EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of sites	Total burden Hours	Average hourly wage rate *	Total cost burden
Asthma questionnaire—Yale	2	6	$59.83	$359
Asthma questionnaire—Nemours	1	11	59.83	658
Obesity questionnaire—Yale	1	6	47.25	284
Obesity questionnaire—Nemours	1	3	47.25	142
Interviews—Yale	1	15	53.54	803
Interviews—Nemours	1	10	53.54	535
Total	5	51	na	2,781

* Based upon the mean of the average wages for other physicians and surgeons, general pediatricians, and pediatric trainees (asthma questionnaire), and general pediatricians and pediatric trainees (obesity questionnaire), National Compensation Survey: Occupational wages in the United States 2008, ''U.S. Department of Labor, Bureau of Labor Statistics,'' and Yale Pediatric Residency Program, 2008.

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the total and annualized cost for this research. Since this project will not exceed one year the total and annualized costs are identical. The total cost is estimated to be $5,703.

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST

Cost component	Total cost	Annualized cost
Project Development	$1,406	$1,406
Data Collection Activities	416	416
Data Processing and Analysis	780	780
Publication of Results	1,601	1,601
Project Management	200	200
Overhead	1,299	1,299
Total	5,703	5,703

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research, quality improvement and information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ' s estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: November 16 2009.

Carolyn M. Clancy,

Director.

[FR Doc. E9–28210 Filed 11–25–09; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0563]

Draft Guidance for Industry and Food and Drug Administration Staff; Preliminary Timetable for the Review of Applications for Modified Risk Tobacco Products Under the Federal Food, Drug, and Cosmetic Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Preliminary Timetable for the Review of Applications for Modified Risk Tobacco Products under the Federal Food, Drug, and Cosmetic Act.'' This guidance is intended for manufacturers, retailers, importers, and FDA staff. The guidance describes FDA's current thinking regarding the appropriate preliminary timetable for its review of applications for Modified Risk Tobacco Products (MRTPs) under the Federal Food, Drug, and Cosmetic Act (the act), as modified by the Federal 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 February 25, 2010.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Preliminary Timetable for the Review of Applications for Modified Risk Tobacco Products under the Federal Food, Drug, and Cosmetic Act'' 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. See the

SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

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. Submit electronic comments to *http://www.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Annette Marthaler, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229, 240–276–1717, *annette.marthaler@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 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 911 of the act, as amended by the Tobacco Control Act, states: ''(a) No person may introduce or deliver for introduction into interstate commerce any modified risk tobacco product unless an order issued pursuant to subsection (g) is effective with respect to such product'' and ''(d) Any person may file with the Secretary an application for a modified risk tobacco product.* * *.'' Section 911(g) of the act provides the criteria under which the agency determines whether to issue an order that an MRTP may be commercially marketed. The Tobacco Control Act provides that, within 2 years and 9 months of the enactment of the Tobacco Control Act, the agency shall issue regulations or guidance regarding MRTP applications, and those regulations or guidance shall ''establish a reasonable timetable for the Secretary to review an application under this section.'' FDA is issuing this guidance to describe a preliminary timetable the agency intends to follow until such time as the agency issues more comprehensive guidance or regulations on MRTP applications. Pending further guidance or rulemaking, FDA intends to issue a decision on an MRTP application within 360 days of its receipt by FDA.

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 ''Preliminary Timetable for the Review of Applications for Modified Risk Tobacco Products under the Federal Food, Drug, and Cosmetic Act.'' 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 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. 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: November 24, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–28515 Filed 11–24–09; 4:15 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2476–FN]

Medicare and Medicaid Programs; Conditional Approval of Application by the American Association for Accreditation of Ambulatory Surgery Facilities for Continued Deeming Authority for Ambulatory Surgical Centers

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our decision to conditionally approve, with a 180 day probationary period, the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) for continued recognition as a national accreditation program for ambulatory surgical centers seeking to participate in the Medicare or Medicaid programs.

DATES: *Effective Date:* This final notice is effective on November 27, 2009 through November 27, 2012, with a 180-day probationary period beginning November 27, 2009 through May 26, 2010.

FOR FURTHER INFORMATION CONTACT: Lillian Williams (410) 786–8636. Patricia Chmielewski (410) 786–6899.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in an ambulatory surgical center (ASC) provided certain requirements are met. Section 1832(a)(2)(F)(i) of the Social Security Act (the Act) establishes distinct criteria for facilities seeking designation as an ASC. Under this authority, the minimum requirements that an ASC must meet to participate in Medicare are set forth in regulations at 42 CFR part 416, which determine the basis and scope of ASC covered services, and the conditions for Medicare payment for facility services. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488.

Generally, to enter into an agreement, an ASC must first be certified by a State survey agency as complying with conditions or requirements set forth in part 416 of our regulations. Then, the ASC is subject to regular surveys by a State survey agency to determine whether it continues to meet those requirements. There is an alternative, however, to surveys by State agencies.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accreditation organization that all applicable Medicare conditions are met or exceeded, we may ''deem'' those provider entities as having met the requirements. Accreditation by an accreditation organization is voluntary and is not required for Medicare participation.

If an accreditation organization is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, a provider entity accredited by the national accrediting body's approved program may be deemed to meet the Medicare conditions. A national accreditation organization applying for