SUPPORTING STATEMENT FOR THE

NATIONAL ADULT TOBACCO SURVEY

0920-0828
Expiration 10/31/2010

Reinstatement with Changes

PART A

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CDC requests OMB approval by June 1, 2012 in order to initiate information collection by July 1, 2012.

A. JUSTIFICATION

This statement supports a request to obtain approval to reinstate clearance for three years to conduct three annual cycles of the National Adult Tobacco Survey (NATS), a stratified, random-digit dialed, telephone survey of non-institutionalized adults 18 years of age and older, starting in in 2012/2013. The NATS seeks to determine tobacco use prevalence and the factors promoting and impeding tobacco use among adults in a nationally representative sample of adults. NATS represents a partnership between CDC's Office on Smoking and Health (OSH), which conducted an earlier cycle of NATS, and the Center for Tobacco Products (CTP) within the Food and Drug Administration (FDA), which has funded this survey.

Conducting the NATS will provide time-critical monitoring data needed to evaluate the effectiveness of new regulatory authorities given to FDA under the Family Smoking Prevention and Tobacco Control Act, also known as the Tobacco Control Act (TCA). Congress passed this legislation to discourage tobacco use among minors and young adults, to encourage cessation among adult smokers and to reduce the public health burden of tobacco related disease in the U.S. Under the TCA, FDA has been granted broad authority to use the best available science to develop and implement effective strategies to protect the public's health. FDA authority includes setting and enforcing standards for tobacco product ingredients and design; establishing good manufacturing practices; instituting tobacco product labeling and health warnings; prohibiting marketing that is misleading to consumers and developing enforcement authorities to act quickly and effectively to remove violating products. In addition, the TCA gives FDA the authority to assert jurisdiction over cigars and currently unregulated tobacco products.

In order to ensure that FDA is in compliance with the TCA's mandate to protect the public health, annual data collection is needed, at least initially, to monitor the benefits and potential adverse consequences of FDA's regulatory actions. As novel tobacco products are introduced onto the market, the FDA must regularly monitor patterns of all tobacco product usage- not just cigarettes- to identify changes in susceptibility and rates of tobacco use initiation, perceptions regarding tobacco use, patterns of use- including use of multiple products-and rates of tobacco use cessation. Rather than develop a completely new system to monitor measures critical to FDA, and thereby increasing burden to the population, FDA has partnered with CDC to leverage the existing NATS system. While NATS has been re-designed to meet critical data needs of the FDA, many of the measures are relevant to CDC's National Tobacco Control Program (NTCP), and CDC will have full access to the data to monitor its programs and policies. By joining forces to conduct NATS to meet the needs of both agencies, CDC and FDA will place burden on the public once rather than twice.

The CDC-FDA NATS Partnership

To place the CDC/FDA collaboration in context, CDC's Office on Smoking and Health (OSH) created the National Tobacco Control Program (NTCP) in 1999 to encourage coordinated efforts nationwide to reduce tobacco-related diseases and deaths. The four goals of the NTCP are to: (1) prevent initiation of tobacco use among young people; (2) eliminate nonsmokers'

exposure to secondhand smoke; (3) promote quitting among adults and young people; and (4) identify and eliminate tobacco-related disparities. As sister Department of Health and Human Services (DHHS) agencies, CDC and FDA activities related to tobacco control are integral to the DHHS *Strategic Action Plan for Ending the Tobacco Epidemic* (DHHS 2010). Under this common vision, the NATS will address Strategic Action #4: Advancing Knowledge, by leveraging an existing surveillance system to monitor the progress of national tobacco control efforts. As industry user fees are funding the upcoming administration of the NATS, the revised system is foremost designed to monitor the impact of FDA regulatory activities. However, since the short, intermediate and long-term public health impacts of FDA authorities are cross-cutting, the data collected via the NATS will also help CDC to evaluate the effectiveness of the NTCP.

Development and Repurposing of the NATS

The CDC and the American Legacy Foundation originated the NATS, which was previously administered as a one-time survey in 2009-2010 (OMB No. 0920-0828, expiration 10/31/2010). The original NATS questionnaire was designed using constructs from the *Key Outcome Indicators for Evaluating Comprehensive Tobacco Control Programs***,** CDC's comprehensive framework for evaluation of tobacco control programs. With technical assistance from CDC, the Global Adult Tobacco Survey (GATS) was conducted in 14 high-burden countries between 2008 and 2010, and is currently being expanded to another eight countries in 2011. The first phase of GATS covered countries with a combined population of 3.6 billion and more than 600 million adult smokers, or an estimated 68% of the world's smokers. New adult surveys in Phase II countries are expected to be completed in early 2012, and another cohort of countries are scheduled to implement GATS later in 2012.

The revision of the NATS questionnaire, funded by FDA, has transformed NATS for use in evaluating the impact of FDA regulatory activities in protecting the public's health. Through a cross-center evaluation planning effort, the FDA's CTP developed a series of logic models that capture short- and long-term public health impacts of tobacco regulatory actions. The Overview logic model (Appendix B) illustrates how FDA's regulatory authority leads to measurable inputs and consumer-level outcomes in the short- and long-term.

The revised NATS was driven by the following areas of FDA activity:

- Advertising restrictions – e.g., bans free cigarette giveaways, sponsorship of sports events, use of product descriptors deemed to be misleading
- Information dissemination – e.g., graphic health warnings on cigarette packs, information about harmful and potentially harmful constituents in tobacco products.
- Product standards – e.g., regulations to reduce tobacco product addictiveness, appeal and/or levels of toxicants
- Modified risk tobacco product applications – e.g., marketing order allowing marketing of reduced harm or reduced exposure products
- Public education – e.g., campaigns to inform the public about FDA regulation and to advance regulatory goals

The revised NATS questionnaire captures the following constructs:

1. **Cigarette use patterns –** Cigarettes are by far the largest contributor to tobacco-related disease and death in the U.S., and the questions in this section address current and past usage patterns. Many of these are the same questions as those in the previous NATS.
2. **Susceptibility (cigarettes)** – These questions are asked among young adults to gauge non-smokers susceptibility to taking up cigarette smoking.
3. **Purchasing behavior (cigarettes)** – The TCA gives FDA the authority to regulate the marketing and distribution of tobacco products. Understanding smokers' purchasing patterns and use of price promotions is necessary to inform future advertising restrictions.
4. **Other tobacco products –** With the emergence of novel tobacco products and potential for future marketing of modified risk tobacco products, FDA must monitor the awareness, use, susceptibility, and risk perceptions of non-cigarette tobacco products, an area incompletely covered by current data systems.
5. **Addiction (all tobacco) –** The most significant driver of continued use and lack of quitting success, addiction will be important to monitor, specifically as tobacco product changes are implemented.
6. **Cessation –** Standard measures of intention to quit, quit attempts, and quitting success, both for cigarettes and for cessation of all tobacco product use.
7. **Secondhand smoke –** A few questions were kept from the previous NATS, in order to measure perceptions about the harmful effects of SHS to non-smokers, one of the warning statements on the new cigarette graphic health warnings.
8. **Marketing/Public Education** – The TCA gives FDA the authority to regulate the marketing of tobacco products and educate the public about the harms of tobacco products. These questions measure exposure to different types of marketing and promotion and responses to health warnings on packages and advertisements.
9. **Demographics** – Important covariates to identify differential impacts among subpopulations
10. **Knowledge/Attitudes/Perceptions** – These questions measure short-term outcomes of efforts to inform the public of the health risks associated with tobacco products, which predict intentions and behaviors.

