(3) Requester's potential for reaching underserved/special populations;

(4) Requester's experience administering national awards programs;

(5) Requester's past or current work specific to national programs or projects in the area(s) of physical activity, fitness, or sports among individuals and in schools and organizations;

(6) Requester's personnel: name, professional qualifications and specific expertise of key personnel who would be available to work on these projects;

(7) Requester's facilities: availability and description of facilities required to administer the program including office space and information technology and telecommunication resources;

(8) Requester's description of financial management: discussion of experience in developing an annual budget and collecting and managing monies from organizations and individuals;

(9) Requester's proposed plan for managing the PCPFS awards programs, including such financial aspects as Web site development and/or enhancement, cost of program materials and distribution of those items.

Availability of Funds: There are no Federal funds available for this co-sponsorship.

Dated: December 22, 2009.

Penelope Slade-Sawyer,

RADM U.S. Public Health Service, Acting Executive Director, President's Council on Physical Fitness and Sports, U.S. Department of Health and Human Services.

[FR Doc. E9–30653 Filed 12–24–09; 8:45 am]

BILLING CODE 4150–35–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, e-mail *paperwork@hrsa.gov* or call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Drug Pricing Program Reporting Requirements (OMB No. 0915–0176)—[Extension]

Section 602 of Public Law 102–585, the Veterans Health Care Act of 1992, enacted section 340B of the Public Health Service Act (PHS Act) ''Limitation on Prices of Drugs Purchased by Covered Entities.'' Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula. Covered entities which choose to participate in the section 340B drug discount program must comply with the requirements of 340B(a)(5) of the PHS Act. Section 340B(a)(5)(A) prohibits a covered entity from accepting a discount for a drug that would also generate a Medicaid rebate. Further, section 340B(a)(5)(B) prohibits a covered entity from reselling or otherwise transferring a discounted drug to a person who is not a patient of the entity.

In response to the statutory mandate of section 340B(a)(5)(C) to develop audit guidelines and because of the potential for disputes involving covered entities and participating drug manufacturers, the HRSA Office of Pharmacy Affairs (OPA) developed a dispute resolution process for manufacturers and covered entities as well as manufacturer guidelines for audit of covered entities.

The annual estimate of burden is as follows:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Audits					
Audit Notification of Entity	2	1	2	4	8
Audit Work Plan	1	1	1	8	8
Audit Report	1	1	1	1	1
Entity Response	0	0	0	0	0
Dispute Resolution					
Dispute Resolution Request	2	4	8	10	80
Rebuttal	2	1	2	16	32
Record Keeping Requirement					
Dispute Records	10	1	10	.5	5
Total Recordkeeping	10				5

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974. Please direct all correspondence to the ''attention of the desk officer for HRSA.''

Dated: December 18, 2009.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E9–30606 Filed 12–24–09; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0600]

Draft Guidance for Industry on Tobacco Health Document Submission; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Tobacco Health Document Submission.'' The draft guidance is intended to assist persons making certain document submissions to FDA under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by January 22, 2010.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Tobacco Health Document Submission'' to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the draft guidance document may be sent.

Submit electronic comments to *http://www.regulations.gov*. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: May Nelson, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229, 240–276–1717, *May.Nelson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On June 22, 2009, the President signed the Tobacco Control Act (Public Law 111–31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*) by, among other things, adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Section 904(a)(4) of the act, as amended by the Tobacco Control Act, requires each tobacco product manufacturer or importer, or agent thereof, to submit all documents developed after June 22, 2009, ''* * * that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives.'' Information required under section 904(a)(4) of the act must be submitted to FDA beginning December 22, 2009. FDA recognizes the challenges associated with the collection, review, organization, and production of documents. We also recognize that additional time may be necessary for the production of documents in a digital format, which FDA strongly encourages in order to improve the management and accessibility of submitted documents. Therefore, FDA does not intend to enforce the December 22, 2009, deadline provided you submit by April 30, 2009, all documents described in section 904(a)(4) of the act developed between June 23, 2009, and March 31, 2010.

II. Significance of Guidance

FDA is issuing this draft guidance document consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on ''Tobacco Health Document Submission.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance document and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Paperwork Reduction Act of 1995

This draft guidance contains proposed collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). As required by the PRA, FDA has published an analysis of, among other information collections, the information collection concerning the submission of tobacco health documents (74 FR 45219, September 1, 2009, as corrected by 74 FR 47257, September 15, 2009) and will submit them for OMB approval.

V. Electronic Access

An electronic version of the guidance document is available on the Internet at *http://www.regulations.gov* and *http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm*.

Dated: December 22, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–30657 Filed 12–22–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose