

Attachment 2b

Summary of Public Comments and CDC Response

Federal Register Notice: A 60-day Notice was published in the *Federal Register* on September 15, 2014
(Volume 79, Number 178, pages 54983-54984)

Public Comment #1

From: jean public [<mailto:jeanpublic1@gmail.com>]

Sent: Monday, September 15, 2014 4:03 PM

To: OMB-Comments (CDC); vicepresident@whitehouse.gov; americanvoices; INFO; media

Subject: Fwd: excuse to do nothing = no real work just studies for eternity - shut it down - we have had enough

THIS AGENCY IS WORTHLESS. THEY CANT EVEN TELL WHERE THEIR ANTHRAX IS STORED. THEY SEEM TO BE ALL VOYEURS WHO WANT TO GET THE MOST INTIMATE DETAILS AND THEN NO ACTION TO HELP ANY AMERICAN EVER ISSUES FROM THIS AGENCY. THIS AGENCY DESERVES AN F MINUS GRADE FOR ITS WORK FOR AMERICANS. I CAN UNDERSTAND THIS BEING DONE ONCE EVERY TEN OR FIVE YEARS, BUT CERTAINLY NOT EVERY YEAR. THE INFORMATION GATHERING AND REPORTS ARE JUST TOO EXTENSIVE, TOO COSTLY AND RESULT IN NOTHING FOR AMERICA. THE WORK OF THIS AGENCY APPEARS TO BE THE EMPLOYEES CONSTANTLY BOTHERING THE US PUBLIC ON TELEPHONE SURVEYS OVER AND OVER AND OVER AGAIN. THEY REALLY LISTEN TO NOTHING THAT THEY ARE TOLD. THEY PUSH DRUGS AND VACCINES CONSTANTLY WHEN IT IS KNOWN THAT VACCINES HURT SOME AMERICANS TREMENDOUSLY AND THAT WE HAVE AN AUTISM PROBLEM RAMPANT IN THOSE WHO HAVE TAKEN VACCINES. THIS COMMENT IS FOR THE PUBLIC RECORD PLEASE RECEIPT JEAN PUBLIC JEANPUBLIC1@YAHOO.COM

Subject: excuse to do nothing = no real work just studies for eternity - shut it down - we have had enough

>

[Federal Register Volume 79, Number 178 (Monday, September 15, 2014)]

[Notices]

[Pages 54983-54984]

From the Federal Register Online via the Government Printing Office [www.gpo.gov]

[FR Doc No: 2014-21909]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60-Day-14-14AYC]

CDC Response to Public Comment #1

CDC provided a courtesy reply

Public Comment #2

(see next page)

CDC Response to Public Comment #2

CDC provided a courtesy reply

CONFIDENTIAL

November 13, 2014

Leroy A. Richardson, M.S., M.P.H., M.S.C.J., C.P.H.A.
Chief, Information Collection Review Office
Office of Scientific Integrity
Office of the Associate Director for Science
Office of the Director
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road N.E., Mailstop D-74
Bldg. 21, Room 8208
Atlanta, GA 30333
Phone: (404) 639-4965
LMR7@CDC.GOV

Re: FR Doc No. 2014-21909: Proposed Data Collections Submitted for Public Comment and Recommendations – Behavioral Risk Factor Surveillance System (BRFSS)

1 Introduction

These comments are submitted in response to the September 15, 2014 Federal Register Notice announcing Proposed Data Collections Submitted for Public Comment and Recommendations [FR Doc No. 2014-21909].

Pinney Associates appreciates the opportunity to provide comments to the Centers for Disease Control and Prevention regarding the Behavioral Risk Factor Surveillance System. **Pinney** Associates' scientists and health policy experts provide science- and public health-based strategic solutions to support decision-making by consumer health and pharmaceutical companies. Our consulting firm provides services for a wide range of companies, including some that market stop-smoking medications and electronic nicotine delivery systems. Some of our principals also are members in a limited liability corporation that owns intellectual property for an as-yet not-commercialized nicotine gum. Although **Pinney** Associates provides advice and guidance to companies with products that are or would be addressed in BRFSS, we are not representing nor speaking on behalf of any client with these comments.

Federal health surveys provide valuable information about the health and health-related behaviors of the United States (U.S.) population. These data are useful for a variety of audiences, including those that seek to monitor the use and misuse of various substances. Our comments on the BRFSS are focused on questions that assess tobacco product use. As a company, we have over 75 years' experience in the tobacco control field, and we believe that our input on these items can provide valuable assistance to the CDC as the BRFSS is adapted to address ongoing changes in the use and availability of tobacco-related products.

2 Recommendations

Our comments are based on our review of the draft 2015 BRFSS questionnaire documents. Each of the federal surveys makes valuable contributions by providing different details about population-level health and behavior, and the greatest value can

CONFIDENTIAL

be obtained when similar questions (and response categories) are used for assessing product use, so that patterns can be examined across surveys and over time using the same metrics. Therefore, we recommend that questions on the BRFSS mirror those on other federal surveys (e.g., National Health Interview Survey [NHIS], Health Information National Trends Survey [HINTS], and National Survey on Drug Use and Health [NSDUH]), where appropriate. Specific recommendations follow.

