

mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**V. Electronic Access**

Persons with access to the Internet may obtain copies of this draft guidance at <http://www.fda.gov/opacom/morechoices/industry/guidedc.htm>.

Dated: June 27, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 05-13121 Filed 7-01-05; 8:45 am]

BILLING CODE 4160-01-S

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of Inspector General**

**Program Exclusions: May 2005**

**AGENCY:** Office of Inspector General, HHS.

**ACTION:** Notice of program exclusions.

During the month of May 2005, the HHS Office of Inspector General imposed exclusions in cases set forth below. When an exclusion is 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
<b>Program-Related Convictions</b>	
Adoff, Arnold ..... Valhalla, NY	6/20/2005
Agett, Deborah ..... Kingsport, TN	6/20/2005
Albanese, Anthony ..... Brooklyn, NY	3/29/2005
Albarracin, Carlos ..... Seatac, WA	6/20/2005

Subject name, address	Effective date	Subject name, address	Effective date
Palmdale, CA		Seagoville, TX	
Aloma, Filomena .....	6/20/2005	Pederson, Randi .....	6/20/2005
Miami, FL		Fargo, ND	
Alvarez, Jose .....	6/20/2005	Porter, Kevin .....	6/20/2005
Miami, FL		Shelby, NC	
Arenales, Anna .....	6/20/2005	Purcell, Donald .....	6/20/2005
Hialeah, FL		Napa, CA	
ARS Professional Pharmacy, LTD .....	6/20/2005	Rascoe, Jessica .....	6/20/2005
Monsey, NY		Windsor, NC	
Barreda, Celina .....	6/20/2005	Reardon, Gina .....	6/20/2005
Miami, FL		Cumming, GA	
Beauchene, Tracey .....	6/20/2005	Reusche, Jane .....	6/20/2005
Aberdeen, WA		Fort Myers, FL	
Birotech Corporation .....	6/20/2005	Ricketts, Donna .....	6/20/2005
Tampa, FL		Hendersonville, TN	
Bonett, Olga .....	6/20/2005	Rivera-Iglesias, Jorge .....	6/20/2005
Camden, NJ		Cabo Rojo, PR	
Canning, Joyce .....	6/20/2005	Rivera-Iglesias, Wilson .....	6/20/2005
Sanford, ME		Cabo Rojo, PR	
Chancy, Luke .....	6/20/2005	Rodriguez-Sorrentini, Eric .....	6/20/2005
Kelso, WA		Cabo Rojo, PR	
Curbelo, Sue .....	6/20/2005	Rodriguez-Sorrentini, Noel .....	6/20/2005
Glendale, CA		Cabo Rojo, PR	
Dean, Nancy .....	6/20/2005	Senquiz, Luz .....	6/20/2005
Danbury, CT		Philadelphia, PA	
Depaula, Grisel .....	6/20/2005	Showell, Stephanie .....	6/20/2005
Miami, FL		Georgetown, DE	
Dubois, Marylin .....	6/20/2005	Stanley A Gorgol, D P M, Inc, Corp .....	6/20/2005
Paradis, LA		Salem, NH	
Espinosa, Sara .....	6/20/2005	Symkowski, Yanina .....	6/20/2005
Miami, FL		Waukesha, WI	
Gibbs, Debra .....	6/20/2005	Taft, William .....	6/20/2005
Fayetteville, NC		Cornelius, NC	
Gilley, Margaret .....	6/20/2005	Tatman, April .....	6/20/2005
Ellsworth, ME		Thornville, OH	
Gladkovister, Petr .....	6/20/2005	Taylor, Patricia .....	6/20/2005
Shorewood, WI		Wiggins, MS	
Goode, Constance .....	6/20/2005	Thomas-Hicks, Michelle .....	6/20/2005
Essex Junction, VT		Taylor, MI	
Hill, Stella .....	6/20/2005	Thurn, Anita .....	6/20/2005
Sacramento, CA		Scott, LA	
Hines, Shelia .....	6/20/2005	Thurn, Melvin .....	6/20/2005
Enfield, NC		Breaux Bridge, LA	
Hoover, Ronald .....	6/20/2005	Uko, Ekong .....	6/20/2005
Manchester, KY		Chatsworth, CA	
Howze, Andreco .....	6/20/2005	Underwood, Paul .....	6/20/2005
Great Falls, SC		Charlotte, NC	
Ince, Karen .....	6/20/2005	Urbano-Jane, Gloria .....	6/20/2005
Hollis, NY		Miami, FL	
Joyner, Connie .....	6/20/2005	Vann, Hoeuth .....	6/20/2005
Clinton, NC		Long Beach, CA	
Karapetyan, Margarita .....	6/20/2005	Warren, Constanza .....	6/20/2005
Los Angeles, CA		Altamonte Springs, FL	
Katherine, Scott .....	6/20/2005	Weir, Burnadett .....	6/20/2005
Minersville, PA		Hollis, NY	
Kaufman, Brian .....	6/20/2005	Williams, Taranika .....	6/20/2005
Honeoye Falls, NY		Minneapolis, MN	
Leafa, Tina .....	6/20/2005	Wright, Carrie .....	6/20/2005
Seatac, WA		Eden, NY	
Lennon, Dionne .....	6/20/2005	<b>Felony Conviction for Health Care Fraud</b>	
Wadesboro, NC		Amato, Nicola .....	6/20/2005
Loveall, Amy .....	6/20/2005	Flanders, NJ	
Fulton, NY		Bass, Theresa .....	6/20/2005
McCloskey, Debra .....	6/20/2005	Imperial, MO	
Schenectady, NY		Cazel, Phillip .....	6/20/2005
Mora, Zoraida .....	6/20/2005	Newcastle, CA	
Miami, FL		Colon, Margaret .....	6/20/2005
Morales-Montalvo, Carlos .....	6/20/2005	E Falmouth, MA	
San German, PR		Crowder, Linda .....	6/20/2005
Nemirovskaya, Viktoria .....	6/20/2005	Lancaster, CA	
Cedarburg, WI		Duhon, Paula .....	6/20/2005
Nsekpang, Michael .....	6/20/2005		