Annual administrations for several years of NATS will enable FDA to measure progress toward meeting the strategic goals of the TCA, particularly during the first years of the program when the regulatory framework is being established. FDA will use the NATS data over time to track progress related to tobacco addiction and cessation; tobacco purchasing; the spectrum of tobacco use patterns; perceptions of new products; product promotions and changes in marketing; and knowledge of new warning labels on tobacco products. NATS data will also be utilized by CDC in evaluating the impact of the NTCP.

Recognizing age, gender and racial/ethnic differences in tobacco use, separate tobacco use estimates will be developed by age group, gender, and racial/ethnic subgroup. In addition to a sample of 56,250 landline respondents, the sample will include 18,750 cell phone users who do not have a landline in recognition of the growing proportion of the population that relies exclusively on cell phones, which disproportionately represents young adults and minority subgroups.

A.1. CIRCUMSTANCES MAKING THE COLLECTION OF INFORMATION NECESSARY

A.1.a Background

Legal justification for a national survey of adult tobacco use can be found in the TCA (H.R. 1256)(Appendix A-1), as well as Section 301 of the Public Health Service Act (42 USC 241) (Appendix A-2). Further justification for a national survey of adult tobacco use is based on three factors: (1) public health implications of tobacco use among adults within the United States; (2) costs of health risk behaviors; and (3) DHHS objectives to reduce tobacco use.

A.1.a.1 The Family Smoking Prevention and Tobacco Control Act

The TCA gives FDA broad regulatory authority to control and reduce the public health impact of tobacco products. As FDA's CTP strives to fulfill Congress's intent to protect the public health, time-critical monitoring data will inform the development of evidence-based regulatory action and assess impact of FDA's regulatory actions.

Pursuant to federal law, the purpose of granting FDA with jurisdiction to regulate tobacco products includes "impos[ing] appropriate regulatory controls on the tobacco industry [and] promot[ing] cessation to reduce disease risk and the social costs associated with tobacco-related diseases". In addition, FDA is authorized to "by regulation require restrictions on the sale of distribution of a tobacco product, including restrictions on the access to, and the advertising and promotion of, the tobacco product, if the Secretary determines that such regulation would be appropriate for the protection of the public health." In making this determination, the law expressly requires FDA to consider "the increased or decreased likelihood that existing users of tobacco products will stop using such products . . ." as well as the impact of non-users initiating tobacco use (especially youth and young adults) or former users relapsing back to tobacco use. In order for FDA to determine whether or not an action is "appropriate for the protection of the public health", evidence indicating population-level risks and benefits must be considered. NATS will provide crucial annual monitoring data that will help identify the most effective strategies for protecting public health.

A.1.a.2 Public Health Implications of Tobacco Use

The Health Consequences of Smoking: A Report of the Surgeon General states that tobacco use remains the leading preventable cause of disease, disability, and death in the United States. . ." (USDHHS, 2004). CDC reports that an estimated 443,000 people die prematurely from smoking or exposure to secondhand smoke each year, while another 8.6 million have a serious illness caused by smoking. For every person who dies from smoking, 20 more people suffer from at least one serious tobacco-related illness. Despite these risks, as of 2010 approximately 19.3% of U.S. adults currently smoke cigarettes (CDC, 2011). On average, adults who smoke die 14 years earlier than nonsmokers (CDC, 2006).

Among U.S. adults 25 years of age or older, 59% of deaths are due to two causes: cardiovascular disease (36%) and cancer (23%)" (CDC/NCHS, 2008). During 2000-2004, cigarette smoking resulted in an estimated annual average of 269,655 deaths among males and 173,940 deaths among females in the United States. The three leading specific causes of

smoking-attributable death were lung cancer (128,922), ischemic heart disease (126,005), and chronic obstructive pulmonary disease (COPD) (92,915). Among adults aged ≥35 years, 160,848 (41.0%) smoking-attributable deaths were caused by cancer, 128,497 (32.7%) by cardiovascular diseases, and 103,338 (26.3%) by respiratory diseases. In addition, although smoking prevalence has declined dramatically since its peak in the 1960s, the number of smoking-attributable deaths has remained relatively unchanged, primarily because of increases in population size (particularly among older age groups with the highest incidence of smoking-related diseases), as well as advances in scientific research that have newly identified tobacco-related disease. Despite declines in the rates of some smoking-related diseases (e.g., coronary heart disease), the absolute number of deaths is increasing as the total population increases. In addition, cohorts of smokers with the highest peak prevalence have now reached the ages with the highest incidence of smoking-attributable diseases (CDC, 2008).

Cigarettes are only one of an emerging spectrum of tobacco products available to consumers. While cigarette sales have recently started to decline, sales of smokeless tobacco products have tripled between 1986-2005 (US FTC 2006; USDA 1989-2006). In 2008, approximately 8.7 million Americans (3.5% of the adult population) reported past-month use of smokeless tobacco, most commonly among young adults aged 18-25 years of age (SAMHSA 2008). In addition, 5.4% of U.S. adults reported cigar use in 2009 (SAMHSA 2009). Reliable national estimates are currently unavailable for the diverse cigar products, as well as the use of novel tobacco products such as hookahs, electronic cigarettes and dissolvable tobacco. In addition, national surveillance data is needed to estimate the proportion of U.S. adults concurrently using multiple tobacco products (i.e. dual use).

All conventional tobacco products and many other products made or derived from tobacco are addictive, harmful and deadly. The use of smokeless tobacco increases the risk of oral, esophageal and pancreatic cancers, and may cause heart disease, gum disease, tooth decay, diabetes and reproductive effects (NIDA 2009; CDC 2011) . As cigar smoke is composed of the same toxic chemicals and carcinogens as cigarette smoke, differences in disease risk reflect differences in patterns of use, depth of inhalation and retention of cigar smoke (Burns 1998). Cigar smoking increases the risk of lung cancer, and other lung diseases such as emphysema and chronic bronchitis; cancers of the esophagus, larynx and oral cavity; and may increase the risk of coronary heart disease (Burns 1998; ACS 2010). Comprehensive national surveillance efforts are needed to monitor the public health burden associated with the use of non-cigarette tobacco products.

A.1.a.3 Costs of Tobacco Use

Average annual smoking-attributable health-care expenditures in 2000 through 2004 were approximately $96 billion. In addition to these direct health care expenditures, smoking accounted for an estimated 5.1 million years of potential life lost (YPLL) (3.1 for males and approximately 2.0 for females) annually, excluding deaths from smoking-attributable residential fires and adult deaths from secondhand smoke. Losses associated with YPLL resulted in $96.8 billion in productivity losses ($64.2 billion for males and $32.6 billion for females) from premature deaths. It has previously been estimated that the total economic cost to society of smoking--$96 billion per year in direct health-care expenditures and nearly $97 billion in productivity losses—is $193 billion per year (CDC, 2008). It is important to note, however,

that productivity loss from the 8.6 million persons living with a tobacco-related disease is not included in this estimate. By comparison, investments in comprehensive, state-based tobacco prevention and control programs in fiscal year 2007 totaled $595 million, approximately 325-times less than the smoking-attributable costs.

