regulations governing requirements for human drug products to establish standardized format and content requirements for the labeling of all marketed OTC drug products in part 201 (21 CFR part 201) (the 1999 labeling final rule). The regulations in part 201 require OTC drug product labeling to include uniform headings and subheadings, presented in a standardized order, with minimum standards for type size and other graphical features. Specifically, the 1999 labeling final rule added new § 201.66 to part 201. Section 201.66 sets content and format requirements for the Drug Facts portion of labels on OTC drug products.

The only burden to comply with the regulations in part 201 is a one-time burden for OTC sunscreen products and new OTC drug products introduced to the marketplace under new drug applications (NDAs) or abbreviated new drug applications (ANDAs). All OTC drug products except sunscreens and new OTC products marketed under NDAs or ANDAs are already required to be in compliance with these labeling regulations. On June 20, 2000 (65 FR 38191), we published a **Federal Register** document that required all OTC drug products marketed under the OTC monograph system except sunscreen products to comply with the regulations by May 16, 2005, or sooner (65 FR 38191 at 38193). Sunscreen products do not have to comply with the regulations until we lift the stay of the sunscreen final rule that was published in the **Federal Register** on May 21, 1999 (64 FR 27666) (the 1999 sunscreen final rule). In the **Federal Register** of December 31, 2001 (66 FR 67485), we stayed the 1999 sunscreen final rule indefinitely. In the **Federal Register** of September 3, 2004 (69 FR 53801), we delayed the § 201.66 implementation date for OTC sunscreen products indefinitely. Because the compliance date has passed for all OTC drug products except sunscreens and drug products introduced under new NDAs or ANDAs, we believe that the labeling burden associated with the 1999 labeling final rule applies only to these products. We do not anticipate receiving any requests for exemptions or deferrals under § 201.66(e) because we have only received one request in the past 8 years.

We estimate that there are 4,750 OTC sunscreen drug product stock keeping units (SKUs) that have not yet complied with the 1999 labeling final rule. All of these SKUs will need to implement the new labeling format by the implementation date included in the 1999 sunscreen final rule when it is published in the **Federal Register**. We estimate that these 4,750 SKUs are marketed by 400 manufacturers and that approximately 2 hours will be spent on each submission (see table 1 of this document). The number of hours per submission (response) is based on our estimate in the 1999 labeling final rule (64 FR 13254 at 13276). If an average of 2 hours is spent preparing, completing, and reviewing each of the estimated 4,750 sunscreen SKUs, the total number of hours dedicated to the labeling of sunscreen products would be 9,500 hours (4,750 SKUs times 2 hours/SKU) (see table 1 of this document).

Based on estimates provided by the Consumer Healthcare Products Association, we believe that approximately 500 new OTC drug product SKUs marketed under NDAs or ANDAs are introduced to the marketplace each year. We estimate that these SKUs are marketed by 300 manufacturers. We estimate that the preparation of labeling for new NDAs and ANDAs will require 5 hours to prepare, complete, and review new labeling prior to submitting the new labeling to us. Based on this estimate, the annual reporting burden for this type of labeling is approximately 2,500 hours (see table 1 of this document).

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
201.66(c) and (d)[2]	400	11.88	4,750	2	9,500
201.66(c) and (d)[3]	300	1.67	500	5	2,500
Total					12,000

[1] FDA estimates that capital costs of 22 to 25 million dollars will result from preparing labeling content and format in accordance with § 201.66. There are no operating or maintenance costs associated with this collection of information.
[2] Burden for manufacturers of sunscreen drug product.
[3] Burden for manufacturers of products marketed under new NDAs or ANDAs.

Dated: May 27, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–13279 Filed 6–2–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality; Notice of Meeting

In accordance with section 10(d) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), announcement is made of a Health Care Policy and Research Special Emphasis Panel (SEP) meeting.

A Special Emphasis Panel is a group of experts in fields related to health care research who are invited by the Agency for Healthcare Research and Quality (AHRQ), and agree to be available, to conduct on an as needed basis, scientific reviews of applications for AHRQ support. Individual members of the Panel do not attend regularly-scheduled meetings and do not serve for fixed terms or a long period of time. Rather, they are asked to participate in particular review meetings which require their type of expertise.

