

safety and effectiveness of the device. This draft guidance document serves as the special control to support the reclassification from class III to class II of the automated blood cell separator device operating on a centrifugal separation principle intended for the routine collection of blood and blood components; and, serves as the special control for the filtration-based device with the same intended use reclassified as class II in the **Federal Register** of February 28, 2003 (68 FR 9530).

For currently marketed products not approved under the premarket approval (PMA) process, the manufacturer should file with FDA for 3 consecutive years an annual report on the anniversary date of the device reclassification from Class III to Class II or, on the anniversary date of the 510(k) clearance. Any subsequent change to the device requiring the submission of a premarket notification in accordance with section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360) should be included in the annual report. Also, a manufacturer of a device determined to be substantially equivalent to the centrifugal or filtration-based automated blood cell separator device intended for the routine collection of blood and

blood components, should comply with the same general and special controls.

The annual report should include, at a minimum, a summary of anticipated and unanticipated donor adverse device events that have occurred, such as those required under (§ 606.160(b)(1)(iii)) 21 CFR 606.160(b)(1)(iii)¹ to be recorded and maintained by the facility using the device to collect blood and blood components, and that might not be reported by manufacturers under Medical Device Reporting (MDR). Also, equipment failures, including software, hardware, and disposable item failures² should be reported. The reporting of adverse device events summarized in an annual report will alert FDA to trends or clusters of events that might be a safety issue otherwise unreported under the MDR regulation.

Reclassification of this device from class III to class II for the intended use of routine collection of blood and blood components will relieve manufacturers of the burden of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by reducing the burden. Although the special control guidance document

recommends that manufacturers of these devices file with FDA an annual report for three consecutive years, this would be less burdensome than the current postapproval requirements under part 814, subpart E (21 CFR part 814, subpart E), including the submission of periodic reports under § 814.84.

Collecting or transfusing facilities, and manufacturers have certain responsibilities under the CFR. Among others, collecting or transfusing facilities are required to maintain records of any reports of complaints of adverse reactions (§ 606.170), while the manufacturer is responsible for conducting an investigation of each event that is reasonably known to the manufacturer and evaluating the cause of the event § 803.50(b)(2) (21 CFR 803.50(b)(2)). In the draft guidance document, we recommend that manufacturers include in their three annual reports a summary of adverse reactions maintained by the collecting or transfusing facility or similar reports of adverse events collected in addition to those required under the MDR regulation.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Annual Report	4	1	4	5	20

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

Based on FDA records, there are approximately four manufacturers of automated blood cell separator devices. We estimate that the manufacturers will spend approximately 5 hours preparing and submitting the annual report. The total annual burden of this collection of information is estimated at approximately 20 hours.

Other burden hours required for proposed 21 CFR 864.9245 are already reported and approved under OMB control number 0910–0120 (premarket notification submission 510(k), 21 CFR part 807, subpart E), and OMB control number 0910–0437 (MDR). Currently, manufacturers of medical devices are required to submit to FDA individual adverse event reports of death, serious injury, and malfunctions (§§ 803.50 and 803.53). The manufacturer is responsible for conducting an investigation of each event and

evaluating the cause of the event (§ 803.50(b)(2)).

The reporting recommended in the special control guidance document broadens the information to be reported by manufacturers to FDA. Although the manufacturer's reporting burden is increased, the collection burden remains unchanged. We are recommending that the manufacturer submit annually, for 3 consecutive years, a summary of all adverse events, including those reported under part 803. The Mandatory MedWatch Reporting Form 3500A: Codes Manual, contains a comprehensive list of adverse events associated with device use, including most of those events that we recommend summarizing in the annual report.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either

<http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: March 1, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–4764 Filed 3–9–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: February 2005

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of February 2005, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusions is

¹ 21 CFR 606.160(b) "Records shall be maintained that include, but are not limited to, the following

when applicable: * * * (1)(iii) Donor adverse

reaction complaints and reports, including results of all investigations and followup."

imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, and all Federal Health Care programs. In addition, no program payment is made to any business or facility, *e.g.*, a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all Executive Branch procurement and non-procurement programs and activities.