A.1.a.4 DHHS Objectives to Reduce Tobacco Use

The justification for the NATS has strong Federal support. Sources of support include the Healthy People 2020 objectives (USDHHS, 2010) and evaluation of the public health impact of FDA authorities under the TCA and of the CDC strategic plan for tobacco control.

The NATS provides multiple measures and data for the several of the Healthy People 2020 objectives, including the following (USDHHS, 2010):

TU-1 Reduce adult tobacco use**.**

The 2020 target in regards to cigarette smoking calls for an approximately 8.6% reduction in the proportion of adults reporting cigarette smoking, to 12% for all population groups- the same as it was for 2010. In addition, the 2020 target for smokeless tobacco products is a prevalence of 0.3%, a decrease in approximately two percentage points from 2005 adult smokeless tobacco use estimates. Lastly, the 2020 objectives call for a 2 percentage point decrease in the prevalence of cigar use, to 0.2%, from 2005 estimates. The NATS monitors multiple forms of tobacco use, including cigarettes, cigars and smokeless tobacco; asks about intentions to quit, and recent quit attempts among consumers using a variety of tobacco products; and monitors exposure to forces impeding and promoting cigarette smoking.

TU-3.5 Increase the average age of first use of tobacco products by young adults aged 18 to 25 years.

The 2020 target is to decrease by two percentage points the proportion of young adults reporting having not previously smoked cigarettes, cigars or used smokeless tobacco products in their lifetime, during the prior 12 months. The NATS gathers data about susceptibility to initiation of tobacco products among young adults, as well as age of initiation in a more robust fashion than other surveys. In addition, NATS monitors exposure to a range of pro- and anti-tobacco influences including sponsorship and marketing, health warnings, and tobacco-free policies, thereby enabling the identification of correlates of initiation (e.g., susceptibility, attitudes, and receptivity).

TU-4 Increase smoking cessation attempts by adult smokers.

The 2020 target is to increase the proportion of adult smokers who stop smoking for at least one day from 48% to 80%, which is the same as the 2010 target. Although the CTP cannot provide cessation assistance, the health warnings will help to increase the awareness of assistance available to tobacco users desiring to quit. Furthermore, one of the main goals of the CDC NCTP is to promote smoking cessation. The NATS assesses a range of factors associated with cessation intentions, including number of cessation attempts, length of abstinence from

tobacco use, and symptoms of withdrawal and addiction. Importantly, the NATS will also assess interest in quitting *all* tobacco use, not just cigarettes.

In addition, tobacco use is named in Healthy People 2020 as one of the USDHHS Secretary's 10 Leading Health Indicators. The Leading Health Indicators reflect the major public health concerns in the United States and were chosen based upon their ability to motivate action, the availability of data to measure their progress, and their relevance as broad public health issues. The Secretary also has recommended regular monitoring of national trends in current tobacco use.

FDA's strategic objectives are to decrease the initiation of tobacco use among young adults and youth, encourage tobacco use cessation and decrease the harms of tobacco products in order to decrease morbidity and mortality associated with tobacco use. These objectives are identical to two of the four the strategic goals laid out in CDC's Strategic Plan (CDC, 2006). While existing national surveys have provided measures for some of FDA's intended long-term public health outcomes (see Overview Logic Model, Appendix B), very few of the immediate, short-term and intermediate public health outcomes are regularly measured in existing surveys. As FDA's regulatory framework is implemented, the NATS will allow FDA to monitor patterns of all tobacco product usage- not just cigarettes- and identify changes in susceptibility and rates of tobacco use initiation, perceptions regarding tobacco use, patterns of use (including dual use of multiple products) and rates of tobacco use cessation.

A.1.b Privacy Impact Assessment Information

This study seeks to collect nationally representative data regarding tobacco use, attempts to quit tobacco use, exposure to forces promoting tobacco use and consumer perceptions regarding tobacco use. Data on tobacco use are generally regarded as being no greater than minimally sensitive. Therefore, the data collection will have little or no effect on the respondent's privacy. Nevertheless, safeguards will be put in place to ensure that all collected data remain private. As discussed below, no Information in Identifiable Form (IIF) will be collected.

A.1.c Overview of the Data Collection System

Modeled after the original OMB-approved NATS, data will be collected using CATI to interview adults via landlines and cell phones. The bulk of the interviews (approximately 56,250) will be conducted via landlines. An additional 18,750 interviews will be conducted via cell phones with respondents who do not have a landline. Customary protocols will be followed based on CDC's long experience in providing technical support to states with the Behavioral Risk Factor Surveillance System, as adapted to support NATS. Samples of landline and cell telephone numbers will be provided by Marketing Systems Group (MSG), which is a private company that maintains the Genesys sampling frame database. In providing the samples, MSG will follow protocols developed by CDC, which are described in Part B.

A.1.d Items of Information to be Collected

Respondents will be asked about their experience in using a variety of tobacco products, including new tobacco products, such as electronic cigarettes and dissolvable tobacco products; susceptibility to cigarette smoking among young adults (age 18-24) who have never smoked; addiction to tobacco among current users; intentions and attempts to quit tobacco use (cigarettes and other tobacco products); exposure to different types of marketing and promotion and responses to health warnings on packages and advertisements; purchasing behavior; household tobacco-free policies; and opinions and attitudes related to tobacco, especially the harm caused by tobacco use to the respondent and others.

Pertinent demographic information (e.g., gender, age group, race/ethnicity, and sexual orientation) will be collected. However, no IIF will be collected. To facilitate the data collection, two types of IIF are used temporarily: household addresses (for the landline sample only, when addresses can be found) and telephone numbers (without which an RDD telephone survey could not be conducted). While advance "dear resident" letters will be sent out to sampled households when feasible (i.e., when a telephone/address match is available) to give its occupants a heads-up that the household will be called soon, the address information derived from reverse directory searches will be used only to send the letters, will not be used in communications with prospective respondents, and will not be retained in the call record or the resulting data file. Similarly, the telephone numbers successfully called will not be retained in the call record or in resulting data file. Moreover, after the data collection has been completed, when tabular data are produced, the data will be reviewed to determine if the subject(s) can be identified when small cell counts occur. If there is the potential for the identification of these subject(s), (cell count fewer than 30 records), the data in these cells will be removed.

A.1.e Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

This information collection does not involve web-based data collection methods or refer respondents to web sites. In addition, it does not involve children under 13 years of age.

A.2 PURPOSE AND USE OF INFORMATION COLLECTION

NATS data will be used foremost by FDA in evaluating the effectiveness of the CTP in performing its new authorities. Results also will be available to and used by CDC in evaluating the NTCP, as well as several other parts of CDC and other Federal agencies. The information will have a broad use by state and local governments, nongovernmental organizations, and others in the private sector.