Substantial segments of the upcoming SEP meeting listed below will be closed to the public in accordance with the Federal Advisory Committee Act, section 10(d) of 5 U.S.C., Appendix 2 and 5 U.S.C. 552b(c)(6). Grant applications for the AHRQ Limited Competition: PROSPECT STUDIES—Building New Clinical Infrastructure for CE (R01) applications are to be reviewed

and discussed at this meeting. These discussions are likely to reveal personal information concerning individuals associated with the applications. This information is exempt from mandatory disclosure under the above-cited statutes.

SEP Meeting on: AHRQ Limited Competition: PROSPECT STUDIES—Building New Clinical Infrastructure for CE (R01).

Date: June 16, 2010 (Open on June 16 from 8 a.m. to 8:15 a.m. and closed for the remainder of the meeting).

Place: Hyatt Regency Bethesda Hotel, 7400 Wisconsin Avenue, 1 Bethesda Metro Center, Bethesda, Maryland 20814.

Contact Person: Anyone wishing to obtain a roster of members, agenda or minutes of the non-confidential portions of this meeting should contact Mrs. Bonnie Campbell, Committee Management Officer, Office of Extramural Research, Education and Priority Populations, AHRQ, 540 Gaither Road, Room 2038, Rockville, Maryland 20850, Telephone (301) 427–1554.

Agenda items for this meeting are subject to change as priorities dictate.

Dated: May 24, 2010.

Carol M. Clancy,

Director.

[FR Doc. 2010–13109 Filed 6–2–10; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality; Notice of Meeting

In accordance with section 10(d) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), announcement is made of a Health Care Policy and Research Special Emphasis Panel (SEP) meeting.

A Special Emphasis Panel is a group of experts in fields related to health care research who are invited by the Agency for Healthcare Research and Quality (AHRQ), and agree to be available, to conduct on an as-needed basis, scientific reviews of applications for AHRQ support. Individual members of the Panel do not attend regularly-scheduled meetings and do not serve for fixed terms or a long period of time. Rather, they are asked to participate in particular review meetings which require their type of expertise.

Substantial segments of the upcoming SEP meeting listed below will be closed to the public in accordance with the Federal Advisory Committee Act, section 10(d) of 5 U.S.C., Appendix 2 and 5 U.S.C. 552b(c)(6). Grant applications for the OS ARRA: Optimizing Prevention and Healthcare Management for Complex Patients (R21) applications are to be reviewed and discussed at this meeting. These discussions are likely to reveal personal information concerning individuals associated with the applications. This information is exempt from mandatory disclosure under the above-cited statutes.

SEP Meeting on: OS ARRA: Optimizing Prevention and Healthcare Management for Complex Patients (R21).

Date: June 24, 2010 (Open on June 24 from 8 a.m. to 8:15 a.m. and closed for the remainder of the meeting).

Place: Hilton Rockville Executive Meeting Center, 1750 Rockville Pike, Conference Room TBD, Rockville, MD 20850.

Contact Person: Anyone wishing to obtain a roster of members, agenda or minutes of the nonconfidential portions of this meeting should contact Mrs. Bonnie Campbell, Committee Management Officer, Office of Extramural Research, Education and Priority Populations, AHRQ, 540 Gaither Road, Room 2038, Rockville, Maryland 20850, Telephone (301) 427–1554.

Agenda items for this meeting are subject to change as priorities dictate.

Dated: May 24, 2010.

Carolyn M. Clancy,

Director.

[FR Doc. 2010–13108 Filed 6–2–10; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0004]

[FDA 225–09–0014]

Memorandum of Understanding by and Between the United States Food and Drug Administration and the International Anesthesia Research Society for the Safety of Key Inhaled and Intravenous Drugs in Pediatrics Public-Private Partnership

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA and the International Anesthesia Research Society (IARS). The purpose of this MOU is to establish a framework for collaboration between FDA and IARS and to support their shared interest of promoting the safe use of anesthetics and sedatives in children.

DATES: The agreement became effective March 21, 2010.

FOR FURTHER INFORMATION CONTACT: Wendy R. Sanhai, Senior Scientific Advisor, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4128, Silver Spring, MD 20993, 301–796–8518.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: May 26, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

BILLING CODE 4160–01–S