

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
11.10	2,500	1	2,500	20	45,000
11.30	2,500	1	2,500	20	45,000
11.50	4,500	1	4,500	20	90,000
11.300	4,500	1	4,500	20	90,000
Total					270,000

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

Dated: May 4, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–9370 Filed 5–10–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0021]

International Conference on Harmonisation; Draft Guidance on Q8 Pharmaceutical Development; Availability; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until June 11, 2005, the comment period for the notice, published in the **Federal Register** of February 9, 2005 (70 FR 6888). In the notice, FDA announced the availability of a draft guidance entitled “Q8 Pharmaceutical Development.” FDA is reopening the comment period to provide additional time for public comment consistent with the time for comment provided by other ICH regulatory entities.

DATES: Submit written or electronic comments on the draft guidance by June 11, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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>. Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–

240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send two self-addressed adhesive labels to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Ajaz Hussain, Center for Drug Evaluation and Research (HFD–3), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2847; or Christopher Joneckis, Center for Biologics Evaluation and Research (HFM–1), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–435–5681.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 9, 2004 (70 FR 6888), FDA announced the availability of a draft guidance entitled “Q8 Pharmaceutical Development,” prepared under the auspices of the ICH. The draft guidance provides recommendations to sponsors concerning pharmaceutical studies as defined in section 3.2.P.2 of module 3 of the Common Technical Document (CTD).

Interested persons were given until April 11, 2005, to submit comments on the draft guidance.

FDA has decided to reopen the comment period on the draft guidance

until June 11, 2005, to allow the public additional time to review and comment on the contents and to be consistent with the time for comment provided by other ICH regulatory entities.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m. Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the documents at <http://www.fda.gov/ohrms/dockets/default.htm>, <http://www.fda.gov/cder/guidance/index.htm>, or <http://www.fda.gov/cber/publications.htm>.

Dated: May 4, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–9369 Filed 5–10–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: April 2005

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of April 2005, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusions 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
<i>Program-Related Convictions:</i>		
Aguiluz, Amable	Whittier, CA	5/19/2005
Alvis, Sandra	Pennsauken, NJ	5/19/2005
Antoine L Garabet, MD, Inc	Glendora, CA	5/19/2005
Avello, Alexis	Miami Beach, FL	5/19/2005
Beal, Darlene	Tulsa, OK	5/19/2005
Bisig, Peggy	Lexington, KY	5/19/2005
Blake, Christine	Alpharetta, GA	5/19/2005
Bolshinsky, Igor	Potomac, MD	5/19/2005
Bondar, Raisa	Mequon, WI	5/19/2005
Brooks, Antonio	Washington, NC	5/19/2005
Brown, Joseph	Florence, SC	5/19/2005
Chand, Puran	Stanton, CA	5/19/2005
Coughlin, Daniel	Metairie, LA	5/19/2005
Cullen, Linda	Kailua Kona, HI	5/19/2005
Cushing, Monica	Barre, VT	5/19/2005
Daniels, Salmon	Los Angeles, CA	5/19/2005
Deguzman, Maria	Cerrutis, CA	5/19/2005
Doll, Charles	Jacksonville, FL	2/11/2005
Esposito, Michelina	Portland, ME	5/19/2005
Fosness, Christopher	Mitchell, SD	5/19/2005
Garabet, Antoine	Glendora, CA	5/19/2005
Gokhman, Boris	Mequon, WI	5/19/2005
Goulette, Billy	Long Beach, CA	5/19/2005
Hall, Harry	Labelle, FL	5/19/2005
Igbinuwa, Newton	Jamaica, NY	5/19/2005
Jamias, Alexander	Buena Park, CA	5/19/2005
Jani, Axat	Saddle River, NJ	5/19/2005
Jimenez, Jose	Camden, NJ	5/19/2005
Johnson, Paul	Loma, CO	5/19/2005
Legro, Danny	Chehalis, WA	5/19/2005
Lemieux, India	Gretna, LA	5/19/2005
Lisak, Alla	Bayside, WI	5/19/2005
Mailyan, Melik	Burbank, CA	5/19/2005
Melendez, Juanita	Camden, NJ	5/19/2005
Moore, Garyl	York, PA	5/19/2005
Munoz, Cynthia	Phoenix, AZ	5/19/2005
Myaskovskaya, Valentina	Milwaukee, WI	5/19/2005
Panshi, Surinder	Wasco, CA	5/19/2005
Passamonte, Christopher	Camp Hill, PA	5/19/2005
Ramos, Robert	Carolina, PR	5/19/2005
Reyes-Lopez, Harry	Hatillo, PR	5/19/2005
Rizzo, Kenneth	Goshen, NY	5/19/2005
Salas, Patricia	Las Cruces, NM	5/19/2005
Salvo, Mark	Glendale, CA	5/19/2005
Schoenborn, Mark	Ponte Verdra Beach, FL	2/11/2005
Skrinskaya, Natalya	Silver Spring, MD	5/19/2005
TBC Products, Inc	Golden Valley, MN	11/12/2004
Tirakian, Harutyun	Glendale, CA	5/19/2005
Turner, Jessie	Chickasha, OK	5/19/2005
Vann, Sinnaro	Long Beach, CA	5/19/2005
Walton, Wanda	Vallejo, CA	5/19/2005
Winding, Devona	New Orleans, LA	5/19/2005
Yelin, Bella	Mequon, WI	5/19/2005
Zarlengo, Phillip	Littleton, CO	5/19/2005
<i>Felony Conviction for Health Care Fraud:</i>		
Budenske, Jerry	Oklahoma City, OK	5/19/2005
Faulkner, Glenna	Ewing, KY	5/19/2005
Fox, Calvin	Tucson, AZ	5/19/2005
Hinds, Sandra	Wheaton, MD	5/19/2005
Holliday, Gregory	Bethany, OK	5/19/2005
Hunt, Kimberly	Oxnard, CA	5/19/2005
Jango, Angela	Newport News, VA	5/19/2005
Libson, Todd	Simi Valley, CA	5/19/2005