A.2.a **Purpose of Information Collection**

The broadest purpose of the study is to collect data to evaluate the impact of FDA regulatory activities and ensure that its efforts are protecting the public's health. Analytically, this means the purposes are to:

1. Estimate the extent to which adults engage in a variety of tobacco use behaviors.

2. Assess the degree to which tobacco use behaviors among adults vary as a function of gender, age, and race/ethnicity.
3. Estimate accomplishment of key short-term, intermediate, and long-term tobacco outcome indicators found in FDA's logic model.
4. Estimate the degree to which exposure to influences expected to promote or impede tobacco use has its expected effects.
5. Assess the degree to which response to influences expected to promote or impede tobacco use varies as a function of gender, age, and race/ethnicity.

A.2.b Anticipated Uses of Results by FDA

The NATS is being funded by FDA to provide progress measurements related to the regulatory activities of the Center for Tobacco Products (CTP). NATS data will be used by the CTP to evaluate the impact of regulatory efforts on the protection of public health, to inform policy and program development and to advance the science base for regulatory decision-making. Some ways the FDA plans to use NATS data include:

<u>Evaluation</u>

- Evaluate short, intermediate and long-term public health outcomes to assess compliance with legal mandates to regulate tobacco for the protection of public health.
- Evaluate FDA Performance Plan in compliance with Government Performance Results Act.
- Assess trends in tobacco use, including initiation and cessation among young adults, to determine the aggregate impact of CTP activities.
- Assess trends in product preferences among consumers, including initiation of novel product usage and multiple tobacco product use.
- Monitor consumer perceptions regarding tobacco products, and monitor whether perceptions change with the introduction of new or modified risk tobacco products.

<u>Policy and Program Development</u>

- Provide FDA with information about trends in the tobacco use behaviors among adults, including young adults, so CTP can identify appropriate regulatory strategies.
- Determine perceptions of users and nonusers to help inform FDA public information campaigns.
- Measure effectiveness of health warnings and CTP-sponsored health education efforts.
- Determine levels of exposure to prohibited marketing to inform compliance and enforcement planning.

<u>Research Synthesis</u>

- Identify research gaps regarding adult tobacco use and responses to FDA regulatory activities.
- Present data in peer-reviewed publications and at scientific meetings.

- Provide U.S. data to other federal agencies for use in supporting FDA and other agency's actions to reduce the morbidity and mortality from tobacco use.
- Provide U.S. data to researchers for use in developing the evidence base to support CTP regulatory-related activities.

A.2.c Anticipated Uses of Results by CDC

Within CDC, aside from OSH, NATS data are likely to be used by several divisions within CDC's National Center on Chronic Disease Prevention and Health Promotion, including the Division of Cancer Control and Prevention, Division of Diabetes Translation, and Division of Heart Disease and Stroke Prevention. Other Centers within CDC are likely data users, including the Center on Environmental Health.

The following uses of NATS data will be made by CDC:

Evaluation

- Provide progress measurements related to related *HP 2020* objectives.
- Evaluate CDC's Performance Plan in compliance with Government Performance Results Act.
- Assess trends in tobacco use among adults and exposure to pro- and anti-tobacco influences to determine the aggregate impact of tobacco prevention and control activities.

Research Synthesis

- Provide states conducting state adult tobacco surveys with a national index against which to compare their data on key short-term, intermediate, and long-term tobacco prevention and control outcome indicators.
- Present data in peer-reviewed publications and at scientific meetings.
- Identify research gaps in adult tobacco prevention and control.
- Provide public health and education officials and the general public with accurate information about tobacco use and exposure to pro- and anti-tobacco influences.
- Provide U.S. data for inclusion in analyses and reports based on cross-national comparisons.
- Provide data that are relevant and can be incorporated into a variety of government publications, including reports from the Surgeon General's office.

Policy and Program Development

- Provide policy makers with information about the tobacco use behaviors among adults so they can identify tobacco prevention and control interventions on which to focus resources.
- Provide state legislatures with information about the tobacco use and tobacco prevention and control interventions that should be preserved during a period of shrinking state budgets.
- Determine how public information campaigns that take into account exposure to pro- and anti-tobacco influences among adults should be devised.

Technical Assistance

- Help identify programs shown to be most effective in reducing tobacco use among adults.
- Assist states in interpreting their ATS data against a national benchmark.
- Provide evidence- and data-based technical assistance to state and local departments of health and education.
- Assess the need for new programs or modify existing programs that focus on reducing tobacco use among adults.
- Assess the cumulative effects of multiple interventions and sources of information (family, community, work, and the media) on tobacco use behaviors among adults.

A.2.d Anticipated Uses of Results by Other Federal Agencies and Departments

The survey results of the NATS may be helpful to other Federal agencies and departments, especially those supporting FDA actions to reduce the morbidity and mortality from tobacco use. For example:

- Department of Health and Human Services will use NATS data to provide progress measures at the national level on several Healthy People 2020 objectives and one of the 10 Leading Health Indicators. NATS also will generate data related to measuring accomplishment of the DHHS Strategic Action Plan for Ending the Tobacco Epidemic, especially related to monitoring.

- National Cancer Institute can use NATS data to help inform its research, educational efforts, and demonstration projects focused on adult tobacco use prevention and the determinants of cessation. NCI also can use NATS data to supplement and provide context for its periodic Tobacco Use Supplement to the Current Population Survey (TUS-CPS).

- Office of National Drug Control Policy can use the NATS data to report on tobacco use rates and determine the impact of media campaigns and enforcement efforts on tobacco use to determine the relative effectiveness of anti-drug vs. anti-tobacco campaigns.

- Substance Abuse and Mental Health Services Administration potentially will use NATS data as a frame of reference when assessing the annual National Survey on Drug Use and Health (NSDUH) and its state-level counterparts. SAMHSA also potentially will direct its grantees to NATS-based publications through various clearinghouses.

A.2.e Anticipated Use of Results by Those Outside Federal Agencies

NATS data are most likely to be used in a variety of ways by state and local governments, researchers, voluntary health organizations, physicians, health educators, workplace wellness programs, and community outreach organizations:

- Policy makers in the legislative and executive branches of government are likely to use NATS data to understand the relationships between tobacco use behaviors and exposure to pro- and anti-tobacco influences, to evaluate existing policies and programs, and to

develop new policies and programs based on evidence regarding effective tobacco use prevention and control programs.

- The NATS will provide an index against which state and local health agencies can compare their state ATS results on comparable questions.

- Family physicians, pediatricians, psychologists, and counselors will use the NATS to provide up-to-date information on tobacco use behaviors and factors that influence tobacco use for application in the patients they treat.

- Health educators will use the NATS to provide information that will bolster and provide a focus for their lesson plans and educational materials.

- Workplace wellness programs will use the NATS in their curriculum development to provide information on tobacco use behaviors and effectiveness of evidence-based tobacco prevention and control interventions.

- Employers will use the NATS results to create awareness of risk behaviors, assist in setting personal/corporate wellness goals, plan or modify existing programs, create/update staff development programs, and seek/target funding.