Subject name, address	Effective date	Subject name, address	Effective date	Subject name, address	Effective date
Lancaster, TX Farrell, Linda .....	6/20/2005	Columbia, MS Friendship, Theodore .....	6/20/2005	San Jose, CA Bolton, Pamela .....	6/20/2005
Rochester, NY Getz, Nicole .....	6/20/2005	Baton Rouge, LA Greaves, Yvette .....	6/20/2005	Batesville, MS Bonner, Julie .....	6/20/2005
Clinton, OH Greenleaf, Janice .....	6/20/2005	Roxbury, MA Johnson, Evelyn .....	6/20/2005	Houston, TX Boswell, Andrea .....	6/20/2005
N Wildwood, NJ Korman, Julie .....	6/20/2005	Elizabeth City, NC Kimmons, Regina .....	6/20/2005	New Bedford, MA Brill, Mary .....	6/20/2005
Hamilton, OH Lamoreaux, Christopher .....	6/20/2005	Holly Springs, MS Kutscher, Laura .....	6/20/2005	Philadelphia, PA Brunson, Judith .....	6/20/2005
Lompoc, CA Landa, Carlos .....	6/20/2005	Pennellville, NY Mathis, Jacqueline .....	6/20/2005	Calusa, CA Burquist, Tammy .....	6/20/2005
Napa, CA Masterson, Pamela .....	6/20/2005	Jackson, MS Mitchell, Virginia .....	6/20/2005	Semmes, AL Byrd, Dena .....	6/20/2005
Niles, OH McCormick, Cynthia .....	6/20/2005	Carbon, IN Moore, Pamela .....	6/20/2005	Lake Charles, LA Byrd, John .....	6/20/2005
Cambridge, OH McCoy, Reginald .....	6/20/2005	Washington, NC Mosley, Gloria .....	6/20/2005	Phoenix, AZ Campbell, Shari .....	6/20/2005
Edinburg, TX Nguyen, Phu .....	6/20/2005	Oklahoma City, OK Rippy, David .....	6/20/2005	Antioch, CA Camuti, Diane .....	6/20/2005
San Jose, CA Ruther Charlotte .....	6/20/2005	Wichita Falls, TX Showell, Cora .....	6/20/2005	Astoria, NY Caraballo, Marcy .....	6/20/2005
West Milton, OH Tsirulsky, Ilya .....	6/20/2005	Berlin, MD Simmons, Tina .....	6/20/2005	Pueblo, CO Carper, Nancy .....	6/20/2005
Los Angeles, CA Wills, Cathy .....	6/20/2005	Buffalo, NY Spomer, Kandise .....	6/20/2005	Sebring, FL Carter, Roselyn .....	6/20/2005
Providence, RI		Enid, OK Tadlock, Amanda .....	6/20/2005	Providence, RI Casimiro, Melissa .....	6/20/2005
<b>Felony Control Substance Conviction</b>		Mapleton, IA Wittscheck, Heather .....	6/20/2005	West Warwick, RI Castorena, Kim .....	6/20/2005
Cockerville, Lawrence .....	6/20/2005	Toledo, OH Zabala, Wilfredo .....	6/20/2005	Brush, CO Cedarwoods Day Spa, Inc .....	6/20/2005
Litchfield, OH Cook, Stephanie .....	6/20/2005	Seattle, WA		Pembroke Pines, FL Champion, Mary .....	6/20/2005
Checotah, OK Dao, David .....	6/20/2005	<b>Conviction for Health Care Fraud</b>		Egg Harbor TWP, NJ Chaney, Mary .....	6/20/2005
