

Centers for Disease Control and Prevention, Room 1110, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone (301) 458-4245. Information also is available on the NCVHS home page of the HHS website <http://www.ncvhs.hhs.gov/>, where further information will be posted when available.

Dated: August 25, 2000.

**James Scanlon,**

*Director, Division of Data Policy, Office of the Assistant Secretary for Planning and Evaluation.*

[FR Doc. 00-22403 Filed 8-31-00; 8:45 am]

BILLING CODE 4151-05-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[30DAY-64-00]

#### Agency Forms Undergoing Paperwork Reduction Act Review

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) 639-7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

**Proposed Project:** List of Ingredients Added to Tobacco in the Manufacture of Smokeless Tobacco Products—(0920-0338)—Extension—Office of Smoking and Health (OSH)—Oral use of smokeless tobacco represents a significant health risk which can cause cancer and a number of noncancerous oral conditions, and can lead to nicotine addiction and dependence. Furthermore, smokeless tobacco use is not a safe substitute for cigarette smoking.

The Centers for Disease Control and Prevention (CDC), Office on Smoking

and Health (OSH) has been delegated the authority for implementing major components of the Department of Health and Human Services' (HHS) tobacco and health program, including collection of tobacco ingredients information. HHS's overall goal is to reduce death and disability resulting from cigarette smoking and other forms of tobacco use through programs of information, education and research.

The Comprehensive Tobacco Health Education Act of 1986 (15 U.S.C. 4401 *et seq.*, Pub.L. 99-252) requires each person who manufactures, packages, or imports smokeless tobacco products to provide the Secretary of Health and Human Services with a list of ingredients added to tobacco in the manufacture of smokeless tobacco products. This legislation also authorizes HHS to undertake research, and to report to the Congress (as deemed appropriate), on the health effects of the ingredients. The total annual burden is 286 hours.

The annualized burden is 286.

Respondents	Number of respondents	Number of responses	Average burden/response (in hours)
Tobacco Manufacturers .....	11	1	26

Dated: August 15, 2000.

**Nancy Cheal,**

*Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 00-22421 Filed 8-31-00; 8:45 am]

BILLING CODE 4163-18-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[30DAY-65-00]

#### Agency Forms Undergoing Paperwork Reduction Act Review

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) 639-7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

#### Proposed Project

List of Ingredients Added to Tobacco in the Manufacture of Cigarette Products—(0920-0210)—Renewal—The Office of Smoking and Health (OSH)—Cigarette smoking is the leading preventable cause of premature death and disability in our Nation. Each year more than 400,000 premature deaths occur as the result of cigarette smoking related diseases.

The Centers for Disease Control and Prevention (CDC), Office on Smoking

and Health (OSH) has the primary responsibility for the Department of Health and Human Services' (HHS) smoking and health program. HHS's overall goal is to reduce death and disability resulting from cigarette smoking and other forms of tobacco use through programs of information, education and research.

The Comprehensive Smoking Education Act of 1984 (15 U.S.C. 1336 Pub. L. 98-474) requires each person who manufactures, packages, or imports cigarettes to provide the Secretary of Health and Human Services with a list of ingredients added to tobacco in the manufacture of cigarettes. This legislation also authorizes HHS to undertake research, and to report to the Congress (as deemed appropriate), on the health effects of the ingredients. The total annual burden is 2,660 hours.

Respondents	Number of respondents	Number of responses	Average burden/response (in hours)
Tobacco manufacturers .....	14	1	190

Dated: August 28, 2000.

**Nancy Cheal,**

*Acting Associate Director for Policy, Planning and Evaluation Centers for Disease Control and Prevention (CDC).*

[FR Doc. 00-22426 Filed 8-31-00; 8:45 am]

BILLING CODE 4163-18-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Reporting of Pregnancy Success Rates From Assisted Reproductive Technology Programs

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).

**ACTION:** Final Notice.

**SUMMARY:** This notice sets forth the requirements for Reporting of Pregnancy Success Rates from Assisted Reproductive Technology Programs as required by the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA). This notice describes who shall report to CDC, describes the reporting system, and describes the process for reporting by each assisted reproductive technology clinic. This notice incorporates comments received by CDC on the draft notice that was published in the Federal Register on September 3, 1999 (64 FR. 48402). This Announcement supersedes the previous notice that was published in the **Federal Register**, August 26, 1997 (62 FR. 45259).