Subject name	Address	Effective date
Moore, Nicole	Broken Arrow, OK	5/19/2005
Pickering, Joanne	Tucson, AZ	5/19/2005
Ray, Natacha	Broken Arrow, OK	5/19/2005
Sanders, Marvin	Charlottesville, VA	5/19/2005
Santamaria, Rene	Apache Junction, AZ	5/19/2005
Schneider, Harvey	Norton, MA	5/19/2005
Thompson, Kimberly	Danville, KY	5/19/2005
Felony Control Substance Conviction:		
Allen, Jana	Kansas City, MO	5/19/2005
Aulner, Kathleen	Norfolk, NE	5/19/2005
Breece, Robin	Groves, TX	5/19/2005
Chaussee, Mary	Rocklin, CA	5/19/2005
Christensen, Kim	Mesa, AZ	5/19/2005
Davis, Keri	Flower Mound, TX	5/19/2005
Fanning, James	Sherman, TX	5/19/2005
Friedman, Eugene	Port Jefferson, NY	5/19/2005
Greening, Brian	Edinburg, TX	5/19/2005
Haskins, Tammy	Midland, TX	5/19/2005
Hermann, Raymond	Vancouver, WA	5/19/2005
Johnson, Karen	Blue Ridge, GA	5/19/2005
Libengood, Stacey	Clearwater, FL	5/19/2005
Moore, Janet	Gainesville, GA	5/19/2005
Moore, Mary	Painesville, OH	5/19/2005
Morelli, Timothy	Mercer, PA	5/19/2005
Palladini, Michael	Beaver, PA	5/19/2005
Renteria, Jeanette	Burleson, TX	5/19/2005
Sibley, Leslie	Tulsa, OK	5/19/2005
Spencer, Verinda	Houston, TX	5/19/2005
Stanton, James	Houston, TX	5/19/2005
Ushio, Keri-Ann	Honolulu, HI	5/19/2005
Varalli, Daniel	Beaver, WV	5/19/2005
Wein, Fred	Brooklyn, NJ	5/19/2005
Wisby, Amy	Hamersville, OH	5/19/2005
Patient Abuse/Neglect Convictions:		
Bemah, Elisha	Washington, DC	5/19/2005
Cage, Christine	Chillicothe, MO	5/19/2005
Chrisman, Christopher	Del City, OK	5/19/2005
Cotten, Bradley	Canon City, CO	5/19/2005
Davis, Rose	Santa Fe, NM	5/19/2005
Garay, Rosalinda	Salt Lake City, UT	5/19/2005
Harris, Linda	Henryetta, OK	5/19/2005
Henry, Jonathan	Malone, FL	5/19/2005
Hewuse, Roselyn	Green Bay, WI	5/19/2005
Jobes, Philip	Towson, MD	5/19/2005
Johnson, Arlin	Oklahoma City, OK	5/19/2005
Jones, David	Hodgen, OK	5/19/2005
Kizziar, Mary	Fairfax, OK	5/19/2005
Lomas, Terena	Grove, OK	5/19/2005
Myers, Roger	Trainer, PA	5/19/2005
Quintero, Mary	Denver, CO	5/19/2005
Russell, Barbara	Sallisaw, OK	5/19/2005
Rutherford, Helen	Ruston, LA	5/19/2005
Simpson, Jimmy	Bartlesville, OK	5/19/2005
Smith, Ada	Pearl, MS	5/19/2005
Stultz, Helen	Hugo, OK	5/19/2005
Thomas, Annamma	Yonkers, NY	5/19/2005
Topel, Lisa	Chillicothe, MO	5/19/2005
Torrez, Pearl	Tulsa, OK	5/19/2005
Turner, Barbara	Louin, MS	5/19/2005
Valenzula, Carlos	Los Angeles, CA	5/19/2005
Watters, Winifred	Visalia, CA	5/19/2005
Wolos, Jeffrey	Swartz Creek, MI	5/19/2005
Woolen, James	Washington, DC	5/19/2005
Conviction for Health Care Fraud:		
Poehlman, Eric	Quebec, H2L3R8,	3/17/2005
License Revocation/Suspension/Surrendered:		
Agygman, Osei	Pomona, CA	5/19/2005
Albus, Rhonda	Knox City, TX	5/19/2005
Alexander, Anu	Tucson, AZ	5/19/2005
Alexander, Julie	Cherry Hill, NJ	5/19/2005
Allen, Chandra	Trotwood, OH	5/19/2005
Ambrose, Dean	Merchantville, NY	5/19/2005
Archer, Teresa	Johnson City, TN	5/19/2005
Arvesen Aebischer, Barbara	San Diego, CA	5/19/2005