Subject name, address	Effective date
PROGRAM-RELATED CONVICTIONS	
ABERNATHY, EVELYN	3/20/2005
HERTFORD, NC	
ADKINS, JO ANN	3/20/2005
FRESNO, CA	
AYRAPETYAN, TIGRAN	3/20/2005
TAFT, CA	
BAKER, CHARLES	3/20/2005
DURHAM, NC	
BAKER, JON	12/30/2004
SCOTTSDALE, AZ	
BARAM, GREGORY	3/20/2005
STUDIO CITY, CA	
BURGER, BARBARA	3/20/2005
MARYLAND HEIGHTS, MO	
CAPERS, KIZZY	3/20/2005
NEWTON GROVE, NC	
COOKE, LENOTRA	3/20/2005
LOS ANGELES, CA	
CRUZ, JULIA	3/20/2005
SANTA ROSA, CA	
CUNNINGHAM, DEATRYCE ...	3/20/2005
SAN PABLO, CA	
DEO, VASU	3/20/2005
TERMINAL ISLANDS, CA	
DIPRIMA, FRANK	3/20/2005
DILLSBURG, PA	
GARCIA, GUSTAVO	3/20/2005
SONOMA, CA	
GERDES, DEBRA	3/20/2005
NORTH PEKIN, IL	
GORE, ANGELA	3/20/2005
NEW ORLEANS, LA	
GUERRERO, GAUDENCIO	3/20/2005
SONOMA, CA	
HAMBRIC, EVERETTE	3/20/2005
MORGANTOWN, WV	
HENSLEY, TIMOTHY	3/20/2005
KNOXVILLE, TN	
HERNANDEZ, BENITA	3/20/2005
LOS ANGELES, CA	
HINTON, PAULA	3/20/2005
SHREVEPORT, LA	
HUTCHINSON, TRENT	3/20/2005
SAN FRANCISCO, CA	
JOHN, NICOLE	3/20/2005

Subject name, address	Effective date	Subject name, address	Effective date
LONG ISLAND CITY, NY		SEATTLE, WA	
JOHNSON, GADSON	3/20/2005	FELONY CONVICTION FOR HEALTH CARE FRAUD	
LOS ANGELES, CA			
JONES, SILVER	3/20/2005		
DURHAM, NC		BAY, DAVID	3/20/2005
KAMRAVA, SID	3/20/2005	SPRINGFIELD, MO	
ENCINO, CA		FAGIN, KEVIN	3/20/2005
KASSABIAN, EMANUEL	3/20/2005	BEREA, KY	
ANAHEIM, CA		FINK, DAVID	3/20/2005
KEEN, KEITH	3/20/2005	METUCHEN, NJ	
WILMINGTON, NC		HOOKE, PETRINA	3/20/2005
KETENDJIAN, AIKAZ	3/20/2005	DELAND, FL	
SACRAMENTO, CA		MAYES, JOSEPH	3/20/2005
LANGLEY, KAREN	3/20/2005	NORTH EAST, PA	
FOUR OAKS, NC		MURRAY, TOMMIE	3/20/2005
MAJCHEN, ELENA	3/20/2005	STONEWALL, MS	
FRESNO, CA		NEWSTADT, RAYMOND	3/20/2005
MALVEAUX, ANNA	3/20/2005	MONTGOMERY, PA	
FT WORTH, TX		NGUYEN, DAVID	3/20/2005
MARTINEZ, ELIZABETH	3/20/2005	CLOVIS, CA	
DENVER, CO		PAULEY, SUSAN	3/20/2005
MAZOR, ANDREW	3/20/2005	HAMPTON, VA	
GRANADA HILLS, CA		PELAEZ, JORGE	3/20/2005
MCBRIDE, HEIDI	3/20/2005	ROSEMEAD, CA	
HEYBURN, ID		ROBINSON, JENNIFER	3/20/2005
MCCOY, JIMMY	3/20/2005	JACKSON, MS	
FRESNO, CA		ROSENFARB, ANDREW	3/20/2005
MOODY, CHERRY	3/20/2005	WESTFIELD, NJ	
COLEMAN, FL		SERRANO, VERONICA	3/20/2005
MUNN, VINCENT	3/20/2005	CHULA VISTA, CA	
LOMPOC, CA		TRIVETT, ELISA	3/20/2005
MUSOYAN, SARKIS	3/20/2005	DUNEDIN, FL	
BURBANK, CA		ZEIGLER, TAMARA	3/20/2005
NAVARRO, PATRICIA	3/20/2005	CORONA, CA	
CYPRUS, CA		FELONY CONTROL SUBSTANCE CONVICTION	
OGANESYAN, VARDAN	3/20/2005		
LONG BEACH, CA		BENTZ, WILLIAM	3/20/2005
PAL, MOHAMMAD	3/20/2005	NEOSHO, MO	
ASTORIA, NY		BOUCHARD, TAMARA	3/20/2005
PARSON, DIANNE	3/20/2005	MENTOR, OH	
MORVEN, NC		CAMPBELL, FRANCES	3/20/2005
RODRIGUEZ, RICARDO	3/20/2005	BROKEN ARROW, OK	
DOWNEY, CA		CAMPOSTRINI, KATHERINE ..	3/20/2005
RUPA, LUZ	3/20/2005	OROVILLE, CA	
DOWNEY, CA		DEDRICK, TAMMY	3/20/2005
SANDOVAL, JOSE	3/20/2005	CORONA, CA	
DOWNEY, CA		FAHTI, CATHERINE	3/20/2005
SCHLUTER, TERRY	3/20/2005	COMPTON, CA	
ST PETERSBURG, FL		FERRO, PAULA	3/20/2005
SCHWARZ, MICHAEL	3/20/2005	PHILADELPHIA, PA	
MARICOPA, AZ		HAKANSON, MARK	3/20/2005
SEPUT, EDGARDO	3/20/2005	ARCADIA, CA	
LA MIRADA, CA		HELMETZ, PAMELA	3/20/2005
SILVESTRE-MEJIA, LUIS	3/20/2005	EUCLID, OH	
JACKSON HEIGHTS, NY		HUMPHRIES, CAROLYN	3/20/2005
SMITH, VICKY	3/20/2005	DAWSON, TX	
COLUMBUS, OH		KAPLAN-CALLAHAN, ROBYN	3/20/2005
SONCO, FREDDY	3/20/2005	WHITMAN, MA	
DOWNEY, CA		KELLEY, SHERMA	3/20/2005
STEELE, SAMUEL	3/20/2005	EAST PRAIRIE, MO	
LAS VEGAS, NV		MCKININ, MICHAEL	3/20/2005
TUREK, RAYMOND	3/20/2005	CHICO, CA	
ATLANTA, GA		SEGURA, IVAN	3/20/2005
URIN, ALEXANDER	3/20/2005	WASECA, MN	
LOS ANGELES, CA		SMITH, MICHAEL	3/20/2005
VILLALVA, VALFRED	3/20/2005	ORLANDO, FL	
SONOMA, CA		STUTZMAN, LAURIE	3/20/2005
VILLAMOR, MANUEL	3/20/2005		
MIAMI, FL			
WATTS, JO ANN	3/20/2005		
TALLAHASSEE, FL			
WILDIN, HEATHER	3/20/2005		
GREAT FALLS, MT			
WILLIAMS, DEWAYNE	3/20/2005		

