environmental concentration in soil PEC_{soil} calculation and the resulting PEC_{soil}, as described in question 17. Therefore, it is important to consider them in the Phase I EIA. At a meeting held June 14 through 16, 2000, the VICH Steering Committee endorsed the final VICH GL6 guidance that incorporates these changes.

VICH GL6 offers guidance on how to assess the environmental impact of VMP's other than veterinary biological products.

In the United States, the environmental impact of VMP's is determined under the requirements established by the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*) and its implementing regulations (40 CFR part 1500 and 21 CFR part 25) and under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(d)). Under NEPA, an environmental assessment (EA) is conducted to determine whether a VMP may have a significant environmental impact. A particular VMP may be categorically excluded from the requirement of an EA, or it may require an EA, an environmental impact statement (EIS), or both.

This final guidance document is intended to be consistent with the laws of the European Union, Japan, and the United States. In an effort to harmonize the different recommendations in each of these areas for assessing the environmental impact of VMP's, this final guidance document adopts the terminology ''Phase I EIA's'' and ''Phase II EIA's.'' Using the terminology of the final guidance document, a Phase I EIA is equivalent under NEPA to either a categorical exclusion or an EA that addresses only environmental exposures (40 CFR 1508.4 and 1508.9). A Phase II EIA is equivalent to an EA with more extensive data than would be necessary under the U.S. equivalent of a Phase I EIA. A Phase II EIA may lead to a finding of no significant impact or preparation of an EIS under NEPA.

This final Level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). This final guidance document represents a portion of FDA's current thinking on the conduct of ecological risk assessment for veterinary medicinal products proposed for marketing in the European Union, Japan, and the United States. It does not create or confer any rights for or on any person, and does not operate to bind FDA or the public. An alternate method may be used as long as it satisfies the requirements of applicable statutes and regulations.

Information collected is covered under OMB control number 0910–0332.

III. Comments

As with all of FDA's guidances, the public is encouraged to submit written comments with new data or other new information pertinent to this final guidance. FDA will periodically review the comments in the docket and, where appropriate, will amend the guidance. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

Interested persons may, at any time, submit written comments to the Dockets Management Branch (address above) regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 5, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–6116 Filed 3–12–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0079]

Acceptance of Foreign Clinical Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance entitled ''Acceptance of Foreign Clinical Studies.'' This final guidance is intended to clarify the ethical principles with which a sponsor must comply before FDA would accept a foreign clinical study not conducted under an investigational new drug application (IND) or investigational device exemption (IDE) in support of a marketing approval application.

DATES: Submit written comments on the final guidance at any time.

ADDRESSES: Submit written requests for single copies of the final guidance entitled ''Acceptance of Foreign Clinical Studies'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1601, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the final guidance.

FOR FURTHER INFORMATION CONTACT: David A. Lepay, Office for Science Coordination and Communication (HF–34), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4000.

SUPPLEMENTARY INFORMATION:

I. Background

FDA regulations allow for the acceptance of foreign clinical studies not performed under an IND or IDE in support of a marketing approval application for a drug, biological product, or device if certain conditions are met. Under these regulations, the study must conform to the ethical principles contained in the Declaration of Helsinki (the Declaration) or with the laws and regulations of the country in which the research was conducted, whichever provides greater protection of the human subjects. In October 2000, the World Medical Association approved a fifth revision of the Declaration. FDA is making this guidance available to clarify which version of the Declaration was incorporated into the drug regulations, and which version of the Declaration was incorporated into the device regulations, and, therefore, which version of the Declaration is applicable to foreign studies conducted without an IND or IDE. FDA will also review any other guidance documents on this subject, and modify them, if necessary, to conform to the clarification expressed in this guidance.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The guidance represents the agency's current thinking on the ethical principles with which a sponsor must comply before FDA would accept a foreign clinical study not conducted under an IND or IDE in support of a marketing approval application. It does not create or confer

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
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
Boyadzhyan, 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., Edgefiled, 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
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
Leistritz, 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., Ebensburg, 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., Ackron, OH	03/20/2001
Veasley, Audrey Nannette, Milwaukee, WI	03/20/2001