- Professional organizations will use NATS data to emphasize the importance of tobacco prevention efforts and monitor progress in tobacco control efforts.

A.2.f Privacy Impact Assessment Information

This study will collect information on a use of a variety of tobacco products, susceptibility to tobacco use among non-users and addiction to tobacco among users, intentions and attempts to quit all tobacco use, and exposure to forces promoting and impeding tobacco use. The data are being gathered to determine nationally the proportion of adults who use tobacco products and intend or have attempted to quit (and, if they have attempted, did so successfully). It also seeks to measure exposure to forces promoting and impeding tobacco use, as well as gather data on consumer perceptions of tobacco use. Data on tobacco use are generally regarded as being no greater than minimally sensitive. Therefore, the data collection will have little or no effect on the respondent's privacy. Nevertheless, safeguards will be put in place to ensure that all collected are safeguarded and remain secure. As indicated above, no IIF will be collected.

A.3 USE OF IMPROVED INFORMATION TECHNOLOGY AND BURDEN REDUCTION

All data collection will involve computer assisted telephone interviewing (CATI). Approximately 18,750 interviews nationwide will be conducted specifically among cell phone users. This stratum attempts to include the growing population of households that are cell phone only and may be missed in traditional RDD land-line surveys. Recent studies indicate that approximately 28% percent of U.S adults live in households that use cell phones only. The population disproportionately represents renters and younger households, certain minority populations, and low SES. By including cell phone numbers as part of our frame, we address

this growing use of information technology to reach beyond the traditional bounds of RDD surveys. There are no legal barriers to the use of information technology to reduce burden.

A.4. EFFORTS TO IDENTIFY DUPLICATION AND USE OF SIMILAR INFORMATION

CDC conducts ongoing searches of all major health-related electronic databases, reviews related literature, consults with key outside partners and other experts, and maintains continuing communications with Federal agencies with related missions through the Federal, interagency Tobacco and Nicotine Research Interest Group (TANRIG). These efforts have identified no previous, current, or planned efforts to conduct a comprehensive cross-sectional survey of tobacco use behaviors, exposure to pro- and anti-tobacco influences, and key short-term and intermediate outcome indicators among a nationally representative sample of non-institutionalized adults. The NATS is the sole national comprehensive cross-sectional adult tobacco survey specifically designed to monitor and evaluate key short term (attitudes and intentions) and intermediate (behaviors) outcome indicators of comprehensive tobacco control programs and policies and also to address indicators relevant to FDA's new responsibilities in regulation of tobacco products.

Other surveys that ask tobacco-related questions include the National Survey on Drug Use and Health (NSDUH) (OMB No. 0930-0110, exp. 8/31/2014) and the Tobacco Use Supplement to the Current Population Survey (TUS-CPS, OMB No. 0925-0368, exp. 3/31/2013). However, this should in no way suggest that other surveys represent duplications. Other national surveys, such as NSDUH, are multi-risk factor surveys that can ask only a limited number of questions about any one behavior. Tobacco use behavior is related to a wide spectrum of other health behaviors and health outcomes, and is thus a critical measure to include in surveys of many topics among youth and adults. However, those questions cannot meet the needs specific to the evaluation of tobacco prevention and control activities at CDC or the regulation of tobacco products by FDA. In addition, the TUS-CPS is administered only once every three years, which limits the timeliness of results, and has a focus on cessation, secondhand smoke exposure and worksite policies, all of which are relevant to the CDC and NIH, but not related to FDA regulatory authorities.

Given the recent passage of theTCA, no existing surveys include measures of particular relevance to FDA's regulatory authorities and actions. The newly-revised NATS has been designed to avoid duplication through collaborative efforts of both CDC and FDA. CDC and FDA are also employing this collaborative approach in measuring outcomes relevant to tobacco regulation focused exclusively on youth in the re-design of the National Youth Tobacco Survey (NYTS).

Appendix E contains item-level justifications for the NATS questionnaire related to FDA's mission. The source for each question is provided in Appendix E. Where appropriate, it has been indicated that some questions were newly developed because no already-existing question could capture the information FDA needs to monitor the implementation, outcomes, and public perception of its tobacco regulatory activities. Appendix F details how NATS measures

correspond to CDC's *Key Outcome Indicators for Evaluating Comprehensive Tobacco Control Programs.*

A.5 IMPACT ON SMALL BUSINESSES OR OTHER SMALL ENTITIES

The planned data collection does not involve small businesses or other small entities.

A.6 CONSEQUENCES OF COLLECTING THE INFORMATION LESS FREQUENTLY

NATS was originally approved by OMB in October 2009 as a one-time data collection to provide baseline for CDC's National Tobacco Control Program as a new five-year funding period began at the start of the third quarter of FY 2009. However, in the information collection request for the 2009-2010 NATS, CDC indicated to OMB that it was possible CDC would seek approval from OMB to conduct a follow-up NATS as a progress measure before the end of the five-year funding-cycle.

On June 22, 2009, the TCA was enacted, which gave FDA the authority to regulate tobacco products. Under this new authority, a number of regulatory and enforcement actions are underway or will be commencing soon, including the prohibition of certain types of tobacco advertising and promotion, prohibition of the sale of single cigarettes, elimination of flavors in cigarettes (other than menthol), enforcement of youth access restrictions, and the introduction of graphic warning labels on cigarette packs. Annual data collection is needed to monitor the impact of FDA's actions on public health as well as to measure potential unintended consequences (such as increased use of currently unregulated tobacco products such as e-cigarettes and little cigars), particularly during the first few years as FDA establishes its regulatory framework. Subsequently, partially at the direction of OMB, CDC and FDA began conversations to collaborate on NATS to meet data needs of both agencies. Subsequent annual cycles of NATS are critical to FDA in monitoring the effectiveness and public perceptions of its regulatory activities so adjustments in programmatic activities can be implemented on a timely basis.

A.7 SPECIAL CIRCUMSTANCES RELATING TO THE GUIDELINE OF 5 CFR 1320.5

The data collection will be implemented in a manner consistent with 5 CFR 1320.5. No special circumstances are applicable to this proposed survey.

A.8 COMMENTS IN RESPONSE TO THE FEDERAL REGISTER NOTICE AND EFFORTS TO CONSULT OUTSIDE THE AGENCY

A.8.a Federal Register Announcement

The 60-day *Federal Register* notice of the proposed data collection was published in the Federal Register on January 12, 2012; Vol.77, Number 8, pages 1938-1939 (Appendix C). CDC received one non-substantive comment and provided a courtesy reply. Substantive comments about the information collection instrument were received from Legacy (formerly, the American Legacy Foundation). A summary of public comments may be found in Appendix D.