Subject name, address	Effective date	Subject name, address	Effective date	Subject name, address	Effective date
CHINO HILLS, CA		FRESNO, CA		RICHMOND, VA	
PATIENT ABUSE/NEGLECT CONVICTIONS		BAUGHMAN, PAMELA	3/20/2005	HAAG, JAMES	3/20/2005
ATKINS, JAY	3/20/2005	HUNKER, PA		SUFFIELD, CT	
MARANA, AZ		BAZE, ANGELA	3/20/2005	HAMILTON, BRIDGETT	3/20/2005
CARROLL, STEVE	3/20/2005	NORMAN, OK		SEATTLE, WA	
WASHINGTON, UT		BECK, DENNIS	3/20/2005	HARRIS, BARBARA	3/20/2005
CELEDIO, CARLO	3/20/2005	SPENCER, IA		LELAND, NC	
DALY CITY, CA		BENNETT, LINDA	3/20/2005	HASTINGS, MARY	3/20/2005
COE, MARLO	3/20/2005	SMYRNA, TN		COLORADO SPRINGS, CO	
BELLINGHAM, WA		BERETTA, TIFFANY	3/20/2005	HEDGIS, NICK	3/20/2005
DAVIS, KATRICE	3/20/2005	MONTROSE, CO		MENLO, GA	
ST MARTINVILLE, LA		BERMAN, BRUCE	3/20/2005	HERSEY, THEA	3/20/2005
DECKER, SHAWN	3/20/2005	FARMINGDALE, NY		NORTON, VA	
MUSKOGEE, OK		BITTINGER, CATHI JO	3/20/2005	HOYT, NANCY	3/20/2005
GINTHER, DEANNA	3/20/2005	SNOW SHOE, PA		SUN VALLEY, CA	
DENVER, CO		BODENCAK, JANET	3/20/2005	ISAACS, BARBARA	3/20/2005
GUY, JUDITH	3/20/2005	HEDGESVILLE, WV		MARICOPA, AZ	
LUTHER, OK		BOSWEIN, DANIEL	3/20/2005	JARAMILLO, RODNEY	3/20/2005
HOWARD, CHARLES	3/20/2005	YOUNGTOWN, AZ		SAN LEANDRO, CA	
SPRINGFIELD, KY		BOWERS, HEATHER	3/20/2005	JONES, BRENDA	3/20/2005
JACKSON, CLIFFORD	3/20/2005	ST PETERSBURG, FL		TULSA, OK	
LOS ANGELES, CA		BRAY, KIRSTEN	3/20/2005	JORDAN, JENNIE	3/20/2005
MARJANOVIC, TANYA	3/20/2005	ALEXANDRIA, VA		HUNTSVILLE, AL	
BEAVERTON, OR		BROOM, KAREN	3/20/2005	JUNE, VIRGINIA	3/20/2005
PATTON, BRANDY	3/20/2005	UNIVERSAL CITY, TX		SALT LAKE CITY, UT	
SUSANVILLE, CA		BUJOR, TITUS	3/20/2005	KAUFFMAN, DINAH	3/20/2005
PINKSTON, AMANDA	3/20/2005	PARADISE, CA		FAYETTEVILLE, PA	
TULSA, OK		CABRERA, DEBORAH	3/20/2005	KERSHAW, SHARON	3/20/2005
REICH, LAURENCE	3/20/2005	VIRGINIA BEACH, VA		LEXINGTON, KY	
BEVERLY HILLS, CA		CETINA, TANYA	3/20/2005	KNECHT, LINDA	3/20/2005
RISER, JARED	3/20/2005	WARREN, OH		MT POCONO, PA	
ROOSEVELT, UT		COLBERT, BEVERLY	3/20/2005	KORMI, TOURAJ	3/20/2005
SNOW-WORKMAN, JOY	3/20/2005	IRVING, TX		EL SOBRANTE, CA	
MCMINNVILLE, OR		COLEMAN, ARLIE	3/20/2005	LAKE, ROBERT	3/20/2005
THOMPSON, LYNN	3/20/2005	MEMPHIS, TN		MURRAY, UT	
