FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF RAPID RESPONSE SURVEYS (0910-0500)

FDA uses the Rapid Response Surveys to further develop tools and science necessary to better understand where vulnerabilities are and the most effective ways to minimize them, as well as to intervene and respond once a problem occurs.

TITLE OF INFORMATION COLLECTION: FDA's Center for Tobacco Products State Department of Health Electronic Cigarette Adverse Event Survey

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **What is the problem to be investigated:**
   In recent weeks, FDA has learned that certain malfunctions of electronic cigarettes have occurred which may impact public health. Because the information regarding malfunctioning electronic cigarettes has the potential to adversely affect public health and safety, it is imperative that OMB approve this generic collection of information no later than Tuesday, February 28, 2012, per the Rapid Response Survey 2011 Justification Statement. With this survey letter, FDA plans to ask each state's Department of Health whether it has information regarding adverse events involving electronic cigarettes.

2. **Please describe the method to obtain the convenience sample:**
   At this time, FDA plans to send a letter of inquiry to each state's Departments of Health regarding possible adverse events with electronic cigarettes. The letter will thank each state for its continued relationship with FDA, and ask the state whether it has information regarding adverse events involving electronic cigarettes. The expected responses will be voluntary and the information will help FDA better understand the health and safety issues associated with electronic cigarettes. This information is being collected through the use of a general letter so as not to impose significant burden on the states, to promote the sharing of information between the states and FDA, and to help FDA in its oversight of public health and safety.

3. **Are there any deviations to the described methods, procedures, and uses of data contained in the Rapid Response Survey 2011 Justification Statement:**
   YES / NO (if no skip to #5)

   No.

4. **If yes, please describe:**
   N/A

5. **Burden Chart and Description:**

   While FDA anticipates allowing each state 5 working days to gather and submit this information to FDA, the burden for collecting this information is expected to take each state's Department of Health approximately 16 hours. FDA has arrived at this estimate based on its expertise and the knowledge that most health departments have an electronic reporting system that categorizes the information by incident type, date, and description of incident. Therefore, the total burden for this collection of information is expected to take 800 hours (50 states x 16 hours).

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 (hours)	Burden (hours)
State Department of Health Inquiry Letter	50	16	800

6. **Attach Questions**

The letter which will be sent to the Departments of Health in all 50 states is included as part of the supporting documentation for this collection of information.

REQUESTED APPROVAL DATE: February 28, 2012 – **PLEASE NOTE**: The information regarding electronic cigarettes noted above has the potential to adversely affect the public's health and safety. In order to begin gathering information from credible sources to protect the health and safety of the public, FDA is requesting that OMB conduct an expedited review and approve this generic collection of information no later than February 28, 2012.

NAME OF PRA ANALYST & PROGRAM CONTACT:

FDA: Daniel Gittleson, 301-769-5156, daniel.gittleson@fda.hhs.gov
CTP: Christopher Colburn, 301-796-8758, christopher.colburn@fda.hhs.gov

FDA CENTER: Center for Tobacco Products