

Subject name and address	Effective date	Subject name and address	Effective date	Subject name and address	Effective date
PAWTUCKET, RI PINKERTON, LINDA .....	1/19/2005	WILLIAMS, APRIL .....	1/19/2005	ROGEL-ELLIOTT, VALERIE .....	1/19/2005
ONEIDA, NY RADOMSKI, JULIENNE .....	1/19/2005	PARACHUTE, CO WILLIAMS, REBECCA .....	1/19/2005	SEMINOLE, FL SMITH, MICHAEL .....	1/19/2005
LEESBURG, VA RAYMOND, JERRY .....	1/19/2005	AURORA, CO WOLAN, NANCY .....	1/19/2005	TORRANCE, CA STANBRIDGE, GARY .....	1/19/2005
SPRINGFIELD, MO RENICK, LISA .....	1/19/2005	TAMPA, FL YOUNG, KISHA .....	1/19/2005	WHITTIER, CA VAFAEE, MOHAMMAD .....	1/19/2005
BOISE, ID RENKEN, CAREY .....	1/19/2005	LONGVIEW, WA		SANTA MONICA, CA YANG, SHENG .....	1/19/2005
DENVER, CO RIVERA, ANGEL .....	1/19/2005	<b>FEDERAL/STATE EXCLUSION/ SUSPENSION</b>		<b>OWNERS OF EXCLUDED ENTITIES</b>	
HONDO, TX ROBERTS, FAITH .....	1/19/2005	RYDER, JON .....	1/19/2005	RATHOD, BABUBHAI .....	1/19/2005
MIAMI, FL SACCONE, MARGUERITE .....	1/19/2005	EUGENE, OR		MT PLEASANT, MI	
FT LAUDERDALE, FL SALTER, DEBORAH .....	1/19/2005	<b>FRAUD/KICKBACKS/PROHIBITED ACTS/ SETTLEMENT AGREEMENTS</b>			
COLUMBIA, AL SANFORD, CYNTHIA .....	1/19/2005	GARCIA, GULLERMO .....	11/4/2004	Dated: January 24, 2005.	
ENGLEWOOD, CO SANTIAGO, JAMIE .....	1/19/2005	MIAMI, FL GONSALVES, WALLACE .....	9/23/2004	<b>Katherine B. Petrowski,</b>	
CLEVELAND, OH SCOTT, CLINTON .....	1/19/2005	MINERSVILLE, PA PATE, JIVA .....	11/1/2004	<i>Director, Exclusions Staff, Office of Inspector General.</i>	
LONG BEACH, CA SHAH, KAMLESH .....	1/19/2005	MYRTLE BEACH, SC		[FR Doc. 05-1788 Filed 1-31-05; 8:45 am]	
ONTARIO, CA SIMMONS, CAROLYN .....	1/19/2005	<b>OWNED/CONTROLLED BY CONVICTED ENTITY</b>		<b>BILLING CODE 4150-04-P</b>	
BRISTOL, VA SMITH, KAREN .....	1/19/2005	ALPHA HERBS & VITAMINS .....	1/19/2005	<b>DEPARTMENT OF HEALTH AND HUMAN SERVICES</b>	
SALT LAKE CITY, UT SMITH, RAMONA .....	1/19/2005	HOUSTON, TX ALPHA SENIOR HEALTH GROUP .....	1/19/2005	<b>Centers for Disease Control and Prevention</b>	
CAROLINA BEACH, NC SOARES, KIM .....	1/19/2005	HOUSTON, TX AVIONIX MEDICAL DEVICES, INC .....	1/19/2005	<b>Reporting of Pregnancy Success Rates From Assisted Reproductive Technology Programs</b>	
SWANSEA, RI SOWLES, CHARLENE .....	1/19/2005	MIDLAND, TX HEALTH RESOURCES & REHAB .....	1/19/2005	<b>AGENCY:</b> Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).	
PHOENIX, AZ STROBLE, LAURA .....	1/19/2005	HOUSTON, TX HEALTH RESOURCES & REHAB CENTER .....	1/19/2005	<b>ACTION:</b> Notice.	
WEST DOVER, VT STUDLEY, KATHLEEN .....	1/19/2005	HOUSTON, TX JORGENSEN DRUG, INC .....	1/19/2005	<b>SUMMARY:</b> The CDC is tasked with implementing the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA), Public Law 102-493. As mandated by this law CDC publishes annual reports of pregnancy success rates from ART clinics and embryo laboratory certification status of these clinics. Section 2(a) of Public Law 102- 493 (42 U.S.C. 263a-1) requires that each assisted reproductive technology (ART) program shall annually report to the Secretary, through the Centers for Disease Control and Prevention, (a) pregnancy success rates achieved by such ART programs, and (b) the identity of each embryo laboratory used by such ART programs, and whether the laboratory is certified or has applied for such certification under this act. Section (6) 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 such section, the name	
RUMFORD, RI SWAIN, JEREMY .....	1/19/2005	ROUNDUP, MT MARITIME HEALTH SERVICES OF TAMPA, INC .....	1/19/2005		
COVENTRY, RI TAYLOR, DONALD .....	1/19/2005	TAMPA, FL SEELIN MEDICAL, INC .....	1/19/2005		
HAVRE, MT TAYLOR, MATTHEW .....	1/19/2005	MIDLAND, TX			
CLEARFIELD, UT TAYLOR, MEL .....	1/19/2005	<b>DEFAULT ON HEAL LOAN</b>			
SAN LEANDRO, CA THAN-RIDDLE, KHIN .....	1/19/2005	BEAMS, JEFFREY .....	1/19/2005		
GAMBRILLS, MD TILLEY-BISBEE, COURTNEY ...	1/19/2005	TAMPA, FL BULEN, JERRY .....	1/19/2005		
SCOTTSDALE, AZ TOPPING, GARY .....	1/19/2005	BRANDON, FL EAGLE, DONALD .....	1/19/2005		
DERBY, KS VALDIVIA, CARLOS .....	1/19/2005	GRAND ISLAND, FL GREEN, MICHAEL .....	1/19/2005		
OXNARD, CA VARGOVICH, KAREN .....	1/19/2005	MAITLAND, FL HASLEY, STEVEN .....	1/19/2005		
OROFINO, ID VARNUM, ROLAND .....	1/19/2005	MELBOURNE, FL HEISLER, HOPE .....	1/19/2005		
LAKE CHARLES, LA VINLUAN, ELEANOR .....	1/19/2005	PUNTA GORDA, FL JOSEPH, BRAD .....	1/19/2005		
CHEYENNE, WY WALLACE, FREDRICK .....	1/19/2005	PITTSBURGH, PA LIGHT, DAVID .....	1/19/2005		
BESSEMER, AL WALLACE, SELENA .....	1/19/2005	WINTER GARDEN, FL MARIN, MELODY .....	1/19/2005		
LAKE CITY, FL WASHINGTON, CARNELLA .....	1/19/2005	VAN NUYS, CA MARQUEZ, EVELYN .....	1/19/2005		
OAKLAND, CA WEBER, SUSAN .....	1/19/2005	LOS ANGELES, CA NEALY, JOY .....	1/19/2005		
COLORADO SPRINGS, CO WILKERSON, NINA .....	1/19/2005	ATLANTA, GA			
PHOENIX, AZ					