BUFFALO, NY		CONKWRIGHT, DEBORAH	3/20/2005	LARRIVEE, MICHELLE	3/20/2005
USATE, HENRY	3/20/2005	SALVISA, KY		VERO BEACH, FL	
SAN JOSE, CA		CONNER, SUSAN	3/20/2005	LEBEL, LANA	3/20/2005
WILL, NANCY	3/20/2005	DALLAS, NC		PUEBLO WEST, CO	
POTEAU, OK		COOK, LORIE	3/20/2005	LESLIE, ROBERT	3/20/2005
CONVICTION FOR HEALTH CARE FRAUD		MIDWEST CITY, OK		IRVINE, CA	
KILMER, GERALDINE	3/20/2005	COTTON, KIMBERLY	3/20/2005	LETTINGTON, ALEXIS	3/20/2005
SILVER GROVE, KY		WILSON, NC		PALM SPRINGS, CA	
LEWIS, KARMON	3/20/2005	CROCKETT, CARA	3/20/2005	LOPEZ, BRANDICE	3/20/2005
GULFPORT, MS		PRAIRIE VILLAGE, KS		CARMICHAEL, CA	
PAYNE, CRYSTAL	3/20/2005	DAVIS, BETTY	3/20/2005	MANZANO, GREGORIO	3/20/2005
CLEVELAND, MS		SEMMES, AL		DALY CITY, CA	
LICENSE REVOCATION/SUSPENSION/ SURRENDERED		DEMESI, MOWOE	3/20/2005	MARQUEZ, CARLOS	3/20/2005
ADAMS, JULIA	3/20/2005	GRAND PRAIRIE, TX		ORANGE, CA	
CHICAGO, IL		DENEAU, JENIFER	3/20/2005	MAYS, KRISTAL	3/20/2005
AHLUWALIA, JASBIR	3/20/2005	MONTROSE, CO		BRADENTON, FL	
RENTON, WA		DESJARDIN, PAUL	3/20/2005	MCCLURE, DEBRA	3/20/2005
ALBERTS, WAYNE	3/20/2005	QUINCY, MA		QUINCY, CA	
VIENNA, VA		DICKERSON, JAMES	3/20/2005	MILLS, STEPHEN	3/20/2005
AMEND, CATHY	3/20/2005	LISLE, IL		TISBURY, MA	
LATONIA, KY		DIEL, RANDALL	3/20/2005	MORENO, LINDA	3/20/2005
ANDERSON, ANGELINA	3/20/2005	TUCSON, AZ		GREAT FALLS, MT	
DALY CITY, CA		DIGREGORIO, EDWARD	3/20/2005	NEECE, STEPHEN	3/20/2005
ANDERSON, C	3/20/2005	WARWICK, RI		PLANO, TX	
DENVER, CO		DIWA, JONATHAN	3/20/2005	NWOSU, JUDE	3/20/2005
ANDERSON, DEBORAH	3/20/2005	UPLAND, CA		TEMPE, AZ	
ALBANY, OR		DOOLEY, HEIDI	3/20/2005	O'MALLEY, MAURA	3/20/2005
ANDERSON, NANCY	3/20/2005	PHOENIX, AZ		WESTFIELD, MA	
NASHVILLE, TN		EVERMAN, SHERRIL	3/20/2005	PALLADINO, ARTHUR	3/20/2005
ATWELL, DEBRA	3/20/2005	INDIANAPOLIS, IN		AMHERST, MA	
RENO, NV		FARRAR, TERESA	3/20/2005	PARKER, RAMONA	3/20/2005
BALDWIN, GRANT	3/20/2005	SANTA PAULA, CA		JONESBORO, AR	
		FRANK, CHERYL	3/20/2005	PARKER, SCOTT	3/20/2005
		SONORA, CA		MEAD, OK	
		GATES, KARLA	3/20/2005	PEARSON, REGINA	3/20/2005
		TULSA, OK		PADUCAH, KY	
		GAUNTT, RICKY	3/20/2005	PERNER, TENA	3/20/2005
		FT STOCKTON, TX		CASTALIAN SPRINGS, TN	
		GORMUS, JOSEPH	3/20/2005	PETTIES, TYREE	3/20/2005