Subject name	Address	Effective date
Baker, Patrick	Corona, CA	5/19/2005
Benninger, Kimberly	Los Angeles, CA	5/19/2005
Benson, Tracy	Murray, UT	5/19/2005
Boulos-Pludowski, Georgeann	Phillipsburg, NJ	5/19/2005
Bowyer, Marvin	St Louis, MO	5/19/2005
Boyer, Bethany	Valrico, FL	5/19/2005
Bradshaw, Minnie	Columbia, SC	5/19/2005
Brennan, Patricia	Punta Gorda, FL	5/19/2005
Britton, Cory	St George, UT	5/19/2005
Brown, Alexandria	Williamstown, NJ	5/19/2005
Brown, Dana	Mount Olive, AL	5/19/2005
Bruce, Julie	Indianapolis, IN	5/19/2005
Bryant, Mark	Jasper, AL	5/19/2005
Bullock, Keith	Detroit, MI	5/19/2005
Cabatic, Virginia	Randolph, NJ	5/19/2005
Carlson, Craig	Minneapolis, MN	5/19/2005
Caron, Marleen	Lincoln, NH	5/19/2005
Carranto, Manuel	Riverside, CA	5/19/2005
Carter, Lynda	Loudon, NH	5/19/2005
Casey, Terry	Covington, KY	5/19/2005
Chagnon, Stephen	Glens Falls, NY	5/19/2005
Chard, Suzanne	Parker, CO	5/19/2005
Charlera, Marie	Boynton Beach, FL	5/19/2005
Charzewski, Stanley	Staten Island, NY	5/19/2005
Childers, Stella	Muskogee, OK	5/19/2005
Clark, Diane	Longmont, CO	5/19/2005
Cochran, Stephanie	Hackleburg, AL	5/19/2005
Cohen, Veronica	Lansdowne, PA	5/19/2005
Collins, Cindy	North Vernon, IN	5/19/2005
Combs, Vontella	Bulan, KY	5/19/2005
Cook, Anthony	Beaver, WV	5/19/2005
Couch, Joann	Bullhead City, AZ	5/19/2005
Crayton, Donna	Alliance, OH	5/19/2005
Cruz, Rosalito	Carson, CA	5/19/2005
Daniels, Arthur	Phoenix, AZ	5/19/2005
Daniels, James	Panama City, FL	5/19/2005
Donegan, Kathleen	Yuma, AZ	5/19/2005
Driscoll, Debra	N Hollywood, CA	5/19/2005
Duffy, William	Mahtomedi, MN	5/19/2005
Duncan, Kimberly	Pisgah Forest, NC	5/19/2005
Ecker, Betty L	Lufkin, TX	5/19/2005
EdInbyrd, Geraldine	San Bernardino, CA	5/19/2005
Edwards, David	Salt Lake City, UT	5/19/2005
Edwards, Michael	Tarzana, CA	5/19/2005
Egloff, Mary	Farmingdale, NJ	5/19/2005
Elder, Kimberly	Marshall, AR	5/19/2005
Ellison, Amy	Anniston, AL	5/19/2005
Eskue, Phyllis	Kilgore, TX	5/19/2005
Esmay, Kristine	Prescott, AZ	5/19/2005
Evans, Catherine	Hager Hill, KY	5/19/2005
Ferry, Lois	Cincinnati, OH	5/19/2005
Fiala, Robin	Manchester, NH	5/19/2005
Foy, Brian	Melbourne, FL	5/19/2005
Ghory, Farooq	Winter Park, FL	5/19/2005
Gill, Joyce	Cincinnati, OH	5/19/2005
Griesemer, Chantal	Ballston Lake, NY	5/19/2005
Guardipee, Josette	Pueblo, CO	5/19/2005
Hart, Eva	Galena, KS	5/19/2005
Hart, Kelly	Verona, PA	5/19/2005
Harvan, Roberto	Glendale, AZ	5/19/2005
Haskie, Julie	Chinle, AZ	5/19/2005
Hatfield, Benjamin	Knoxville, TN	5/19/2005
Hill, Beverly	Phoenix, AZ	5/19/2005
Hopkins, Mary	Clute, TX	5/19/2005
Horwitz, Harlene	Oklahoma City, OK	5/19/2005
Hughes, Joyce	Las Vegas, NV	5/19/2005
Hunter, Angela	Gainesboro, TN	5/19/2005
Illingworth, Donna	Forked River, NJ	5/19/2005
Ingles, Sandra	Palm Desert, CA	5/19/2005
James, Nicholas	Phoenix, AZ	5/19/2005
Jarke, Cheryl	Rittman, OH	5/19/2005
Johnson, Anthony	Beverly Hills, CA	5/19/2005
Johnson, Callie	Tulsa, OK	5/19/2005
Johnson, Mary	Taft, CA	5/19/2005

