

CFR reference	Data collection	No. of respondents	Responses per respondent	Avg burden per response (in hrs.)
73.7(b)	Registration Application	575	1	3.75
73.7(b)	BSL4 Supplement	4	1	2
73.7(e)	Amendment to Registration Application	575	2	1
73.17(a)(e)	Notification Form	10	1	1
73.6(c-e)	Request for Exemption	17	1	1.16
73.14	Transfer of Select Agent	575	5	1.75
73.6(a)(2)	Clinical and Diagnostic Laboratory Exemption Report	1,000	4	1
73.7(i)	Notification of Inactivation	6	1	30/60
73.8(g)	Request Expedited Review	6	1	30/60
73.10(b)	Documentation of Self-inspection	575	1	1
73.13(f)	Documentation of Training	575	1	2
73.18	Administrative Review	14	1	4
73.15(d)	Ensure Secure Record keeping System	575	1	30/60

Dated: August 25, 2003.

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[FR Doc. 03-22254 Filed 8-29-03; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-68-03]

Proposed Data Collections Submitted for Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 498-1210. Send written comments to CDC, Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 or by fax to (202) 395-6974. Written comments should be received within 30 days of this notice.

Proposed Project

Menthol Crossover Study—New—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC). CDC proposes a study to measure differences in African-American and Caucasian smokers in the dose and metabolism of chemicals in smoke from menthol and non-menthol cigarettes.

African-American smokers are more likely than Caucasian smokers to develop some forms of cancer and to have shorter long-term survival after diagnosis. More than 65% of African American smokers smoke menthol cigarettes, compared with about 23% of white smokers. Smoking menthol cigarettes has been associated with higher blood-cotinine levels. Cotinine is a product of the metabolism of nicotine, and the higher cotinine levels suggest that menthol may enable a smoker to obtain more nicotine from each cigarette. In addition, people who smoke menthol cigarettes also have higher levels of carbon monoxide in their breath than do people who smoke non-menthol cigarettes, and an elevated carbon monoxide level is a risk factor for cardiovascular disease. Additionally, the presence of menthol in cigarettes may change the way people smoke cigarettes.

All previous studies have compared people who smoke menthol cigarettes

with those who smoke non-menthol cigarettes; and it is not known whether increased cotinine and carbon monoxide levels in people who smoke menthol cigarettes are attributable to racial or ethnic differences, or a combination of multiple factors. In addition, no previous study has examined the differences between urinary levels of cancer-causing chemicals in people who smoke menthol or non-menthol cigarettes and correlated these findings with smoke exposure intake estimates using salivary cotinine and filter solanesol.

For this two-part crossover study, we will recruit African-American and Caucasian smokers of both sexes who smoke either menthol or non-menthol cigarettes as study subjects. We will determine smoking history then randomly assign each participant to smoking either menthol or non-menthol cigarettes for an initial 2-week period. Study participants then will switch to the opposite type of cigarette for the next 2 weeks. At baseline, and after each 2-week period, we will measure the way the participants smoke the test cigarettes to determine smoking topography. Saliva, urine, and breath samples will be collected to measure by-products of smoking, and participants will complete a brief smoking-history questionnaire. There is no cost to respondents.

Forms	No. of respondents	No. of responses/respondent	Average burden/response (in hours)	Total burden in hours
Response to Flyer: Screening Interview Form	200	1	5/60	17
Site Visits: Check in, Study Information, Visit 1, 2, 3	71	3	15/60	53
Consent Form, Questionnaire, Visit 1, 2, 3	71	3	15/60	53
Urine Sample and Saliva Sample, Visit 1, 2, 3	71	3	15/60	53
Breath Carbon monoxide (CO) Sample: Test Smoke 1, Breath CO Sample; Test Smoke 2, Breath CO Sample; Visit 1, 2, 3	71	3	45/60	160
Sample Test Cigarettes, Distribute Baggies & Cigarettes, Visit 1 and 2	71	2	15/60	36
Instructions and Check out, Visit 1 and 2	71	2	15/60	36
Smoking Cessation Advice, Visit 3 only	71	1	15/60	18