

any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

Under FDA's good guidance practice regulations, this guidance is being issued as a Level 2 guidance because it sets forth the agency's existing practices (21 CFR 10.115(c)(2); 65 FR 56468, September 19, 2000). Therefore, FDA is issuing this document as a final guidance prior to receiving public comment. However, as with all FDA guidance, the public is encouraged to submit written comments with new data or other new information pertinent to this guidance. The comments in the docket will be periodically reviewed, and, where appropriate, the guidance will be amended.

III. Comments

Interested persons may, at any time, submit written comments on the final guidance to the Dockets Management Branch (address above). Two copies of any 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 final guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain this guidance at <http://www.fda.gov/cder>.

Dated: March 5, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01-6135 Filed 3-12-01; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: February 2001

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of February 2001, the HHS Office of Inspector General imposed exclusions in the 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, City, State	Effective date
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Program-Related Convictions

Abcunas, Maryann, Lowell, MA	03/20/2001
Adler, Jacob, Valley Village, CA	03/20/2001
Agcaoili, Sonia Maritess, Long Beach, CA	03/20/2001
Allbritton, Carolyn Diane, Shreveport, LA	03/20/2001
Anderson, Susan Hope, Pocola, OK	03/20/2001
Azu, Philip, White Deer, PA	03/20/2001
Bennett, Vincent, Bernard, Detroit, MI	03/20/2001
Bonsu, Osei A., Lilburn, GA	03/20/2001
Boodram, Suresh, Massapequa, NY	03/20/2001
Boyardzhyan, Nerses, Los Angeles, CA	03/20/2001
Cararie, Francis N., Finleyville, PA	03/20/2001
Chhugani, Jagi, Rego Park, NY	03/20/2001
Clayton, Nolan C., Walterboro, SC	03/20/2001
Cottle, John P., Edgefield, SC	03/20/2001
Davis, Troy R., Glendale, AZ	03/20/2001
Dunster, Misty L., Montpelier, VT	03/20/2001
Eastman, Kathryn, Coloma, MI	03/20/2001
Evans, Clarence J., Brooklyn, NY	03/20/2001
Evans, Linda Faye, Simsboro, LA	03/20/2001
Fann, Edward C., St. Louis, MO	03/20/2001
Gaumond, Jody Lynn, Methuen, MA	03/20/2001
Gibbs, Lisa A., Providence, RI	03/20/2001
Green, Michael Jerome, Jackson, MS	03/20/2001
Guzek, Robert, Valparaiso, IN	03/20/2001
Guzman, Emilia, Miami, FL	03/20/2001
Halladay, Kathryn Clara, Torrance, CA	03/20/2001
Healthtek, Inc., Vancouver, WA	03/20/2001
Hope, Robert B., Ogden, UT	03/20/2001
Hughes, Larry M., Kansas City, MO	03/20/2001
Johnson, Deana Tanner, Hurst, TX	03/20/2001
Karu, Louise May, Oakland, CA	03/20/2001
Ketsoyan, Levon, Eloy, AZ	03/20/2001

Subject, City, State	Effective date
King, John Victor, III, Southfield, MI	03/20/2001
Kleaveland, Joan Sherry, Benton Harbor, MI	03/20/2001
Koral, Allen, Jericho, NY	03/20/2001
Lang, Joel J., Cheverly, MD	03/20/2001
Leistriz, Mark Brandon, Austin, TX	03/20/2001
Meulener, Lazaro, Miami, FL	03/20/2001
Ochoa, Marlene Santana, Miami, FL	03/20/2001
Oni, Oluremi, Providence, RI	03/20/2001
Papisian, Hagop, Granada Hills, CA	03/20/2001
Prater, Carolyn Sue, Hueysville, KY	03/20/2001
Redonado, Ileana, Fort Lee, NJ	03/20/2001
Sand, Scott Robert, Lake Arrowhead, CA	03/20/2001
Santana, Ana Luisa Gonzalez, Hialeah, FL	03/20/2001
Santana, Milagro, Miami, FL	03/20/2001
Sefiljian, Karine M., Valencia, CA	03/20/2001
Simmons, Stephanie, Baltimore, MD	03/20/2001
Syal, Harshbala, Northridge, CA	03/20/2001
Turner, Thomas Phares, Oklahoma, OK	03/20/2001
Villamor, Manuel A., Miami, FL	03/20/2001
Virzi, Nina, Bryn Mawr, PA	03/20/2001
Wilner, Alan, Roslyn Estates, NY	03/20/2001
Wilson, Susan Arnsdorff, Leavenworth, WA	03/20/2001
Zarza, Jose, Blounstown, FL	03/20/2001

