FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF CUSTOMER SATISFACTION SURVEYS GROUPS (0910-0360)

The generic clearance will only be used for customer satisfaction and website usability surveys where FDA seeks to gather information that is planned for internal use only, and can provide a justification for qualitative or anecdotal collections that may nonetheless produce useful information for program and service improvement.

TITLE OF INFORMATION COLLECTION: FDA Tobacco Regulatory Requirement Information Survey

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**
   The Center for Tobacco Products at FDA has undertaken an effort to educate its many stakeholders about its new role in regulating the manufacturing, advertising, distribution, and sale of certain tobacco products. As a first part of this activity, the Center will assess the knowledge and information currently available to stakeholders by conducting a needs assessment through an information interview.

2. **Intended use of information:**
   This information will be used to assess stakeholder's understanding of the processes, availability, and accessibility of materials pertaining to procedures and processes related to FDA's tobacco program and requirements. The information gained by this assessment will also help FDA understand how effective the material is in conveying how to interact and engage with the FDA's Center for Tobacco Products (CTP) staff.

3. **Description of respondents:**
   Respondents to this collection of information are FDA CTP stakeholders who partner with FDA or are impacted by FDA requirements and regulations for tobacco products.

4. **Date(s) to be Conducted:**
   The stakeholder assessments will be conducted by CTP's contractor, Information Experts from March 15, 2012 through May 15, 2012.

5. **How the Information is being collected:**
   Stakeholder assessments will be conducted by Information Experts. It is anticipated that up to 300 telephone interviews will be attempted, with 200 telephone interviews, each lasting 10 minutes, conducted. The public reporting burden for this collection of information is estimated to total 15 minutes for each interview, which includes time for reviewing instructions, searching existing data sources, gathering and maintaining data needed, and completing and reviewing the stakeholder assessment survey.

6. **Confidentiality of Respondents:**
   In the stakeholder assessment survey, the following statement will be read to each participant at the beginning of the survey, "Your participation or nonparticipation in this survey is completely voluntary and your responses will not have an effect on your eligibility for receipt of any FDA services. In instances where respondent identity is needed (e.g., for follow up), this information collection fully complies with all aspects of the Privacy Act and data will be kept private to the fullest extent allowed by law."

7. **Amount and justification for any proposed incentive**

N/A. There is no proposed incentive being offered for completing this voluntary stakeholder assessment survey.

8. **Questions of a Sensitive Nature**
   N/A. There are no questions of a sensitive nature being asked on either survey.

9. **Description of Statistical Methods**
   The sample size for the stakeholder needs assessment survey was based on a percentage of the number of prospective users of the Regs 101 class and Web audience anticipated to access Regs 101 on a regular basis. In order to educate stakeholders in how FDA regulates tobacco products, CTP has contracted a project to assess and develop educational materials to meet the educational needs of key audiences. The contractor will develop these materials by first conducting an environmental scan and then a needs assessment with key stakeholders to understand their requirements. It is anticipated that up to 300 telephone interviews will be attempted, with 200 telephone interviews lasting approximately 10 to 15 minutes eventually conducted. FDA estimates that it will take the stakeholder approximately 15 total minutes to complete the stakeholder assessment survey, which includes time for reviewing instructions, searching existing data sources, and completing the survey.

BURDEN HOUR COMPUTATION *(Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours):*

Type/Category of Respondent	**No. of Respondents**	**Participation Time (minutes)**	**Burden (hours)**
Completion of CTP's Stakeholder's Needs Assessment Survey	200	15 (0.25 hours)	50

REQUESTED APPROVAL DATE: March 15, 2012

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FDA CENTER: Center for Tobacco Products (FDA/CTP)