

publish this guidance by August 1, 2003.

Respondents will be businesses or other for-profit organizations. FDA

estimates the burden of this information collection as follows:

TABLE 1. — ESTIMATED ANNUAL REPORTING BURDEN¹

FDA Form Number	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3602	3,000	1	3,000	1	3,000

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA based these estimates on conversations with industry, trade association representatives, and from internal FDA estimates. This represents FDA's estimate on the number of small businesses that will submit a premarket notification, a premarket application, a premarket report, a panel track supplement, efficacy supplement, 180-day supplement, or a real time supplement to FDA during a single fiscal year from FY 2004 through 2007.

Dated: July 11, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration

(SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443-7978.

*2004 National Survey on Drug Use and Health—(OMB No. 0930-0110, Revision)—*The National Survey on Drug Use and Health (NSDUH), formerly the National Household Survey on Drug Abuse (NHSDA), is a survey of the civilian, noninstitutionalized population of the United States 12 years old and older. The data are used to determine the prevalence of use of tobacco products, alcohol, illicit substances, and illicit use of prescription drugs. The results are used by SAMHSA, ONDCP, Federal government agencies, and other organizations and researchers to establish policy, direct program activities, and better allocate resources.

As with all NSDUH/NHSDA surveys conducted since 1999, the sample size of the survey for 2004 will be sufficient to permit prevalence estimates for each of the fifty states and the District of

Columbia. For the 2004 survey, additional questions in the following substantive areas are planned: adult mental health treatment (three additional questions to obtain more detail on unmet mental health treatment need, and on alternative mental health treatment received); drug treatment (four questions on age at first treatment for alcohol and/or drug use); prior substance use (expanded 2003's prior marijuana and cigarette use module to collect information on age at last use for each core substance respondent reported last using over 30 days); depression (separate modules for adolescents and adults based on adaptations of existing modules used in the National Comorbidity Survey). The following questions are planned to be deleted from the 2004 survey: speciality cigarettes (questions about clove and bidi use); amount paid for cigarettes in the past 30 days; and youth access to cigarettes. Three to four years of data have been collected on these questions, which may be included again in future surveys as the need arises. The total annual burden estimate is shown below:

	Number of respondents	Responses per respondent	Average burden per response (hr.)	Total burden (hrs)
Household Screening	182,250	1	0.083	15,127
Interview	67,500	1	1.0	67,500
Screening Verification	5,559	1	0.067	372
Interview Verification	10,125	1	0.067	678
Total	182,250	83,677