Felony Conviction for Health Care Fraud

Bates, Tammy Lavon, Perkin, IL	03/20/2001
Hayes, Ruth Ann, Roanoke, VA	03/20/2001
Sanchez Christina, L., Albuquerque, NM	03/20/2001

Felony Control Substance Conviction

Banerjee, Haradhan, Cleveland, OH	03/20/2001
Burke, Debra L., Ebsensburg, PA	03/20/2001
Cobb, Timothy L., Yuma, AZ	03/20/2001
Deberry, Carroll S., Beaver, WV	03/20/2001
Fredebaugh, Loreal L., Mentor, OH	03/20/2001
Frisby, Julie Ann, Fayetteville, AR	03/20/2001
Gormley, Daniel Littleton, Co	03/20/2001
Hinds, Donald Edward, II, Indianapolis, IN	03/20/2001
Khan, Mudassir Ali, New York, NY	03/20/2001
Kovach, Kathleen A., Sheffield, OH	03/20/2001
Miller, Robert J., Akron, OH	03/20/2001
Veasley, Audrey Nannette, Milwaukee, WI	03/20/2001

Subject, City, State	Effective date	Subject, City, State	Effective date	Subject, City, State	Effective date
Patient Abuse/Neglect Convictions					
Argueta, Edward A., Seaside Park, NJ	03/20/2001	Connell, Christopher, Oklahoma City, OK	03/20/2001	Langer, Lisa Ann, Champaign, IL	03/20/2001
Bationg, Geobi W., Enid, OK ...	03/20/2001	Cookson, Philip Andrew, San Diego, CA	03/20/2001	Lanza, Dorothy, Derby, CT	03/20/2001
Briscoe, Willie Earl, Houston, TX	03/20/2001	Cooper, Lucinda Henderson, Jefferson, NY	03/20/2001	Lee, Yoon Bom, New Smyrna Beach, FL	03/20/2001
Clark, Vunner, Sledge, MS	03/20/2001	Cooper, Sarah H., Charles, SC	03/20/2001	Lindsey, Joseph Fidel, Norton, OH	03/20/2001
Dukes, Tia A., Bioloxi, MS	03/20/2001	Cundiff, David Keith, Long Beach, CA	03/20/2001	Long, Shirley M., Dormont, PA	03/20/2001
Foster, Synthia Ann, Enid, OK	03/20/2001	Custer, Christine L., Oakdale, CT	03/20/2001	Lozano, Tony Atilano, Anaheim, CA	03/20/2001
Gillis, David H., Cincinnati, OH	03/20/2001	Defelice, Louis J., Parker, CO ..	03/20/2001	Luh, Hsiou-Kuang, Fountain Valley, CA	03/20/2001
Griggs, Della, Mooreland, IN	03/20/2001	Dell, Gary L., Jr., London, OH ..	03/20/2001	Madison, Veronica Sue, Wood River, IL	03/20/2001
Howell, Hollis Dewayne, Meridian, MS	03/20/2001	Dinkel, Arthur R., Jr., Denville, NJ	03/20/2001	Madsen, Steven, Fargo, ND	03/20/2001
Hughes, Kinsha, Forest, MS	03/20/2001	Domke, Michele S., Salt Lake City, UT	03/20/2001	Magina, Maria Katherine, Mountain View, CA	03/20/2001
Laferriere, James A., Cranston, RI	03/20/2001	Dunn, Mary Frances, Waco, TX ..	03/20/2001	Maples, Jerald Eugene, Harrah, OK	03/20/2001
Lamley, Sybil D., Laoreal, MS	03/20/2001	Ebbs Barbara Ann, Bellevue, ID	03/20/2001	Mathes, Michael Eugene, Boise, ID	03/20/2001
Linzay, Philip Andrew, Alexandria, LA	03/20/2001	Fisch, Alan, Brookline, MA	03/20/2001	McGuines, Christina J., Buffalo, NY	03/20/2001
Luvine, Jennifer, Mount Olive, MS	03/20/2001	Folsom, Cay M., Mason City, IA	03/20/2001	Mcillece, Elizabeth Campbell, Cedar Park, TX	03/20/2001
McCormack, Alvin Peter, Carson, WA	03/20/2001	Fuller, Sharon Denise, Atlanta, GA	03/20/2001	McMillan, Kris Phillip, Roselle, IL	03/20/2001
Moore, Mary L., Summerton, SC	03/20/2001	Gahner, Duane, Jamestown, ND	03/20/2001	McRae, Elizabeth, Norwalk, CT ..	03/20/2001
O'Connor, Gayle Lee, Glendale, CA	03/20/2001	Gaither, James, Indianapolis, IN	03/20/2001	Montano, Grethe Martens, Anatone, WA	03/20/2001
Oglesby, Willie, Ripley, MS	03/20/2001	Gonzalez, Gilbert J., Atlanta, GA	03/20/2001	Morales, Jorge A., Plymouth, NH	03/20/2001
People, Donald, Decatur, AL	03/20/2001	Gray, Sheri A., Anderson, SC ..	03/20/2001	Morris, Sharon W., Savannah, GA	03/20/2001