After reviewing the substantive comments, CDC and FDA reached agreement that suggestions from Legacy's points 1 and 4 (see below) could be readily incorporated into the NATS survey, and made those additions. On March 27, 2012, CDC and FDA met with Cristine Delnevo, a nationally recognized tobacco researcher with extensive knowledge of the diversity of cigar products, to discuss in detail how to address point 2 from Legacy about including separate questions for cigars, cigarillos and little filtered cigars into the NATS questionnaire. CDC and FDA concluded that, given the on-going changes to the physical appearance of cigar-type products as a response to differential tobacco tax structures, development of valid questionnaire items that can measure prevalence of use of these various cigar products has been an ongoing concern among tobacco researchers, and a very difficult one to reconcile. After extensive discussion, there was consensus that the best way to address use of the various types of cigars was to include a question on size, filter and brand.

These changes have been incorporated into the revised questionnaire. Below is a summary of Legacy's comments and the actions CDC (and FDA) have agreed to take on the basis of Legacy's comments:

1. Include better descriptions of each product in the questions about these products.
- Prior to the set of questions dealing with cigars, cigarillos and little filtered cigars, we have developed an introductory script to be read to all participants, which defines each cigar product separately, and includes common brand names of each product to help trigger respondents' recall of cigars, cigarillos and/or little filtered cigars that they may have used in the past.

2. Ask questions about cigarillos and little filtered cigars separately.
- Among all respondents who indicate any current use of cigar products (daily use, some-day use or rare use), respondents will be asked to report on the size, filter and brand of cigars used.

3. Ask more questions about usage patterns.
- As the first step in better understanding the usage of cigar products, FDA's Center for Tobacco Products is currently in the planning phase of focus group research, the goal of which is to specifically explore how cigar smokers conceptualize each cigar product and how they differentiate one type of product from another. In addition, usage patterns of cigars will be explored, including the extent to which depth of inhalation may differ among products and how the social context in which the individual is smoking a cigar, cigarillo or little filtered cigar may affect usage.
- The focus groups will be based in 4 major U.S. cities and involve adolescents (12-17 years of age), young adults (18-24 years of age) and adults (25 years of age and older), with diverse representation of demographic characteristics, cigar product use, and frequency of cigar product use.
- These focus groups are intended to serve as formative research to inform the development of future measures that will enhance the capacity of our national surveillance systems to identify and track use and diversity amongst cigar products.

4. Ask about flavored individual products.

- Among all respondents who indicate any current use of cigar products (daily use, some-day use or rare use), respondents will be asked whether any of the cigar products they may have used in the past 30 days were flavored to taste like menthol or mint, clove, spice, candy, fruit or other sweets. Focus group research as outlined in #3, above, will explore the extent to which menthol flavoring in cigar products is perceived as having a similar or varied effect on the experience of smoking cigar products, compared to other flavorings.

A.8.b Consultations

CDC originally engaged the users of the State ATS and representatives of the scientific community and of other Federal agencies in designing the NATS questionnaire. A telephonic conference call involving representatives of 22 States on March 13, 2008, provided CDC with suggestions and feedback on the plan and design for NATS. Comments were again sought in the Fall 2008 and again in May/June 2009 in anticipation of a presentation to be made by CDC staff at the National Conference on Tobacco or Health in Phoenix, AZ, on June 11, 2008. Numerous states submitted questions and suggestions prior to that presentation.

In addition, CDC participated in a telephonic conference call on March 19, 2008, of the NIH Tobacco and Nicotine Research Interest Group (TANRIG). Formed in January 2003, TANRIG then had 48 members from NIH and other DHHS agencies, including 6 members from CDC. TANRIG's mission is to increase collaboration, coordination, and communication of tobacco- and nicotine-related research among NIH Institutes and Centers, and among partnering DHHS agencies outside of NIH. Members of TANRIG provided feedback on the plan and design for NATS, plus FDA's representative to CDC, in design of the NATS and alignment of questionnaire content with an expanded Federal need for the data.

In anticipation of the 2012-2013 NATS, FDA consulted additional representatives of Federal agencies and the scientific community to review the content of NATS to eliminate questions of less relevance to FDA and to add additional questions reflecting advancements in the science of measuring tobacco-use behavior and reflecting the specific data needs of FDA in tobacco regulation.

Appendix G contains a list of individuals who participated in the original consultations and the more recent consultations to update the NATS questionnaire to accommodate FDA's data needs. This appendix includes the consultations that occurred to address the comments submitted by Legacy during the 60-day public comment period.

A.9 EXPLANATION OF ANY PAYMENT OR GIFT TO RESPONDENTS

No payments will be made to respondents.

A.10 ASSURANCE OF CONFIDENTIALITY PROVIDED TO RESPONDENTS

The CDC Human Research Protection Office and the Assistant Directors of Science within OSH and the National Center on Chronic Disease Prevention and Health Promotion have

determined that NATS exempt from IRB review because it constitutes "public health practice" and, by definition, is not human subjects research.

As indicted in A.1, no IIF is collected from respondents. Two types of information are used to facilitate contacts with prospective respondents that would constitute IIF if they were collected from respondents or if they were otherwise added to and retained in the response record: telephone numbers and addresses. As noted, as feasible, the sample data obtained from MSG will include cross-referenced address information so that an advance "dear resident" letter may be sent to sampled landline households. However, no attempt will be made in the interview to determine whether the address used in the advance letter was correct. Both telephone and address information will be maintained in a file other than the response data file. The telephone information can be made available to interviewers temporarily so they can respond intelligently if a household member asks, "What number did you call?" The response data file will not contain any IIF; in particular, it will include neither the address nor the telephone number.

To ensure that respondent data are appropriately safeguarded, all interviewers will undergo extensive training prior to the start of data collection. The training will include modules on safeguarding response data and on procedures for reporting respondent complaints and unanticipated problems. All interviewers will sign a non-disclosure agreement (Appendix J) in which they agree to safeguard all collected data. In addition, interviewers will be instructed to discontinue a call if they feel someone is listening on another line. An unscheduled callback will be attempted at a later date for calls that are discontinued in this manner.

A.10.a Privacy Impact Assessment Information

This study will collect nationally representative data on uses of a variety of tobacco products, attempts to quit tobacco use, exposure to industry marketing and promotions, tobacco purchasing and consumer perceptions regarding tobacco use.

A. Privacy Act Determination. This submission has been reviewed by ICRO, who determined that the Privacy Act does not apply. Although information on respondents' addresses will be used to generate advance letters (Appendix L), response data will not be linked to respondent addresses or telephone numbers. The response data file will contain no IIF.

B. Safeguards. Precautions will be taken to ensure that all data are secure and that the contact information needed to facilitate data collection remains separate from the response data. Response data and the IIF used to facilitate data collection (telephone number, address) will remain in separate files and will be managed in ways that prevent unauthorized access at any point during the study. No part of the telephone number is included in the final data file submitted to CDC by the contractor. Similarly, the address information used to mail advance "dear respondent" letters will not be included in the response data and will not be in the data file submitted to CDC. As a result, a respondent's answers cannot be connected to a specific person, address, or telephone number. When reports or tabular data are produced, the data will be reviewed to determine if the subject(s) can be identified when small cell counts

occur. If there is the potential for the indirect identification of these subject(s), (cell count fewer than 30 records), the data in these cells will be removed. Respondents will be told during the initial screener that the information they provide will be maintained in a secure manner. All interviewers will be required to sign a non-disclosure agreement on the date of hire, which will be reinforced at training (Appendix K).