Elizabethtown, KY Johnson, Russell .....	6/20/2005	Redman, Chelsea .....	6/20/2005	Fort Wayne, IN Christon, Shannon .....	6/20/2005
Chester, VA Kenward, John .....	6/20/2005	Statesville, NC		Fresno, CA Cinsavich, Scott .....	6/20/2005
San Diego, TX Martin, Katherine .....	6/20/2005	<b>Conviction—Obstruction of an Investigation</b>		Westford, MA Cline, Sarah .....	6/20/2005
Burlington, VT Marzen, Matthew .....	6/20/2005	OPI Properties, INC .....	2/11/2005	Puyallup, WA Cloys, Donald .....	6/20/2005
Macungie, PA McDowell, Jerri .....	6/20/2005	St Louis Park, MN		Richmond, KY Clyburn, Vickie .....	6/20/2005
Somerset, KY Nesbitt, Aaron .....	6/20/2005	<b>License Revocation/Suspension/ Surrendered</b>		Loxley, AL Collymore, Kerri .....	6/20/2005
Lawton, MI Petersen, Penny .....	6/20/2005	Abarca, Cheryl .....	6/20/2005	Houston, TX Colon, Karen .....	6/20/2005
Denver, CO Portales, Arturo .....	6/20/2005	Newark, NJ Alexander, Melissa .....	6/20/2005	Toms River, NJ Craig, Donna .....	6/20/2005
Manchester, KY Rick, Roxanne .....	6/20/2005	Clarksville, IN Allen, Deanna .....	6/20/2005	Noblesville, IN Crudale, Ann .....	6/20/2005
Alexandria, VA Rudolph, Jeanette .....	6/20/2005	Kilgore, TX Amato, Frank .....	6/20/2005	Warwick, RI Cupolo, Stacy .....	6/20/2005
Clinton, MO Withington, Pamela .....	6/20/2005	Bellport, NY Atkinson, Kristin .....	6/20/2005	Lakewood, NJ Currier-Hill, Theresa .....	6/20/2005
Flemington, NJ Worcester, Keith .....	6/20/2005	Winston-Salem, NC Austin, Todd .....	6/20/2005	Delta, OH Danieli, Alexis .....	6/20/2005
Stockton, CA		Eaton, IN Baguss, Loraine .....	6/20/2005	Tiverton, RI Daniels, Jennifer .....	6/20/2005
<b>Patient Abuse/Neglect Convictions</b>		Louisville, KY Baker, Richard .....	6/20/2005	Syracuse, NY Davidson, Jean .....	6/20/2005
Anderson, Lisa .....	6/20/2005	Lima, OH Barlow, Mary .....	6/20/2005	Lutz, FL Dean, Elizabeth .....	6/20/2005
Dallas, TX Bah, Haja .....	6/20/2005	Glendale, AZ Bass, Jean .....	6/20/2005	Satellite Beach, FL Demara, Toni .....	6/20/2005
Hyattsville, MD Brasley, Michael .....	6/20/2005	South Hero, VT Batchan, Danette .....	6/20/2005	El Monte, CA Dinovo, Linda .....	6/20/2005
E Rochester, NY Breakfield, Jimmy .....	6/20/2005	Chandler, AZ Baxter, Tabatha .....	6/20/2005	Largo, FL Downes, Dennis .....	6/20/2005
Columbia, MS Browder, Clarissa .....	6/20/2005	Anniston, AL Bohanon, Terri .....	6/20/2005	McKeesport, PA Duff, Charlette .....	6/20/2005
Centreville, MS Coleman, Charlotte .....	6/20/2005				

