

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

| 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     |

<sup>1</sup>There 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#### International Conference on Harmonisation; Draft Guidance on Q8 Pharmaceutical Development; Availability; Reopening of Comment Period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 In the notice, FDA announced the availability of a draft guidance entitled “Q8 Pharmaceutical Development.”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**DATES:** Submit written or electronic comments on the draft guidance by June 11, 2005.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**ADDRESSES:** Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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      |
| Igbinaduwa, 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, Natailya .....                      | 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      |
| <b>Felony Conviction for Health Care Fraud:</b> |                              |                |
| 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 .....                     | Mema, 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          | Hackleburt, 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      |
| Kahalioumi, 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.

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**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 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