Tillman, George A., Paris, MO ..	03/20/2001	Greenwell, Nancy H., Deary, ID ..	03/20/2001	Morris, Marjorie Christine, Kearns, UT	03/20/2001
Tucker, Roshae, Laurel, MS	03/20/2001	Hall, Sybil M., New Albany, IN ..	03/20/2001	Murray, Theodore Banal, Monterey, CA	03/20/2001
Weitz, Todd N., Titusville, FL ...	03/20/2001	Halligan, Mavis E., Garland, TX ..	03/20/2001	Musick, Janna Denise, Davie, FL	03/20/2001
Conviction for Health Care Fraud					
Kutcher-Olivo, Robert, Condado, PR	03/20/2001	Harcastle, Brian, Grainesville, FL	03/20/2001	Nantt, Luella, Dickinson, ND	03/20/2001
License Revocation/Suspension/Surrendered					
Adams, Shirley Ann, Bellevue, IA	03/20/2001	Havet, Keith E., Covina, CA	03/20/2001	Neil, Edwin J., Beaverton, OR ..	03/20/2001
Alamillo, Raquel, Denver, CO ..	03/20/2001	Hawkins, Renee K., Moore, SC ..	03/20/2001	Norton, Kathy L., Dawson, IA ...	03/20/2001
Anderson, Sharron Lee, Boise, ID	03/20/2001	Herring, Cynthia, Hempstead, TX	03/20/2001	Nowik, James A., Rhinebeck, NY	03/20/2001
Andrews, Sharlie Jane, Palm Desert, CA	03/20/2001	Hersey, Leslie E., Woodsville, NH	03/20/2001	O'Toole, Rita Kay Atwood, Winn, Jerome, ID	03/20/2001
Banayan, Farajollah, Mordechai, Los Angeles, CA ..	03/20/2001	Hicks, Jennifer A., Lyme, NH ...	03/20/2001	Ogle, Linda Louise, Seattle, WA ..	03/20/2001
Barton, Tammy R., Iowa City, IA	03/20/2001	Hinnen, Gerhard J., Dadeville, AL	03/20/2001	Orr, Penny Lee, Wyoming, IL ...	03/20/2001
Booth, Jamie Lee, Simi Valley, CA	03/20/2001	Holmes, Linda K., Rock Hill, SC	03/20/2001	Pennington, Ellen M., Mt Sterling, OH	03/20/2001
Borresen, Elizabeth Anne, Apple Valley, MN	03/20/2001	Janic, Michael Arthur, Irwin, PA ..	03/20/2001	Perugini, Katherine A., Oakville, CT	03/20/2001
Bowles, Theodore Archie, Macon, GA	03/20/2001	Johnson, Cora Beth, Marquette Hgts, IL	03/20/2001	Peters, Susan Kay, Houston, TX	03/20/2001
Brown, Dorothy I., Plymouth MTG, PA	03/20/2001	Johnson, James E., Nashville, TN	03/20/2001	Piech, Christie Lynn, Hammond, IN	03/20/2001
Bugbee, Michele Sue, Claremont, NH	03/20/2001	Jones, Michael R., Gainesville FL	03/20/2001	Piecznski, Bradley John, Warrenville, IL	03/20/2001
Burton, Cori Ann, Ft. Worth, TX ..	03/20/2001	Jordan, Terry Lee, Sherman, TX	03/20/2001	Plante, Elizabeth A., Hollis, NH ..	03/20/2001
Byrd, Marie S., Fayetteville, Ga ..	03/20/2001	Jubert, Angela K., Carmel, IN ..	03/20/2001	Pool, Dennis Ray, Covina, CA ..	03/20/2001
Cekala, Pamela S., N. Stonington, CT	03/20/2001	Kaplan, Herbert Arthur, Los Angeles, CA	03/20/2001	Porter, Ola M., Corpus Christi, TX	03/20/2001
Charron, Keith R., Lyndonville, VT	03/20/2001	Kerner, Jacqueline S., Woodridge, IL	03/20/2001	Pratis, Jennifer Lynn, Morris, IL ..	03/20/2001
Chimento, Tammy D., Goose Creek, SC	03/20/2001	King, Grant M., Pomona, CA ...	03/20/2001	Prince, Vicki Lynn, Troy, IL	03/20/2001
Cohen, Jack J., Brooklyn, NY ..	03/20/2001	Klein, Alice R., Austin, TX	03/20/2001	Pryor, Mario Antwan, Chicago, IL	03/20/2001
Conant, Mark R., Brawley, CA	03/20/2001	Klein, Jerri Lynn, Granite City, IL	03/20/2001	Qualls, Marilyn, Chicago, IL	03/20/2001
		Kotz, Teri Ross, Smithland, IA ..	03/20/2001	Quandt, Marian L., Waterloo, IA ..	03/20/2001
		Krain, Lawrence Stirling, Chicago, IL	03/20/2001	Quarles, Norrice Lamon, E Moline, IL	03/20/2001
		Kupczynski, Richard B., Chicago, IL	03/20/2001	Ray, Stephen Christop, Chicago, IL	03/20/2001
		Laforest, Janet, Manchester, CT	03/20/2001		