C. Consent. As is the norm in telephone surveys, verbal consent will be elicited from prospective respondents. Before an interview commences. The interviewer will read the informed consent script (see D below) to each participant. The consent script describes the interview, the types of questions to be asked, the risks and benefits of participation, and participants' rights, and provides information on whom to contact with questions about any aspect of the study. The consent script also indicates that participation is completely voluntary and that participants can refuse to answer any question or discontinue the interview at any time. The interviewer will enter a code via the keyboard to signify that the participant was read the informed consent script and agreed to participate. The consent scripts for landline respondents may be found at L7 (p. 7 of both Appendix H and Appendix I) and for cellphone respondents in C7 (p. 10 of Appendix H and pp. 10-11 of Appendix I).

D. Nature of Response. Participation in NATS is voluntary. Interviewers will tell respondents that, "Your participation in the study is voluntary. You don't have to answer any question you don't want to, and you can end the interview at any time. I won't ask for your full name, address, or other personal information that can identify you. The interview takes about 15 to 25 minutes to complete, depending on your situation. There are no known risks to you for taking part in this interview. There are no direct benefits to you for taking part in this interview, but your answers are important and will help the CDC better understand health issues and plan health programs. Your answers will be maintained in a secure manner. Any information that might identify you, such as your telephone number, will never be linked to your answers and will not appear in any written reports or publications. If you have any questions about this survey, I will provide a telephone number for you to call to get more information. This call may be monitored for quality assurance." In addition to providing the telephone number at CDC, a callback telephone number will be provided to anyone who wishes to speak with a supervisor at the data collection company (Westat).

A.11 JUSTIFICATION FOR SENSITIVE QUESTIONS

Excluding screeners, there are 126 questions on the NATS, of which 108 are specific tobacco-related questions (Appendix H/I). While an individual may be sensitive about answering such questions, the items are for the most part not of a sensitive nature and are commonly found in surveys of health behavior. Data on tobacco use are generally regarded as being no greater than minimally sensitive. Therefore, the data collection will have little or no effect on the respondent's privacy. Nevertheless, safeguards will be put in place to ensure that all collected data remain private. There are no questions concerning illegal drug use or other

criminal acts. There are no questions about emotionally charged experiences such as parental or sexual abuse. The one question that may be considered sensitive concerns sexual orientation.

Research on smoking and reasons for starting smoking have established some links between sexual orientation and propensity to smoke. Published literature on smoking among gay, lesbian, and bisexual individuals consistently finds higher rates of smoking compared to the general population (Ryan et al., 2001). Sexual orientation has been identified with health--related disparities in Healthy People 2020 and also is part of OSH's activities to identify and eliminate tobacco-related disparities.

Questions on sexual orientation (question 126A-D) were tested previously in cognitive interviews in preparation of questionnaires for other OMB-approved studies (Hispanic/Latino ATS, OMB No. 0920-0726, expiration: 8/31/2008; and the American Indian/Alaska Native ATS, OMB No. 0920-0671, expiration: 1/31/2008). Cognitive interviews revealed there was no issue of embarrassment in answering. Interviewers will be trained to ask the sexual orientation question in a neutral manner. If the interviewer senses any discomfort or reluctance to answer the question, the interviewer will be instructed to remind the respondent that he/she may choose to not answer the question. The question on sexual orientation has been updated for the new cycles of NATS because the National Center on Health Statistics (NCHS) within CDC has recently developed new questions about sexual orientation that are expected to be adopted throughout DHHS.

There are 18 demographic questions (counting those about cell phone use asked of landline respondents, and two closing questions). Five of the 18 ask about race and ethnicity (questions 94 through 98). OMB considers questions about race and ethnicity to be sensitive; however, they are important in determining whether disparities exist in health behavior , health status, and access to health services. On October 30, 1997, the Office of Management and Budget (OMB) published "Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity" (*Federal Register*, 62 FR 58781 - 58790). The 1997 standards reflect a change in data collection policy, making it possible for Federal agencies to collect information that reflects the increasing diversity of the U.S. population stemming from growth in interracial marriages and immigration. Under this policy, federal agencies are required to offer respondents the option of selecting one or more race responses from a list of five designated racial categories. Additionally, the standards provide for the collection of data on whether or not a person is of "Hispanic or Latino" culture or origin. Such standards also foster comparability across data collections carried out by various agencies. The race and ethnicity questions in the NATS follow all guidelines for the development of data collection questions, formats, and associated procedures to implement the 1997 standards, including the Oct. 31, 2011, final standards published by DHHS for data collection on race, ethnicity, sex, primary language and disability status as required under the Affordable Care Act.

A.12 ESTIMATES OF ANNUALIZED BURDEN HOURS AND COSTS

A.12.a Estimated Burden Hours

The estimated burden for this information collection is based on experience conducting the baseline NATS in 2009-2010 and on timed tests of burden derived from small-scale pilot testing described in B.5 below. The planned information collection involves administration of

the NATS questionnaire to approximately 75,000 adults. The English language version of the instrument is included as Appendix H and the Spanish language version of the instrument is included as Appendix I. Each appendix includes a screener for landline phone users (H-1 and I-1), a screener for cell phone users (H-2 and I-3), the main questionnaire (H-3 and I-3), and a cover letter with a Table of Contents (H-4 and I-4). Each interview is administered seamlessly.

The total average time to recruit, screen, and conduct the interview is 22 minutes. Approximately 2 minutes are needed to introduce the survey and screen for an eligible respondent, 1 minute is devoted to the informed consent process, and 20 minutes are required to complete the interview. A final pretest of the NATS questionnaire demonstrated that the vast majority of NATS interviews will take from 10 minutes to 30 minutes, with a mean of approximately 20 minutes. The total annual burden hours estimated for the NATS and associated support activities is 29,850.

The burden per response is the same as the burden on the prior cycle of NATS. The number of respondents is smaller because the prior cycle of NATS was designed to generate state-level estimates, whereas the new cycles of NATS will generate national estimates. Additional information on differences may be found in A.15.

Table A-12.a. Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden Per Response (in hours)	Total Burden (in hours)
Adults ages 18 or older	Screener for land-line users (pp. 3-8 of the NATS)	125,000	1	2/ 60	4,167
	Screener for cell phone users (pp. 9-10 of the NATS)	41,000	1	1/ 60	683
	National Adult Tobacco Survey (pp. 12-end of the NATS) - landline	56,250	1	20/ 60	18,750
	National Adult Tobacco Survey (pp. 12-end of the NATS) - cell phone	18,750	1	20/ 60	6,250
				Total	29,850

A.12.b Estimated Annualized Cost to Respondents

For this information collection, there are no direct costs to the respondents themselves. However, the cost to adult respondents can be calculated in terms of their time in responding to the NATS as seen in Table A-12.a. Table A-12.b illustrates the total calculation of costs to respondents for the NATS. The estimated respondent burden hours have been multiplied by an estimated

average hourly salary for persons in that category. The estimated burden cost in terms of the value of time adults spend in responding is based on information provided by the U.S. Department of Labor, Bureau of Labor Statistics, at http://www.bls.gov/oes/current/oes_nat.htm, which estimates the latest (May 2011) mean hourly earnings among adults across all occupations of $21.74/hour. At that hourly rate, the total annual cost burden for the time spent by participants is $648,939.