Subject name	Address	Effective date
Junge, Rebecca	Saint Louis, MO	5/19/2005
Kahaloui, Ronald	Modesto, CA	5/19/2005
Kaplan, Claudette	Port Orchard, WA	5/19/2005
Katzorke, Michael	Sioux Falls, SD	5/19/2005
Kee, Jimmy	Huntingdon, TN	5/19/2005
Kessler, Susan	Tamarac, FL	5/19/2005
Kirkpatrick, Molly	Punta Gorda, FL	5/19/2005
Koscinski, Charles	Downey, CA	5/19/2005
Kovar, Grace	Brick, NJ	5/19/2005
Kroeger, Susan	Evansville, IN	5/19/2005
Kurtz, Joel	Livingston, NJ	5/19/2005
Lange, Dennis San	Mateo, CA	5/19/2005
Langley, Troy	Erin, TN	5/19/2005
Lester, Linda	Tucson, AZ	5/19/2005
Leveque, Phillip	Portland, OR	5/19/2005
Linn, David	Craig, CO	5/19/2005
Logue, Bridgette	Shelbyville, TN	5/19/2005
Long, Andrew	Fayetteville, NC	5/19/2005
Lovett, Asante	Tulsa, OK	5/19/2005
Lyde, Marlene	Norwalk, CA	5/19/2005
Lyon, Robin	Lynnwood, WA	5/19/2005
Machicek, Sherri	Victoria, TX	5/19/2005
Malone, Joanne	Dallas, TX	5/19/2005
Maloney, Jeffrey	Phoenix, AZ	5/19/2005
Manuel, Christal	Evergreen, LA	5/19/2005
Marshall, Brenda	Bellevue, FL	5/19/2005
Martinez, Christina	Sahuarita, AZ	5/19/2005
McLaurin, Mildred	Carrboro, NC	5/19/2005
McNamara, Peggy	Puyallup, WA	5/19/2005
Mohalla, Aiman	Long Beach, CA	5/19/2005
Moore, Tiffany	Chandler, AZ	5/19/2005
Morrissey, Maryellen	Ormond Beach, FL	5/19/2005
Moss, Albert	Somerset, NJ	5/19/2005
Mullins, Lonnie	Columbus, OH	5/19/2005
Murphree, Arlene	Tulsa, OK	5/19/2005
Nagel, Tiffany	League City, TX	5/19/2005
Neide, Deborah	Umatilla, FL	5/19/2005
Nemitz, Lacey	Mount Vernon, WA	5/19/2005
Nenadov, Barney	Canyon Country, CA	5/19/2005
Nesbit, Harriet	Rutland, VT	5/19/2005
Newington, Marlene	Hartford, MI	5/19/2005
Newmark, Malinda	Monroe TWP, NJ	5/19/2005
Noel, Beverly	New Hall, CA	5/19/2005
Nugent, Dana	Pineville, LA	5/19/2005
Nunnery, Larita	Kent, WA	5/19/2005
OBright, Teresa	W Chicago, IL	5/19/2005
Osborne, Robelto	Miami, FL	5/19/2005
Ottenstein, Alan	Washington Crossing, PA	5/19/2005
Owens, Catherine	Glencoe, AL	5/19/2005
Pagano, Dwight	New York, NY	5/19/2005
Parker-Robinson, Letrice	Long Beach, CA	5/19/2005
Paulsen, John	Beaver, UT	5/19/2005
Paxton, Marla	Delong, IN	5/19/2005
Pearson, Shirley	Rapid City, SD	5/19/2005
Penalver, Faith	Roosevelt, NJ	5/19/2005
Perry, Regan	Huntsville, AL	5/19/2005
Plaia, Daneta	Hickory Hills, IL	5/19/2005
Potter, Joan	Ventura, CA	5/19/2005
Presilla, Alejandro	Weehawken, NJ	5/19/2005
Ramsey, James	Concord, NH	5/19/2005
Rice, Ginger	Newport, TN	5/19/2005
Robinson, Anne	Redondo Beach, CA	5/19/2005
Robles, Karin	Yelm, WA	5/19/2005
Rodriguez, Callis	Fontana, CA	5/19/2005
Roring, Kellie	Orem, UT	5/19/2005
Rudolph, Angaharad	Bradenton, FL	5/19/2005
Sanders, Cheryl	Riverside, AL	5/19/2005
Schick, Peter	Van Nuys, CA	5/19/2005
Schirmer, Christopher	North Bennington, VT	5/19/2005
Schultz, Becky	Greeley, CO	5/19/2005
Schunk, Brenda	Tucson, AZ	5/19/2005
Sieverding, Gregory	Peru, NY	5/19/2005
Silver, Maria	Las Vegas, NV	5/19/2005
Simon, Lynn	Cape Coral, FL	5/19/2005