Subject, City, State	Effective date	Subject, City, State	Effective date	Subject, City, State	Effective date
Reddy, Janardhan Bokka, Schenectady, NY	03/20/2001	Williams, Martin R., Monteray, CA	03/20/2001	Matthews, William E., Mars, PA	03/20/2001
Rhodes, Robin Arlene, Granbury, TX	03/20/2001	Williams, Needra A., Chicago, IL	03/20/2001	Meshesha, Moges M., Houston, TX	03/20/2001
Rivera, Pedro I., Hutchins, TX	03/20/2001	Wineinger, Nancy Ann, Amarillo, TX	03/20/2001	Muszik, Joseph K., Sharon, PA	03/20/2001
Rivera, Santos, Jr., Chicago, IL	03/20/2001	Zevallos, Carlos A., Sun Valley, CA	03/20/2001	Namie, Ruth F., Benicia, CA	03/20/2001
Rodriguez, Cynthia V., San Antonio, TX	03/20/2001	Federal/State Exclusion/Suspension		Nigro, Bruce M., Sebring, FL	03/20/2001
Rodriguez, Karen Dawn, Ft Myers, FL	03/20/2001	Benedict, Gisele, Joshua Tree, CA	03/20/2001	Ninomiya, Jesse K., Honolulu, HI	03/20/2001
Romanowski, Melanie Laura, Wheaton, IL	03/20/2001	Cheregi, Ioan, Skokie, IL	03/20/2001	Nkuku, Christopher N., Berkeley, IL	03/20/2001
Safarczyk, Luke Allen, Morris, IL	03/20/2001	Garcen-Ciallella, Gina, Ford, NJ	03/20/2001	Owen, Michael D., Ashland, OR	03/20/2001
Sanchez, Susanna, Chicago, IL	03/20/2001	Krivoruchoko, Arkadiy, Vernon Hills, IL	03/20/2001	Pham, Vinh H., Las Vegas, NV	03/20/2001
Sanders, Sandra L., Greenfield, TN	03/20/2001	Fraud/Kickbacks		Phillips, Constance K., San Francisco, CA	03/20/2001
Schmitt, George M., Pittsburgh, PA	03/20/2001	Krepps, Cathleen S., Grand Junction, CO	06/29/2001	Powell, Dorothy J., Temple Hills, MD	03/20/2001
Schnelten, Eric Dewayne, Roodhouse, IL	03/20/2001	Owned/Controlled by Convicted Excluded		Rose Myrtle F., Dallas, TX	02/08/2001
Schurman, Virginia A., Portsmouth, RI	03/20/2001	Knoxville Medical Mgmt. Group, Knoxville, TN	03/20/2001	Russell, Mark D., Columbia, MO	03/20/2001
Seagle, Iris Jean, Muskogee, OK	03/20/2001	W. Knoxville Family Medical Ctr., Knoxville, TN	03/20/2001	Shelton, Annette Marie, Arlington, TX	03/20/2001
Seale, Shay Lynn, Mountain View, OK	03/20/2001	Worthington Family Medical Ctr., Knoxville, TN	03/20/2001	Thames, Douglas A., Pitman, NJ	03/20/2001
Sealy, Shurland Hassim, Orlando, FL	03/20/2001	Failure To Provide Payment Information		Villaverde, John J., Birmingham, AL	03/20/2001
Seiz, Eric Kent, Springfield, IL	03/20/2001	Brown, Virgious B., Painscourtville, LA	03/20/2001	Wahl, David G., Montgomery, MN	01/25/2001
Sheldon, Peggy, Boise, ID	03/20/2001	Default on Heal Loan		Washington, George L., Antioch, TN	03/20/2001
Sieber, Cori Lynn, Oak Harbor, WA	03/20/2001	Buford, John I., Philadelphia, PA	03/20/2001	Wheeler, Cynthia L., Belleville, IL	03/20/2001
Sivas, Edward Daniel, Apple Valley, CA	03/20/2001	Chambers, Jamie L., Seattle, WA	03/20/2001		