Subject name, address	Effective date	Subject name, address	Effective date	Subject name, address	Effective date
Bruce, MS		Tacoma, WA		Littleton, NH	
Dunn, Deborah .....	6/20/2005	Keegan, Barbara .....	6/20/2005	Norwood, Elizabeth .....	6/20/2005
Louisville, KY		North Cape May, NJ		Atmore, AL	
Eddy, Vickie .....	6/20/2005	Keeton, Heather .....	6/20/2005	Perry, Marc .....	6/20/2005
High Point, NC		Willows, CA		Addison, IL	
Elder, Lisa .....	6/20/2005	Kelly, Sherry .....	6/20/2005	Peters, Janice .....	6/20/2005
Pittsburgh, PA		Philadelphia, PA		Marshalltown, IA	
Eyler, Kelley .....	6/20/2005	Kent, Kim .....	6/20/2005	Petillo, Larry .....	6/20/2005
Churubusco, IN		Huntington, WV		Coeur d'Alene, ID	
Fennell, Leslie .....	6/20/2005	Knowles, Abbey .....	6/20/2005	Pleat, Donna .....	6/20/2005
Port St Lucie, FL		Orlando, FL		Sunrise, FL	
Fenzel, Carl .....	6/20/2005	Koeller, Bambi .....	6/20/2005	Quidgeon, Maureen .....	6/20/2005
Goodyear, AZ		Midvale, UT		Thomaston, CT	
Fhrye, Karen .....	6/20/2005	Kolinsky, Carol .....	6/20/2005	Quinn, Eamonn .....	6/20/2005
Sacramento, CA		Berlin, NH		Ft Lauderdale, FL	
Fletcher, Constance .....	6/20/2005	Land, Cindy .....	6/20/2005	Rabon, Judy .....	6/20/2005
Enosburg Falls, VT		Claremore, OK		Rembert, SC	
Fritts, Larry .....	6/20/2005	Landry, Danielle .....	6/20/2005	Remmers, Janice .....	6/20/2005
Phillipsburg, NJ		West Warwick, RI		Mooresville, IN	
Fuster, David .....	6/20/2005	Laughlin, Lee .....	6/20/2005	Richardson, Katherine .....	6/20/2005
Bethesda, MD		Brandon, VT		Gary, IN	
Gagnon, Kimberly .....	6/20/2005	Lehman, Lori .....	6/20/2005	Riggs, Dezirae .....	6/20/2005
Woonsocket, RI		Nine Mile Falls, WA		Madison, IN	
Garcia, Marcy .....	6/20/2005	Lesieur, Sandra .....	6/20/2005	Rivera, Mary .....	6/20/2005
Avenal, CA		Grover, NC		Las Animas, CO	
Gardner, Charlotta .....	6/20/2005	Lewis, Cassandra .....	6/20/2005	Robertson, Blythe .....	6/20/2005
Jackson, MS		Nicholasville, KY		Paisley, FL	
Godwin, Carla .....	6/20/2005	Lewis, Jeanette .....	6/20/2005	Romanauskas, Vincent .....	6/20/2005
Dothan, AL		Elizabethton, TN		Harrisburg, PA	
Goodie, James .....	6/20/2005	Lindquist, Beth .....	6/20/2005	Rose, Rebecca .....	6/20/2005
Mount Vernon, NY		Greencastle, IN		Leitchfield, KY	
Grim, Donald .....	6/20/2005	Logan, Michael .....	6/20/2005	Rothwell, Frances .....	6/20/2005
Peshastin, WA		Palmdale, CA		Palm Bay, FL	
Groothand, Kimberly .....	6/20/2005	Luque, Vita .....	6/20/2005	Roy, Leona .....	6/20/2005
Sanford, ME		Griffith, IN		Port St Lucie, FL	
Guttman, Dennis .....	6/20/2005	Maack, Don .....	6/20/2005	Rudd, Carol .....	6/20/2005