Subject name	Address	Effective date
Smith, Nicholas	Oviedo, FL	5/19/2005
Steidl, Elizabeth	Palm Bay, FL	5/19/2005
Stiver, Dorothea	Clanton, AL	5/19/2005
Suggs, Sharon	Adamsville, TN	5/19/2005
Sutphin, Mary	Goodview, VA	5/19/2005
Swartz, Theresa	Jacksonville, FL	5/19/2005
Taylor, Ronald	Carson, CA	5/19/2005
Tebo, Elizabeth	Grover, MO	5/19/2005
Thomas, Cynthia	Brooksville, FL	5/19/2005
Turk, Harold	West Hills, CA	5/19/2005
Valandry, Kelly	Tucson, AZ	5/19/2005
Vaughn, Barbara	Kingsport, TN	5/19/2005
Vidal, Emalee	Gig Harbor, WA	5/19/2005
Vincelette, Brandi	Enosburg Falls, VT	5/19/2005
Von Hoffen, Laura	Chicago, IL	5/19/2005
Vu, Uong	San Diego, CA	5/19/2005
Walker, Robert	Sand Springs, OK	5/19/2005
Wamsley, Patricia	Mansfield, OH	5/19/2005
Watkins, William	Vista, CA	5/19/2005
Wilson, Michael	Chicago, IL	5/19/2005
Wilson, Orphia	Orlando, FL	5/19/2005
Wizes, Adrian	Lake George, NY	5/19/2005
Wood, Danielle	Irving, TX	5/19/2005
Wood, Margaret	Denver, CO	5/19/2005
Wukawitz, Thomas	St Paul, MN	5/19/2005
Zapata, Francisco	Oxnard, CA	5/19/2005
Zini, Julie	Annandale, MN	5/19/2005
Federal/State Exclusion/Suspension:		
Gonzales, Thomas	Las Vegas, NV	5/19/2005
Groombridge, Colleen	Gillette, WY	5/19/2005
Umansky, Olga	Los Angeles, CA	5/19/2005
Fraud/Kickbacks/Prohibited Acts/Settlement Agreements:		
Masri, Asad	Chesterfield, VA	10/6/1994
Owned/Controlled by Convicted Entities:		
Advanced Physicians Management, Inc	Ocoee, FL	5/19/2005
Americare Medical Supply, Inc	Los Angeles, CA	5/19/2005
Default on Heal Loan:		
Kilmer, David	Troutville, VA	2/22/2005
Mazhar, Mark	Woodland Hills, CA	4/18/2005