**FOR FURTHER INFORMATION CONTACT:** Assisted Reproductive Technology Epidemiology Unit at (770) 488-5250.

**SUPPLEMENTARY INFORMATION:** Section 2(a) of Pub. L. 102-493 (42 U.S.C. 263a-1(a)) requires that each assisted reproductive technology (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.

Pub. L. 102-493, Sec. 8 (42 U.S.C. 263a-7) defines "assisted reproductive technology" (ART) as "all treatments or procedures which include the handling of human oocytes or embryos, including in vitro fertilization, gamete intrafallopian transfer, zygote intrafallopian transfer, and such other specific technologies as the Secretary may include in this definition, after

making public any proposed definition in such manner as to facilitate comment from any person (including any federal or other public agency)."

The Secretary is directed in Section 2(b) (42 U.S.C. 263a-1(b)) to define pregnancy success rates and "make public any proposed definition in such a manner as to facilitate comment from any person during its development."

Section 2(c) (42 U.S.C. 263a-1(c)) states "the Secretary shall consult with appropriate consumer and professional organizations with expertise in using, providing, and evaluating professional services and embryo laboratories associated with assisted reproductive technologies."

Section 6 (42 U.S.C. 263a-5) states that the Secretary, through the CDC, shall annually "publish and distribute to the States and the public, pregnancy success rates reported to the Secretary under section 2(a)(1) and, in the case of an assisted reproductive technology program which failed to report one or more success rates as required under each section, the name of each such program and each pregnancy success rate which the program failed to report."

In developing the definition of pregnancy success rates, CDC has consulted with representatives of the Society for Assisted Reproductive Technology (SART, a national professional association of ART clinical programs), the American Society for Reproductive Medicine (ASRM, a national society of professional individuals who work with infertility issues), 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 first **Federal Register** notice that outlined reporting requirements for ART programs was published August 26, 1997 (62 FR 45259) and solicited public comment. Because SART in conjunction with CDC made a number of revisions to the reporting process shortly after the publication of the first **Federal Register** notice, a second **Federal Register** notice was published on September 3, 1999 (64 FR 48402) that incorporated changes made to the reporting process. CDC also solicited public comment on this second draft document for the Reporting of Pregnancy Success Rates from Assisted Reproductive Technology Programs. The current Announcement incorporates comments received by CDC on the September 3, 1999, draft notice and supersedes both the August 26, 1997, and the September 3, 1999, notices.

### Response to Comments

In response to our request for comments to the September 3, 1999, draft document outlining reporting requirements, we received two letters, one from a laboratory professional organization, and one from an individual serving as the laboratory director of an ART clinic. These letters contained 15 separate comments. Responses to these comments are as follows:

1. There was concern that no consultation or communication had been conducted with the American Association of Bioanalysts (AAB) or its College of Reproductive Biology regarding the reporting requirements.

*Response:* The AAB was consulted early during the process in which CDC explored mechanisms to implement FCSRCA. Specifically, a representative of AAB attended a 1996 meeting convened by CDC to discuss issues related to the collection and reporting of ART clinic success rate statistics. Other professional organizations were represented as well. Although AAB did not participate in the most recent round of discussions on the clinic reporting requirements, a laboratory professional has been included in all discussions about reporting requirements.

2. There was an objection to the collection of data related to laboratory accreditation by the College of American Pathologists/American Society of Reproductive Medicine (CAP/ASRM) program.

*Response:* The 1992 Pub. L. 102-493 (42 U.S.C. 263a-1(a)), FCSRCA, requires CDC to report information on whether laboratories used by ART programs are certified under the CDC model state certification program. The model certification program was published in the **Federal Register**, July 21, 1999 (64 FR 39374). The model contained a set of quality standards for the performance of embryo laboratory procedures, maintenance of records, qualifications for laboratory personnel, and criteria for the inspection and certification of embryo laboratories. At this point, no state has adopted the model certification program, and thus no clinic is eligible for certification under the CDC model program. As a public service, CDC has agreed to include data on three non-federal laboratory accreditation programs in the annual ART Success Rates Reports. These are through the College of American Pathologists/American Society for Reproductive Medicine (CAP/ASRM), Joint Commission on Accreditation of Healthcare Organizations (JACHO) and the New York State Tissue Bank