Smith, Sarah C., Powder Springs, GA	03/20/2001	Darish, Susan B., Malden, MA	03/20/2001		
Smotherman, Charlie Joe, Denison, TX	03/20/2001	Donaghe, Brian L., Templeton, CA	03/20/2001		
Snyder, Jeremiah Jay, Ralston, OK	03/20/2001	Ellis, Detra L., Hamilton, AL	03/20/2001		
Sorensen, Dorothy, Santa Fe, NM	03/20/2001	Evans, Carl D., Chagrin, Falls, OH	03/20/2001		
Stafford, Robert Wesley, Denison, TX	03/20/2001	Friedman, Gary S., Old Bridge, NJ	03/20/2001		
Stamos, George Peter, Chicago, IL	03/20/2001	Girault, Gisele J., Grantham, NH	03/20/2001		
Stewart, Ralph Christopher, Richmond, VA	03/20/2001	Goldstein, Sheryl L., Perkasio, PA	03/20/2001		
Sundry, Vincent, Tarpon Springs, FL	03/20/2001	Gross, George E., Arlington, TX	01/31/2001		
Thomas, Shawn K, Gardena, CA	03/20/2001	Hensgen, Kara L., Portland, OR	03/20/2001		
Thomas, Elizabeth Ann, Chicago, IL	03/20/2001	Holahan, Gordon V., Jr., Narragansett, RI	03/20/2001		
Thompson, Gerone Thadius, San Bernardino, CA	03/20/2001	Holloway, Jimmy D., El Paso, TX	03/20/2001		
Tracey, Matthew A., Miami, FL	03/20/2001	Hudgins, Mark A., Fort Wayne, IN	03/20/2001		
Tran, Yen NGOC, Chicago, IL	03/20/2001	Hunger, Edwin L., Jr., San Diego, CA	03/20/2001		
Tremallo, Fayette, Stratford, CT	03/20/2001	Klein, Howard Seth, Pompano Bch, FL	03/20/2001		
Triplett, Wallace, Jr., Chicago, IL	03/20/2001	Ladore-McFarland, Bonnie G., Riverside, CA	03/20/2001		
Tripp, Loring, Sarasota, FL	03/20/2001	Martin, Deo Victor, San Francisco, CA	03/20/2001		
Tucker, James Edward, Manhattan Bch, CA	03/20/2001				
Ventrucchi, Timothy M., Hurley, WI	03/20/2001				
Vest, Richard, Ririe, ID	03/20/2001				
Wallace, Cathy A., Chicago, IL	03/20/2001				
Weigand, David W., Somerset, NJ	03/20/2001				
Wheat, William, Palm Harbor, FL	03/20/2001				

Dated: March 5, 2001.

Calvin Anderson, Jr.,*Director, Health Care Administrative Sanctions, Office of Inspector General.*

[FR Doc. 01-6206 Filed 3-12-01; 8:45 am]

BILLING CODE 4150-04-M**DEPARTMENT OF THE INTERIOR****Fish and Wildlife Service****Notice of Receipt of Applications for Permit****Endangered Species**

The following applicants have applied for a permit to conduct certain activities with endangered species. This notice is provided pursuant to Section 10(c) of the Endangered Species Act of 1973, *as amended* (16 U.S.C. 1531, *et seq.*). Written data or comments should be submitted to the Director, U.S. Fish and Wildlife Service, Division of Management Authority, 4401 North Fairfax Drive, Room 700, Arlington, Virginia 22203 and must be received by the Director within 30 days of the date of this publication.

Applicant: Exotic Feline Breeding Compound, Inc., Rosamond, CA, PRT-37998