2.1 Add questions about cigarette consumption and nicotine dependence

The tobacco use survey items that provide significant value for public health professionals and tobacco control researchers include cigarettes per day (CPD) and time to first cigarette (TTFC), which are two of the key items on the Fagerström Test for Nicotine Dependence (FTND). In fact, they are the only two items on the Heaviness of Smoking Index (HSI), another measure of nicotine dependence. Therefore, we recommend that the BRFSS include both of these questions on this and future surveys, and specifically the following question (Q) and response options for current smokers:

2.1.1 Cigarettes per day

Q: On the average, about how many cigarettes do you now smoke a day? (for everyday smokers)

- ___ = Number of cigarettes
- DK/NS (Don't Know/Non-Smoker)
- Refused

Note: This CPD question was part of the BRFSS core questionnaire for most of the BRFSS survey years from 1984-2000. There was a slight change in one of the response categories in 1994 (i.e., changed from "Don't smoke regularly" to "DK/NS" (Don't Know/Non-Smoker), but the question remained the same.¹

Q: On the average, when you smoked during the past 30 days, about how many cigarettes did you smoke a day? (for someday smokers)

- ___ = Number of cigarettes
- Enter '1' if less than 1
- Enter '95' if 95 or more cigarettes

Note: This CPD question was part of the BRFSS core questionnaire during several survey years (i.e., 1994-2000).

2.1.2 Time to first cigarette

Q: How soon after you wake up do you usually have your first cigarette?

¹ Centers for Disease Control and Prevention, Office of Surveillance, Epidemiology, and Laboratory Services. Behavioral Risk Factor Surveillance System Historical Questions Detail (query system): <http://apps.nccd.cdc.gov/BRFSSQuest/DisplayV.asp?PermID=63&startpg=1&endpg=10&TopicID=14&text=cigarettes&Join=OR&FromYr=Any&ToYr=Any>

CONFIDENTIAL

- within 5 minutes
- from 5 to 30 minutes
- from 30 minutes to 1 hour
- more than 1 hour

Note: This TTFC question appeared on the Iowa state-level BRFSS survey in 2012.²

2.2 Add questions about use of electronic nicotine delivery devices (electronic-cigarettes)

Due to the rapidly evolving tobacco and nicotine-product use landscape, we recommend that CDC consider adding questions about electronic cigarettes (e-cigarettes, also called vaping devices) to the core BRFSS questionnaire, because they will provide important information on the use of these products.

Specifically, we recommend two additional questions for inclusion on the core survey, with the first question being asked of everyone, regardless of smoking status, and the second question being asked of those who have ever used e-cigarettes. We suggest the following explanatory introduction for these questions:

The next question is about electronic cigarettes or e-cigarettes. You may also know them as vape-pens, hookah-pens, e-hookahs, or e-vaporizers. Some look like cigarettes, and others look like pens or small pipes. These are battery-powered, usually contain liquid nicotine, and produce vapor instead of smoke.

Q: Have you EVER used an e-cigarette EVEN ONE TIME?

- Yes
- No
- Don't know/Not sure
- Refused

Q: Do you now use electronic cigarettes or e-cigarettes every day, some days, or not at all?

- Every day
- Some days
- Not at all
- Don't know/Not sure
- Refused

² Brandstad T. and Miller-Meeks, M. Health in Iowa Annual Report from the Behavioral Risk Factor Surveillance System, Iowa 2012. Iowa Department of Public Health
<http://www.idph.state.ia.us/brfss/common/pdf/2012BRFSSannual.pdf>

CONFIDENTIAL

2.3 Add a question about menthol cigarette use

The Food and Drug Administration (FDA) banned characterizing flavors in cigarettes, but the legislation exempted menthol from this flavor ban. Although the FDA Tobacco Products Scientific Advisory Committee (TPSAC) called for the FDA to ban menthol cigarettes, menthol cigarettes are still marketed in the U.S. without restrictions. We recommend that BRFSS include a question asking about use of menthol cigarettes to monitor their use and changes in their use over time.

Q: During the past 30 days, were the cigarettes you smoked usually menthol?

- Yes
- No

Note: This menthol question appeared on the Iowa state-level BRFSS survey in 2012.³

We believe that the above recommended additions to the BRFSS core questionnaire will provide important data for public health professionals concerned about the use of tobacco-related products. Thank you for the opportunity to provide comments on this instrument. Please contact Karen Gerlach, Senior Scientist and Co-Director, Clinical and Behavioral Research, at kgerlach@pinneyassociates.com or 724-749-5141 if you have any questions or need further information.

Sincerely,

Karen Gerlach, PhD, MPH
Deirdre Lawrence Kittner, PhD, MPH
Janine Pillitteri, PhD
Mark A. Sembower, MS

³ Brandstad T. and Miller-Meeks, M. Health in Iowa Annual Report from the Behavioral Risk Factor Surveillance System, Iowa 2012. Iowa Department of Public Health
<http://www.idph.state.ia.us/brfss/common/pdf/2012BRFSSAnnual.pdf>