

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**

Assisted Reproductive Technology (ART) Program Reporting System—Extension—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

Section 2(a) of Public Law 102-493 (known as the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA), 42 U.S.C. 263a-1(a)) requires that each ART program shall annually report to the Secretary through the Centers for Disease Control and

Prevention—(1) pregnancy success rates achieved by such ART program, and (2) the identity of each embryo laboratory used by such ART program and whether the laboratory is certified or has applied for such certification under this Act. The Act defines ART as all treatments and procedures that include the handling of human oocytes and sperm or embryos for the purpose of establishing a pregnancy.

The Centers for Disease Control and Prevention seeks to extend approval of a reporting system for the Assisted Reproductive Technology (ART) Program from the Office of Management and Budget (OMB) for a period of 3 years. The reporting system includes all ART cycles initiated by any of the approximately 400 ART programs in the United States, and covers the pregnancy outcome of each cycle as well as a number of data items deemed important to explain variability in success rates across ART programs and across individuals. An ART cycle is started

when a woman begins taking medication to stimulate the ovaries to develop eggs or starts ovarian monitoring with the intent of having embryos transferred. Data will be collected through a Web-based data collection system, developed by Westat in consultation with CDC, that complies with FCSRCA requirements.

In developing the definition of pregnancy success rates and the list of data items to be reported, CDC has consulted with representatives of the Society for Assisted Reproductive Technology (SART), the American Society for Reproductive Medicine (ASRM), and RESOLVE, the National Infertility Association (a national, nonprofit consumer organization), as well as a variety of individuals with expertise and interest in this field. The average annual cost to each ART program responding to the survey, including data entry and validation, is estimated to be \$6,720.

**Estimated Annualized Burden Table**

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden (in hours)
ART Programs (data entry) .....	*400	*288	37/60	71,040
ART Programs (selected for data validation) .....	**40	**83	23/60	1,273
Total .....				72,313

\*Approximately 400 ART programs (respondents) reported data in 2002. The average number of ART cycles (responses) per ART program was 288.

\*\*Approximately 10% of the ART programs are selected for validation. An average of 83 ART cycles per ART program were selected for validation in 2002.

Dated: December 7, 2005.

**Joan F. Karr,**

*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-06-06AI]

**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 404-639-4766 or send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to [omb@cdc.gov](mailto: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**

Metropolitan Atlanta Stillbirth Management Survey: Knowledge, Attitudes and Practice Patterns from Obstetricians, new collection, National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

The U.S. Congress House Report 108-792 (joint conference report for the Fiscal Year 2005 omnibus appropriations bill) provides specific funding to devise a comprehensive strategy for expanding existing birth defects surveillance systems to incorporate surveillance data on all intrauterine fetal deaths of 20 or more week's gestation into the Metropolitan Atlanta Congenital Defects Program (MACDP). Stillbirth is largely an understudied adverse pregnancy outcome even though it accounts for nearly one half of all perinatal mortality. There is currently no nationally

accepted definition of what constitutes a stillbirth, and there are no universally recommended, standardized stillbirth evaluation protocols in use for the evaluation of fetal deaths. The proposed survey has been designed to evaluate and assess the knowledge, attitudes and practice management patterns of obstetricians in the metropolitan Atlanta area regarding stillbirths in general, as well as in their medical practice. This

information will be used to identify prevailing deficiencies leading to incomplete and inaccurate reporting of data relative to stillbirths, and to develop targeted awareness and educational strategies for participating MACDP facilities. Ongoing, accurate and reliable population-based registries of stillbirths are essential for conducting epidemiologic studies on the causes of and risk factors for this pregnancy

outcome. This survey will be mailed to randomly selected obstetricians whose practices serve residents of the 5 counties comprising metropolitan Atlanta. This survey will be conducted once and will take approximately 2–3 months to collect the data. NCBDDD is requesting OMB clearance for 1 (one) year. There is no cost to the survey respondents except for the time necessary to complete the survey.

#### ESTIMATED ANNUALIZED BURDEN TABLE

Respondents (type)	Respondents (number)	Number of responses per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
Obstetricians .....	600	1	30/60	300
Total .....	600	.....	.....	300

Dated: December 7, 2005.

**Joan F. Karr,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005N-0479]

#### International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Butorphanol; Delta-9-tetrahydrocannabinol (Dronabinol); Gamma-Hydroxybutyric Acid; Ketamine; Khat; Tramadol; Zopiclone; Buprenorphine; Oripavine

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is requesting interested persons to submit comments concerning abuse potential, actual abuse, medical usefulness, trafficking, and impact of scheduling changes on availability for medical use of nine drug substances. These comments will be considered in preparing a response from the United States to the World Health Organization (WHO) regarding the abuse liability and diversion of these drugs. WHO will use this information to consider whether to recommend that certain international restrictions be placed on these drugs. This notice requesting comments is required by the Controlled Substances Act (CSA).

**DATES:** Submit written or electronic comments by January 12, 2006.

**ADDRESSES:** Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** James R. Hunter, Center for Drug Evaluation and Research (HFD-9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5563, e mail: [hunterj@cder.FDA.gov](mailto:hunterj@cder.FDA.gov).

**SUPPLEMENTARY INFORMATION:** The United States is a party to the 1971 Convention on Psychotropic Substances. Article 2 of the Convention on Psychotropic Substances provides that if a party to the convention or WHO has information about a substance, which in its opinion may require international control or change in such control, it shall so notify the Secretary General of the United Nations and provide the Secretary General of the United Nations with information in support of its opinion.

The CSA (21 U.S.C. 811 *et seq.*) (Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970) provides that when WHO notifies the United States under Article 2 of the Convention on Psychotropic Substances that it has information that may justify adding a drug or other substances to one of the schedules of the convention, transferring a drug or substance from one schedule to another, or deleting it from the schedules, the Secretary of State must transmit the notice to the Secretary of the Department of Health and Human Services (the Secretary of HHS). The Secretary of HHS must then publish the notice in the **Federal Register** and provide opportunity for interested persons to submit comments that will be considered by HHS in its

preparation of the scientific and medical evaluations of the drug or substance.

#### I. WHO Notification

The Secretary of HHS received the following notices from WHO:  
Ref: C.L.29.2005

#### WHO Questionnaire for Collection of Information for Review of Dependence-Producing Psychoactive Substances

The WHO presents its compliments and has the pleasure of informing Member States and Associate Members that the Thirty-fourth Expert Committee on Drug Dependence will meet from March 28 to 31, 2006 to review the following substances:

1. Butorphanol (INN)
2. Dronabinol (INN)<sup>1</sup>
3. Gamma-hydroxybutyric acid
4. Ketamine (INN)
5. Khat (*Catha edulis* Forsk)
6. Tramadol (INN)
7. Zopiclone (INN)

As a follow-up for the thirty-third meeting of the Expert Committee on Drug Dependence, final decisions will be taken for buprenorphine (INN) and oripavine (INN).

One of the essential elements of the established review procedure is for the Secretariat to collect relevant information from Member States to prepare a Critical Review Report for submission to the Expert Committee on Drug Dependence. WHO invites Member States to collaborate, as in the past, in this process by providing pertinent information mentioned in the attached questionnaire concerning substances listed above.

Further clarification on any of the above items can be obtained from Quality Assurance and Safety: Medicines, Department of Medicines Policy and Standards, WHO, Geneva, to which replies should be sent not later than January 3, 2006.

WHO takes this opportunity to renew to Member States and Associate Members the assurance of its highest consideration.

GENEVA, October 27, 2005

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<sup>1</sup>Including its stereo-isomers.