of each such program and each pregnancy success rate which the program failed to report.

This Announcement includes information on the change in the data collection contractor and the change in the approved data reporting system for the 2004, 2005, 2006, 2007, and 2008 ART data reporting years in accordance with the FCSRCA. This Announcement supplements the September 1, 2000 and the February 5, 2004, notices.

**SUPPLEMENTARY INFORMATION:** CDC has contracted with Westat to develop a data reporting system and to collect annual clinic-specific and cycle-specific data from all practicing assisted reproductive technology clinics in the U.S. and its territories for the 2004, 2005, 2006, 2007, and 2008 ART data reporting years. The contract covers clinic tracking, data collection and quality assurance, and validation activities. As such, Westat is the new contractor for ART data collection for the 2004 through 2008 ART data reporting years.

The new Web-based data reporting system (developed by Westat) for the 2004, 2005, 2006, 2007, and 2008 ART data reporting years will be called the National ART Surveillance System (NASS). As such, NASS will be the only approved data reporting system for 2004 through 2008 ART data submissions. ART programs should be aware that Westat will develop and provide all necessary instruction materials for extracting and importing data from other electronic medical record systems into NASS and for checking imported data to ensure that it retains the accuracy and compatibility of the data entry system from which it was extracted.

The anticipated deadline for reporting is December 15 of the year 1 year subsequent to the reporting year in question. (For example, the anticipated deadline to report data on cycles initiated in 2004 is December 15, 2005.) An ART program will not be considered to be in compliance with the federal reporting requirements of FCSRCA if the ART program was in operation in the full year that is being reported, *i.e.*, the clinic was in operation after January 1 of the reporting year, and fails to submit a dataset to Westat in the required data reporting system (NASS) by the reporting deadline. ART programs considered to not be compliant with the federal reporting requirements of FCSRCA will be listed as non-reporters in the published report.

The data reporting activities and the amount and type of data collected will be similar to the current system

requirements outlined in the September 1, 2000 **Federal Register** notice (Volume 65, No. 171, pages 53310–53316). CDC has completely funded the data reporting activities for the 2004 through 2008 reporting years. Thus, ART programs will not be charged fees to obtain the new reporting system or to submit data using the new reporting system.

Validation activities for the 2004 through 2008 data reporting years will be similar to those described in the September 1, 2000 **Federal Register** notice (Volume 65, No. 171, pages 53310–53316). Westat will provide the necessary personnel to perform the validation site visits.

Each ART program should be aware that the Paperwork Reduction Act is applicable to this data collection. Under the Paperwork Reduction Act of 1995, a Federal agency shall not conduct or sponsor a collection of information from ten or more persons other than Federal employees, unless the agency has submitted a Standard Form 83, Clearance Request, to the Director of the Office of Management and Budget (OMB), and OMB has approved the collection of information. A person is not required to respond to a collection of information unless it displays a currently valid OMB control number. CDC has obtained OMB approval to collect this data under OMB control No. 0920–0556.

CDC will continue to provide information to all ART programs regarding data collection activities as information becomes available.

**FOR FURTHER INFORMATION CONTACT:** Victoria Wright, Assisted Reproductive Technology Epidemiology Unit at (770) 488–6384.

Dated: January 25, 2005.

**James D. Seligman,**

*Associate Director for Program Services,  
Centers for Disease Control and Prevention.*  
[FR Doc. 05–1787 Filed 1–31–05; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005N–0029]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Infant Formula Recall Regulations

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requirements related to the recall of infant formula.

**DATES:** Submit written or electronic comments on the collection of information by April 4, 2005.

**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>. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the