Dated: April 28, 2005.

Katherine B. Petrowski,

Director, Exclusions Staff, Office of Inspector General.

[FR Doc. 05-9374 Filed 5-10-05; 8:45 am]

BILLING CODE 4152-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Inventory and Evaluation of Clinical Research Networks

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on September 30, 2004, page

58451 and 58452 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection:

Title: Inventory and Evaluation of Clinical Research Networks.

Type of Information Collection Request: NEW.

Need and Use of Information

Collection: This project is part of the NIH Roadmap to improve the speed and effectiveness of translating basic scientific discoveries into clinical products and practices that improve health care. The project, which is related to the Reengineering of the Clinical Research Enterprise, has been designed to enhance the efficiency and productivity of clinical research by promoting clinical research networks to

rapidly conduct high quality clinical studies where multiple research questions can be addressed. Specifically, this study involves (1) developing an inventory and database of clinical research networks, (2) asking representatives from these networks to respond to an Inventory Questionnaire (Tier 1) that will allow us to update information we collected from public sources and gather additional information on network characteristics, and (3) conducting more in-depth surveys (Tier 2) with 1/3 of the identified networks (Tier 2). Data will be used to characterize the selected networks in terms of network focus, management and governance, effectiveness in changing clinical practice, informatics infrastructure, and training and training infrastructure. Best practices will be identified and presented at a national leadership forum.

Frequency of Response: Networks will be asked to respond to the Inventory Questionnaire (Tier 1) once. It is anticipated that 60% of the networks queried will actually meet the network eligibility criteria. A 1/3 sample of the