Attachment 2

Federal Register Notice, Volume 73, No. 70, pp. 19507-08, April 10, 2008

Proposed Project

Formative Evaluation of Adults' and Children's Views Related to Promotion of Healthy Food Choices—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In FY 2004, Congress directed the Centers for Disease Control and Prevention (CDC) to conduct formative research on the attitudes of children and parents regarding nutrition behavior and the characteristics of effective marketing of foods to children to promote healthy food choices. In response, CDC will work with a contractor to conduct focus groups to explore barriers and motivations to the adoption and maintenance of healthy food choices among children at different developmental stages. Current literature and opinion-leaders both strongly suggest that ''tweens'' (ages 9–12) greatly influence their parents' and younger siblings' nutritional decisions. The focus groups will also explore the topic of family interactions around decision-making about food choices. The information gathered will be used to develop, refine, and modify messages and strategies to increase healthy food choices by children and parents.

A total of 90 focus groups will be conducted in three phases: Phase 1 will address tweens and parents of tweens; Phase 2 will focus on children 5–8 years old and their parents; and Phase 3 focus groups will be conducted with parents of children ages 1–4 years old. Thirty-six focus groups will be conducted in Phase 1; 36 focus groups will be conducted in Phase 2; and 18 focus groups will be conducted in Phase 3.

All focus groups will incorporate appropriate representation of diverse ethnic groups, and the groups will be held in several cities to ensure broad geographic representation. Participants will be recruited by focus group facilities utilizing their database to solicit and screen interested parties. Each focus group discussion will be limited to no more than two hours.

There is no cost to respondents other than their time. The total estimated annualized burden hours are 1,556.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	No. of respondents	No. of responses per respondent	Average burden (in hours)
Children	Screener D1 for Parent & Child Groups	384	1	3/60
	Screener D2 for Child Only Groups	384	1	3/60
	Focus Group Moderator's Guide for Children/ Youth.	384	1	2
Parents	Screener D1 for Parent & Child Groups	192	1	7/60
	Screener D2 for Child Only Groups	192	1	7/60
	Screener D3 for Parent Only Groups	288	1	7/60
	Focus Group Moderator's Guide for Parents	336	1	2

Dated: April 1, 2008.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–08–08AX]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–5960 or send comments to Maryam Daneshvar, Acting CDC Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov*.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection 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 on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Nationally Notifiable Sexually Transmitted Disease (STD) Morbidity Surveillance—New—Division of STD Prevention (DSTDP), National Center for HIV, Viral Hepatitis, STD and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Because the STD epidemiology in the United States is changing rapidly, CDC must monitor disease indicators that are not currently included in the STD surveillance currently being implemented. CDC is proposing a new electronic information collection which will include information elements that will be integrated into the existing nationally notifiable STDs. These new information elements are beyond the scope of the OMB-approved collection called Weekly and Annual Morbidity and Mortality Reports (*MMWR*, OMB #0920–0007). The new collection will be epidemiologically superior to the existing system and will provide evidence to better define STD distribution and epidemiology in the United States. The proposed surveillance system will modify several data elements currently included in the *MMWR* collection and add others to produce a new set of sensitive indicators. This new surveillance will provide the evidence to enhance our understanding of STDs, develop intervention strategies, and evaluate the impact of ongoing control efforts.

CDC works closely with state and local STD control programs to monitor

and respond to STD outbreaks and trends in STD-associated risk behavior. Users of data include, but are not limited to, congressional offices, state and local health agencies, health care providers, and other health-related groups.

CDC disseminates all STD surveillance information through the MMWR series of publications, including the MMWR, the CDC Surveillance Summaries, the Recommendations and Reports, and the annual Summary of Notifiable Diseases, United States. Additionally, DSTDP publishes an annual STD-specific surveillance summary and supplements in hard copy on CD–ROM and on the Internet *http://www.cdc.gov/nchstp/dstd/Stats_Trends/Stats_and_Trends.htm.*

CDC will use the findings from this and other STD surveillance to develop guidelines, control strategies, and impact measures that monitor trends in STDs in the United States.

We expect a total of 57 sites in state, city, and territory health departments will be submitting STD morbidity information to CDC each week.

ESTIMATE OF ANNUALIZED BURDEN TABLE

Types of data collection	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden in hours
States	50	52	20/60	867
Territories	5	52	20/60	87
Cities	2	52	20/60	35
Totals	57	.....	.....	989

Dated: April 3, 2008.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E8–7575 Filed 4–9–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0027] (formerly Docket No. 2007N–0495)

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device User Fee Amendments of 2007; Foreign Small Business Qualification Certification, Form FDA 3602A

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 12, 2008.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0613. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Device User Fee Amendments of 2007; Foreign Small Business Qualification Certification, Form FDA 3602A—(OMB Control Number 0910–0613)—Extension

The FDA Amendments Act of 2007 includes the ''Medical Device User Fee Amendments of 2007'' (the 2007 Amendments), which reauthorizes medical device user fees for fiscal years (FY) 2008 through 2012 and which makes significant changes to the medical device user fee provisions of the act. The 2007 Amendments provide a new way for a foreign business to qualify as a small business eligible to pay a significantly lower fee when a medical device user fee must be paid.

Before passage of the 2007 Amendments, the only way a business could qualify as a small business was to submit a Federal (U.S.) income tax return showing its gross receipts or sales that did not exceed a statutory threshold, (currently $100 million). If a business could not provide a Federal income tax return, it did not qualify as a small business and had to pay the standard (full) fee. Because many foreign businesses have not, and cannot, file a Federal (U.S.) income tax return, this requirement has effectively prevented those businesses from qualifying for the small business fee rates. Thus, foreign governments, including the European Union, have objected.

In lieu of a Federal income tax return, the 2007 Amendments will allow a foreign business to qualify as a small business by submitting a certification from its national taxing authority, the foreign equivalent of our Internal Revenue Service. This certification, referred to as a ''National Taxing Authority Certification,'' must:

- Be in English;
- Be from the national taxing authority of the country in which the business is headquartered;
- Provide the business' gross receipts or sales for the most recent year, in both the local currency and in U.S. dollars, and the exchange rate used in converting local currency to U.S. dollars;
- Provide the dates during which the reported receipts or sales were collected; and
- Bear the official seal of the national taxing authority.

The new FDA Form 3602A, ''FY 2008 MDUFMA Foreign Small Business Qualification Certification,'' will collect the information required by the statute and allows a foreign business to qualify for the same small business benefits as a domestic U.S. business.

In the **Federal Register** of January 15, 2008 (73 FR 2503), FDA published a 60-day notice requesting public comment on the information collection