Subject name, address	Effective date	Subject name, address	Effective date	Subject name, address	Effective date
CHICAGO, IL		FRUITA, CO		LOS ANGELES, CA	
PISANO, SALLIE	3/20/2005	VALENCIA, MARIA	3/20/2005	CHIANG, PHILIP	3/20/2005
LACEY, WA		DENVER, CO		MOUNTAIN VIEW, CA	
POOLE, WILLIAM	3/20/2005	VALENTINE, CHRISTINE	3/20/2005	FERNANDO, ANTONIO	3/20/2005
EAGLESVILLE, TN		RICHMOND, VA		PHILADELPHIA, PA	
POULSEN, JERRY W	3/20/2005	VANDENBOS, GREGORY	3/20/2005	LINDLY, MAURICE	3/20/2005
VALLEY CITY, UT		RENO, NV		SALINAS, CA	
POYATOS, DANILO	3/20/2005	VAWTER, KAREN	3/20/2005	MULLINAX, JEFFREY	3/20/2005
VICTORVILLE, CA		COEUR D'ALENE, ID		WINDSOR, CA	
PRONTO, DAVID	3/20/2005	WALLACE, PATRICK	3/20/2005	NEWBY, EDGAR	3/20/2005
HUDSON FALLS, NY		ABINGDON, VA		LAWTON, OK	
PRUGH, JAMES	3/20/2005	WIJNHAMER, JAN	3/20/2005	PASCALE, MICHELE	3/20/2005
SCOTTSDALE, AZ		BELLINGHAM, WA		AUGUSTA, GA	
RAIMAN, GARII	3/20/2005	WILLIAMS, MICHELLE	3/20/2005	RAPPA, RICHARD	3/20/2005
CONCORD, CA		PAINTSVILLE, KY		N HAVEN, CT	
ROSS, LINDA	3/20/2005	WILSON, DONNA	3/20/2005		
EL DORADO, KS		JASPER, TX			
SABATINO, DAVID	3/20/2005	WRIGHT, STEVIE	3/20/2005		
ELIZABETHTON, TN		SEYMOUR, TN			
SARVIS, AMANDA	3/20/2005	YOUNG, SANDRA	3/20/2005		
FREMONT, NC		CARTERVILLE, IL			
SAVAGE, SANDRA	3/20/2005	ZEGARRA, GLORIA	3/20/2005		
S BOSTON, MA		GLENDALE, CA			
SAYED, SAQUIB	3/20/2005				
CRANFORD, NJ					
SCHAEFFER, BRANDON	3/20/2005				
CHICAGO, IL					
SCHWARZ, ANN	3/20/2005				
RANDOLPH, MA					
SCOTT, OTIS	3/20/2005				
ABINGTON, PA					
SEJALBO, MARYANN	3/20/2005				
HAYWARD, CA					
SHELL, JOAN-MARIE	3/20/2005				
PORT HADLOCK, WA					
SHERMAN, AHRON	3/20/2005				
EUREKA, CA					
SHINDORE, SHREELAL	3/20/2005				
NAPLES, FL					
SHORT, LEA ANN	3/20/2005				
NEW ALBANY, IN					
SILVA, LINDA	3/20/2005				
IONE, CA					
SIMPSON, LISA	3/20/2005				
LOUISVILLE, KY					
SMITH, LESLIE	3/20/2005				
TEMPE, AZ					
SMITH, SUSAN	3/20/2005				
ROCKFORD, IL					
SMITH, TRICIA	3/20/2005				
OSSIPEE, NH					
SOUSA, BONNIE	3/20/2005				
STOCKTON, CA					
STAPLETON, KELLY	3/20/2005				
CRESTWOOD, IL					
STELLHORN, JEANNE	3/20/2005				
CAHOKIA, IL					
STEVENS, ANNA	3/20/2005				
ROOSEVELT, UT					
STOLLOF, KELLY	3/20/2005				
INDIO, CA					
STROMBERG, WILLIAM	3/20/2005				
DE SOTO, IL					
SUPPLEE, PENNY	3/20/2005				
WEST CHESTER, PA					
SUSS, BEVERLY	3/20/2005				
GRAFTON, MA					
SUTTON, CURTIS	3/20/2005				
LAYTON, UT					
TAYLOR, REGINA	3/20/2005				
CHICAGO, IL					
TEE, MIKE	3/20/2005				
AURORA, CO					
VAHLE, TREVOR	3/20/2005				

