration by SACHRP about whether guidance and/or additional regulations are needed for research involving individuals with impaired decision-making capacity. This subcommittee was formed as a result of discussions during the July 31–August 1, 2006 SACHRP meeting. The afternoon session will consist of an invited panel of community and consumer representatives who will discuss their reaction and provide feedback on the subcommittee's recommendations.

Public attendance at the meeting is limited to space available. Individuals who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the designated contact persons. Members of the public will have the opportunity to provide comments on both days of the meeting. Public comment will be limited to five minutes per speaker. Any members of the public who wish to have printed materials distributed to SACHRP members for this scheduled meeting should submit

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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 recently complete census available, for arriving at the 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.

materials to the Acting Executive Director, SACHRP, prior to the close of business Tuesday, October 14, 2008. Information about SACHRP and the draft meeting agenda will be posted on the SACHRP Web site at: *http://www.hhs.gov/ohrp/sachrp/index.html.*

Dated: October 7, 2008.

Ivor A. Pritchard,

Acting Director, Office for Human Research Protections, Acting Executive Secretary,Secretary's Advisory Committee on Human Research Protections.

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BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Toxicology Program (NTP); Report on Carcinogens (RoC); Availability of the Draft Background Document for Cobalt-Tungsten Carbide Powders and Hard Metals; Request for Comments on the Draft Background Document; Announcement of the Cobalt-Tungsten Carbide Powders and Hard Metals Expert Panel Meeting

AGENCY: National Institute of Environmental Health Sciences (NIEHS); National Institutes of Health (NIH).

ACTION: Availability of Background Document; Request for Comments; and Announcement of a Meeting.

SUMMARY: The NTP announces the availability of the draft background document for cobalt-tungsten carbide powders and hard metals by October 10, 2008 on the RoC Web site (*http://ntp.niehs.nih.gov/go/29679*) or in printed text from the RoC (see **ADDRESSES** below). The NTP invites the submission of public comments on the draft background document for cobalt-tungsten carbide powders and hard metals. The expert panel will meet on December 9–10, 2008, at the Sheraton Chapel Hill Hotel, One Europa Drive, Chapel Hill, NC 27514 to peer review the draft background document for cobalt-tungsten carbide powders and hard metals and, once completed, make a recommendation regarding the listing status (i.e., *known to be a human carcinogen, reasonably anticipated to be a human carcinogen,* or not to list) for cobalt-tungsten carbide powders and hard metals in the 12th Edition of the RoC (12th RoC). The RoC expert panel meeting is open to the public with time scheduled for oral public comments. Attendance is limited only by the available meeting room space. Following the expert panel meeting and completion of the expert panel report, the NTP will post the final background document and the expert-panel peer review report on the RoC Web site.

DATES: The expert panel meeting for cobalt-tungsten carbide powders and hard metals will be held on December 9–10, 2008. The draft background document for cobalt-tungsten carbide powders and hard metals will be available for public comment by October 10, 2008. The deadline to submit written comments is November 24, 2008, and the deadline for pre-registration to attend the meeting and/or to provide oral comments at the meeting is December 1, 2008.

ADDRESSES: The RoC expert panel meeting on cobalt-tungsten carbide powders and hard metals will be held at Sheraton Chapel Hill Hotel, One Europa Drive, Chapel Hill, NC 27514. Access to on-line registration and materials for the meeting are available on the RoC Web site (*http://ntp.niehs.nih.gov/go/29679*). Comments on the draft background document should be sent to Dr. Ruth M. Lunn, NIEHS, P.O. Box 12233, MD EC–14, Research Triangle Park, NC 27709, FAX: (919) 541–0144, or *lunn@niehs.nih.gov.* Courier address: Report on Carcinogens Office, 79 T.W. Alexander Drive, Building 4401, Room 3118, Research Triangle Park, NC 27709. Persons needing interpreting services in order to attend should contact 301–402–8180 (voice) or 301–435–1908 (TTY). Requests should be made at least seven business days in advance of the meeting.

FOR FURTHER INFORMATION CONTACT: Dr. Ruth M. Lunn, Director, RoC Office, 919–316–4637, *lunn@niehs.nih.gov.*

SUPPLEMENTARY INFORMATION:

Background

The NTP announced the RoC review process for the 12th RoC on April 16, 2007 in the **Federal Register** (72FR18999 available at *http://ntp.niehs.nih.gov/go/15208*). An expert panel meeting is being convened on December 9–10, 2008, to review cobalt-tungsten carbide powders and hard metals for possible listing in the 12th RoC. The draft background document for cobalt-tungsten carbide hard metals and powders will be available on the RoC Web site by October 10, 2008 or in printed text from the RoC Office (see **ADDRESSES** above). Persons can register free-of-charge with the NTP listserv to receive notification when draft RoC background documents for candidate substances for the 12th RoC are made available on the RoC Web site (*http://ntp.niehs.nih.gov/go/231*).

Cobalt-tungsten carbide hard metals are composites of carbides (including tungsten carbide alone or in combination with small amounts of other carbides) with a metallic cobalt binder, pressed into a compact, solid form at high temperatures by a process known as ''sintering.'' Cobalt-tungsten carbide hard metals are used primarily in cutting tools. Cobalt-tungsten carbide hard metals are manufactured and used in the United States. Occupational exposure to cobalt-tungsten carbide hard-metal particles can occur during hard-metal production, recycling of hard-metal products, and grinding and sharpening of hard-metal tools.

Preliminary Agenda, Request for Comments, and Registration

Preliminary agenda topics include:

- Oral public comments on cobalt-tungsten carbide powders and hard metals.
- Peer review of the draft background document on cobalt-tungsten carbide powders and hard metals.
- Recommendation for listing status in the 12th RoC for cobalt-tungsten carbide powders and hard metals and scientific justification.

The meeting is scheduled for December 9–10, 2008, from 8:30 a.m. to adjournment each day. A copy of the preliminary agenda, expert panel roster, and any additional information, when available, will be posted on the RoC Web site or may be requested from the Director of the RoC Office (see **ADDRESSES** above). Individuals who plan to attend the meeting are encouraged to register on-line by December 1, 2008, to facilitate planning for the meeting.

Request for Comments

The NTP invites both written and oral public comments on the draft background document on cobalt-tungsten carbide powders and hard metals. All written comments received will be posted on the RoC Web site prior to the meeting and distributed to the expert panel and RoC staff for their consideration in the peer review of the draft background document and/or preparation for the expert panel meeting. Persons submitting written comments are asked to include their name and contact information (affiliation, mailing address, telephone and facsimile numbers, e-mail, and sponsoring organization, if any) and send them to Dr. Lunn (see **ADDRESSES** above) for receipt by November 24, 2008. Time will be set aside at the expert panel meeting for the presentation of oral public comments. Seven minutes will be available for each