Gainesville, FL		W Fargo, ND		Orlando, FL	
Hall, John .....	6/20/2005	Macavoy, Sonia .....	6/20/2005	Sanderson, Lynn .....	6/20/2005
Cornelius, NC		Port St Lucie, FL		Trenton, NJ	
Hart, Kimberly .....	6/20/2005	MaLear, Jeremy .....	6/20/2005	Schoening, Linda .....	6/20/2005
Lodi, CA		Hemet, CA		Winston-Salem, NC	
Hatten, Candace .....	6/20/2005	Marcotte, Julie .....	6/20/2005	Scott, Jason .....	6/20/2005
Lone Star, TX		Phoenix, AZ		Calvert City, KY	
Hayes-Bolster, Lori .....	6/20/2005	Martin, Thomas .....	6/20/2005	Shatzer, Bonnie .....	6/20/2005
Chicago, IL		St Petersburg, FL		Westminster, MD	
Hendrickson, Molly .....	6/20/2005	Mauri, Sandy .....	6/20/2005	Shelton, Joshua .....	6/20/2005
Morganfield, KY		Totowa, NJ		Richland, WA	
Henry, Andrea .....	6/20/2005	McArthur, Teri .....	6/20/2005	Sheperd, Anne .....	6/20/2005
Marrero, LA		Pueblo West, CO		Ashland, KY	
Herron, Jerry .....	6/20/2005	McDonald, Mary .....	6/20/2005	Shiraldi, Teresa .....	6/20/2005
Murfreesboro, TN		Vacaville, CA		Abingdon, MD	
Herschel, Layne .....	6/20/2005	McGinnis, Susan .....	6/20/2005	Siddall, Donley .....	6/20/2005
Chester, VT		Leesburg, OH		Collegedale, TN	
Hodges, Donna .....	6/20/2005	McKinney, Sheila .....	6/20/2005	Skowron, Tadeusz .....	6/20/2005
Rancho Cordova, CA		Oakland, MS		Avon, CT	
Howerton, Cynthia .....	6/20/2005	McLain, Jennifer .....	6/20/2005	Smargiassi, Suzanne .....	6/20/2005
Saucier, MS		Oklahoma City, OK		Leesburg, FL	
Hu, Ming .....	6/20/2005	Medley, Ginger .....	6/20/2005	Smith-Moore, Tonya .....	6/20/2005
Baldwin Park, CA		Winchester, KY		Omaha, IL	
Hubbard, Russelle .....	6/20/2005	Meza, Patricia .....	6/20/2005	Stachkunas, Matthew .....	6/20/2005
Alabaster, AL		Orosi, CA		Bristol, CT	
Hursh, Susan .....	6/20/2005	Michaelis, David .....	6/20/2005	Stevenson, Cathy .....	6/20/2005
Fort Wayne, IN		Paso Robles, CA		Mancos, CO	
Johanson, Leeann .....	6/20/2005	Mills, Jane .....	6/20/2005	Stone, Tammy .....	6/20/2005
Draper, UT		Mt Vernon, KY		Pawtucket, RI	
Johnson, Sarah .....	6/20/2005	Miranda, Rose .....	6/20/2005	Sullivan, Jackie .....	6/20/2005
Riverside, CA		Tucson, AZ		Orlando, FL	
Jones, Janet .....	6/20/2005	Moran, Finn .....	6/20/2005	Sullivan, Janice .....	6/20/2005
Fort Collins, CO		Webster, MA		Stockton, CA	
Jones, Joy .....	6/20/2005	Mullen, Priscilla .....	6/20/2005	Swicegood, Joseph .....	6/20/2005
Lawrenceville, GA		Mesa, AZ		Louisville, TN	
Jones, Luella .....	6/20/2005	Navas, Jennifer .....	6/20/2005	Tambo, Brenda .....	6/20/2005
Richmond, KY		Jacksonville, FL		Los Osos, CA	
Kantola, Jeffrey .....	6/20/2005	Niemiec, June .....	6/20/2005	Tate, Larry .....	6/20/2005