FRAUD/KICKBACKS/PROHIBITED ACTS/ SETTLEMENT AGREEMENTS

MED-CON, INC	12/29/2004
PAINTSVILLE, KY	
PRICE, HARRY	9/20/2004
MARTINSBURG, VA	
SHAW, JOHN	12/29/2004
PAINTSVILLE, KY	

OWNED/CONTROLLED BY CONVICTED ENTITIES

AMERICAN FAMILY PHARMA- CEUTICALS, INC	3/20/2005
NAPLES, FL	
CONVENIENT MEDICAL SERVICES, INC	3/20/2005
NAPLES, FL	
LADD MANAGEMENT COR- PORATION	3/20/2005
LEAWOOD, KS	
MARIN CHIROPRACTIC, INC VAN NUYS, CA	3/20/2005
MICHAEL E SMITH, D P M, P A	3/20/2005
ORLANDO, FL	
MOBILE DENTISTRY, LLC	3/20/2005
NEW CASTLE, PA	
PAIN RELIEF MEDICAL CEN- TER	3/20/2005
VAN NUYS, CA	
S FT MYERS MEDICAL CEN- TER, INC	3/20/2005
FT MYERS, FL	
SHREELAL M SHINDORE, MD, PA	3/20/2005
NAPLES, FL	
SYNERGISTICS MEDICAL CARE PA	3/20/2005
LEAWOOD, KS	

DEFAULT ON HEAL LOAN

BAKER, WALTER	3/20/2005
VALLEJO, CA	
BARNETT, RUTH	2/1/2005
DETROIT, MI	
BELL, HERMAN	3/20/2005

CMP

O'CONNOR, THOMAS	2/28/2005
MILWAUKEE, WI	

Dated: March 2, 2005.

Katherine B. Petrowski,

Director, Exclusions Staff, Office of Inspector General.

[FR Doc. 05-4680 Filed 3-9-05; 8:45 am]

BILLING CODE 4150-04-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Assessment of the Use of Special Funding on Research on Type 1 Diabetes Provided by the Balanced Budget Act of 1997, the FY 2001 Consolidated Appropriations Act, and the Public Health Service Act Amendment for Diabetes

SUMMARY: 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 National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: *Title:* Assessment of the Use of Special Funding for Research on Type 1 Diabetes Provided by the Balanced Budget Act of 1997 (Pub. L. 105-33), the FY 2001 Consolidated Appropriations Act (Pub. L. 106-554), and the Public Health Service Act Amendment for Diabetes (Pub. L. 107-360). *Type of Information Collection Request:* Revision, OMB control number 0925-0503; expiration date: 06/30/2005. *Need and Use of Information Collection:* This