Table A-12.b. Annualized Estimated Cost to Respondents

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden Per Response (in hours)	Hourly Wage Rate	Total Annualized Respondent Costs
Adults ages 18 or older	Screener for land-line users	125,000	1	2/ 60	$21.74	$90,583
	Screener for cell phone users	41,000	1	1/ 60	$21.74	$14,856
	National Adult Tobacco Survey - landline	56,250	1	20/ 60	$21.74	$407,625
	National Adult Tobacco Survey - cell phone	18,750	1	20/ 60	$21.74	$135,875
				Total		**$648,939**

A.13 ESTIMATES OF OTHER TOTAL ANNUAL COST BURDEN TO RESPONDENTS OR RECORD KEEPERS

There will be no respondent capital and maintenance costs.

A.14 ANNUALIZED COSTS TO THE GOVERNMENT

The first of the three cycles of NATS for which clearance is requested is funded under Contract No Contract 200-2008-27960, Task Order 11. The total contract award to Westat, Inc. for the first cycle of data collection is $3,499,824 over a 26-month period. Extrapolating from this figure to the other two planned cycles of data collection, we estimate that the other two cycles will cost the government approximately the same dollar amount per cycle, or a total of $3,499,824 x 3 = $10,499,472 for all three cycles. Completion of all three cycles will occur over a 48-month period. Thus the estimated annualized contract cost is $10,499,472 divided by 4 = $2,624,868. These costs cover the activities in Table A-14 below.

Additional costs will be incurred indirectly by the government in personnel costs of staff involved in oversight of the study and in conducting data analysis. It is estimated that 3 CDC employees will be involved for approximately 25 %, 20%, and 15% of their time (for federal

personnel 100% time = 2,080 hours annually). The three salaries are $40.97, $50.03, $56.48 per hour. The direct annual costs in CDC staff time will be approximately $30,676 annually.

The annualized cost to the government for the study will be $2,624,865 + $ 59,736 = $ 2,684,601.

Activity	**Costs**
Contract Costs	
Cognitive testing of questionnaire items	$ 92,688
Design and plan study	$ 126,051
Program CATI questionnaire	$ 49,439
Train and provide quality control over data collectors	$ 305,626
Collect data	$ 1,918,313
Process data and maintain database	$41,785
Clean and weight data	$51,072
Produce data file with documentation	$39.894
Subtotal	$2,624,865
Federal Employee Time Cost	
25% time for one FTE@$40.97/hour	$ 21,304
20% time for one FTE@$50.03/hour	$20,812
15% time for one FTE@$56.48/hour	$ 17, 621
Subtotal	$ 59,736
Total Cost	$ 2,684,601

A.15 EXPLANATION FOR PROGRAM CHANGES OR ADJUSTMENTS

The proposed new cycles of NATS differ from the 2009/2010 NATS in two main respects. While the burden per response remains the same by design, the number of respondents is smaller because the current NATS seeks to develop national estimates, whereas the 2009/2010 NATS sought to develop state-level estimates. In terms of content, the NATS has been repurposed to meet the needs of both CDC and FDA through a single data collection rather than through two, separate, similar, overlapping data collections. The new NATS questionnaire contains core questions needed to address informational needs of both CDC and FDA in achieving their separate missions. Additional questions have been revised to meet the particular needs of FDA in evaluating the efforts of the CTP in accomplishing its legislated mandates regarding use of tobacco products, which were detailed in the introduction to Part A.

Because of the smaller number of respondents for a cycle of the proposed new NATS, the total respondent burden for a cycle is substantially lower than the prior cycle. The 2009/2010 NATS involved a total respondent burden of 38,303 hours. The new 2012/2013 NATS involves a total respondent burden of 29,850 hours, which amounts to 8,453 fewer hours, or 22.1% fewer hours, than the 2009/2010 cycle of NATS.

A.16 PLANS FOR TABULATION AND PUBLICATION AND PROJECT TIME SCHEDULE

A.16.a Tabulation Plans

Data will be tabulated in ways that will address the principal research purposes outlined in A.2. The planned analyses to be conducted are described briefly below:

1. *Estimate the extent to which adults engage in a variety of tobacco product use behaviors*. Percentages and confidence intervals will be calculated to address this objective.
2. *Assess the degree to which tobacco use behaviors among adults vary as a function of gender, age, and race/ethnicity*. Cross tabulations, Chi-square analyses, and regression analysis initially will be conducted to address this objective.
3. *Estimate accomplishment of key short-term, intermediate, and long-term tobacco prevention and control outcome indicators.* Cross tabulations, Chi-square analyses, and regression analysis initially will be conducted to address this objective.
4. *Estimate the degree to which exposure to influences expected to promote or impede tobacco use has its expected effects*. Chi-square and logistic regression analyses will be used.

5. *Assess the degree to which response to influences expected to promote or impede tobacco use varies as a function of gender, age, and race/ethnicity*. Chi-square and logistic regression analyses will be used.

Examples of the table shells that will be completed through analysis of the data are in Appendix K.

A.16.b Publication Plans

CDC and FDA plan to release NATS results through a variety of government publications, refereed journals, and annual conferences of national organizations focused on tobacco use, prevention and control, preventive medicine, health promotion, and epidemiology. FDA and CDC will publish main NATS results initially through the *MMWR,* which will be distributed to other Federal agencies, state and local health agencies, national health organizations, universities, and the general public. Additionally, NATS results, and eventually a public use data set, will be released via the CDC web site.

A.16.c Time Schedule for the Project

The following represents our proposed schedule of activities for the 2012-2013 NATS, in terms of months after receipt of OMB clearance. Data collection is scheduled to start on July 1, 2012 and end 12 months later on June 30, 2013. The schedule for subsequent annual cycles of NATS will be identical to the actual schedule for the 2012-2013 NATS. The urgency of receipt of timely clearance is driven by: (1)) the need for baseline data for FDA and (2) the immediacy of FDA's roll-out of various activities related to FDA's regulation of tobacco products. Key project dates will occur during the following time periods for the data collection:

Activity	Time Period
Program and test CATI instrument	Prior to OMB clearance *
Train interviewers	Prior to OMB clearance *
Conduct pre-testing	1 month after OMB
Collect NATS data	2 to 13 months after OMB clearance, beginning approximately May 1, 2012
Process data and maintain database	2 to 15 months after OMB clearance
Clean and weight data	16 to 17 months after OMB clearance
Produce data file with documentation	18 months after OMB clearance
Analyze data	19 to 22 months after OMB clearance
Publish results	23 to 25 months after OMB clearance

A.17 REASON(S) DISPLAY OF OMB EXPIRATION DATE IS INAPPROPRIATE

The expiration date of OMB approval of the data collection will be displayed.

A.18 EXCEPTIONS TO CERTIFICATION FOR PAPERWORK REDUCTION ACT SUBMISSIONS

No exemptions from the certification statement are being sought.

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