Subject name, address	Effective date
Phoenix, AZ Therivil, Yolette .....	6/20/2005
Miami, FL Thurber, Pauline .....	6/20/2005
Lakewood, CO Tidd, Miles .....	6/20/2005
Trenton, NJ Tiscornia, Kimberly .....	6/20/2005
W Milford, NJ Tofflemire, Andrew .....	6/20/2005
San Francisco, CA Trentacosta, Gregory .....	6/20/2005
Wayne, NJ Trombley, Laurie .....	6/20/2005
Bradford, VT Vaughn-Bey, David .....	6/20/2005
Colorado Springs, CO Vitols, Britt .....	6/20/2005
Essex Junction, VT Wells, Larry .....	6/20/2005
Louisville, KY Wheat, Patricia .....	6/20/2005
Louisville, KY Wheeler, Marsha .....	6/20/2005
Cheshire, CT White, Jeannie .....	6/20/2005
Fresno, CA Wilburn, Robert .....	6/20/2005
North Point, FL Williamson, Christina .....	6/20/2005
Chewelah, WA Willie, Dennis .....	6/20/2005
Salt Lake City, UT Wimmer, Jan .....	6/20/2005
Providence, RI Wood, Kristy .....	6/20/2005
Hopbottom, PA Yancey, Dawn .....	6/20/2005
Yerington, NV Yrigoyen, Florence .....	6/20/2005
Denver, CO Zink, Tricia .....	6/20/2005
Mt Vernon, IN	

**Fraud/Kickbacks/Prohibited Acts/  
Settlement Agreements**

Ahmad, Vimlesh .....	10/5/2004
Seattle, WA Day, Floyd .....	3/7/2005
Portland, OR	

**Owned/Controlled By Convicted Entities**

Amgu, Inc .....	6/20/2005
McKinney, TX Health & Wellness Medical Clinic, Inc .....	6/20/2005
Los Angeles, CA Southern California Respiratory Care Services .....	6/20/2005
Long Beach, CA	

**Default on Heal Loan**

Bayles, Jay .....	6/20/2005
Westlake Village, CA Duong, Chau .....	6/20/2005
Brooklyn, NY Mohammadkhani, Alireza .....	6/20/2005

Subject name, address	Effective date
Chatsworth, CA	

**Owners of Excluded Entities**

Edoho-Ukwa, Grace .....	6/20/2005
McKinney, TX Greer, Leta .....	6/20/2005
St. Louis, MO	

Dated: June 1, 2005.  
**Katherine B. Petrowski,**  
*Director, Exclusions Staff, Office of Inspector General.*  
 [FR Doc. 05-12693 Filed 7-1-05; 8:45 am]  
**BILLING CODE 4152-01-M**

**DEPARTMENT OF HEALTH AND  
HUMAN SERVICES**

**National Institutes of Health**

**Notification of Request for Emergency  
Clearance; Evaluation of the Impact of  
the New Conflicts of Interest  
Regulations on the National Institutes  
of Health's Ability To Recruit and  
Retain Staff**

In accordance with Section 3507(j) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) hereby publishes notification of request for Emergency Clearance for the information collection related to the Evaluation of the Impact of the New Conflicts of Interest Regulations on the National Institutes of Health's Ability to Recruit and Retain Staff.

This information collection is essential to the mission of the NIH [42 U.S.C. 241 and 282(b)(1)]. In December 2003, the House Energy and Commerce Committee raised concerns about potential conflicts of interest at NIH. In response to these concerns, the NIH Director, Dr. Elias Zerhouni, ordered an internal investigation into consulting agreements at NIH and in June 2004 proposed changes to the agency's conflict-of-interest policies. Effective February 3, 2005, the new regulations (5 CFR parts 5501 and 5502, "Supplemental Standards of Ethical Conduct and Financial Disclosure Requirements for Employees of the Department of Health and Human Services," **Federal Register**, Vol. 70, No. 22 Thursday, February 3, 2005, 5543-5565 ) apply to all NIH employees and place limits on certain financial holdings of employees, their spouses, and minor children and on certain outside activities in which NIH staff may engage. In the brief time since the implementation of the new ethics rules, many key NIH senior scientists have

chosen to leave NIH rather than comply with the new regulations.

In the preamble to the rule, HHS stated its intent to evaluate the impact of the new rules within the next year. Gauging both the immediate and longer term impact of these new rules is crucial to NIH's ability to develop and maintain a world-class staff. This project will produce data that will help NIH and HHS leaders determine the impact of the regulations and whether changes should be made, so it is essential that the data are collected while the review of the regulations is still in progress.

NIH cannot reasonably comply with the normal clearance procedures for information collection, because the use of normal procedures will delay the collection and hinder the agency in accomplishing its mission, to the detriment of the public good. NIH has taken all practicable steps to consult with the scientific community and the public in reaching the determination. Several months have elapsed since the publication of the new conflict of interest regulations, and NIH has had several meetings with employees, interviewed senior scientists and has made plans to survey current NIH employees, as well as reviewed more than 1800 comments on the regulations. At this point, NIH intends to survey recent applicants, applicants who have declined to accept employment offers from NIH and potential applicants from scientific organizations from which NIH has traditionally drawn leading scientific personnel. This will allow NIH to determine whether the regulations impact an individual's attitudes about employment at NIH and the likelihood of their joining the agency.

NIH and HHS leaders are still examining and modifying some aspects of the rules. It is essential that these leaders obtain information on the impact of the rules on the career aims and choices of non-NIH scientists and the perception of the scientific community to inform their decision making.

**Proposed Collection**

*Title:* Evaluation of the Impact of the New Conflicts of Interest Regulations on the National Institutes of Health's Ability to Recruit and Retain Staff. *Type of Information Collection Request:* Emergency. *Need and Use of Information Collection:* To assess the impact of new NIH ethics regulations on the agency's ability to continue to attract and recruit highly qualified scientific personnel. *Frequency of Response:* One time. *Affected Public:* Individuals and households. *Type of Respondent:* Highly