

1843) (BHC Act) and Regulation Y (12 CFR Part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act. Additional information on all bank holding companies may be obtained from the National Information Center website at [www.ffiec.gov/nic/](http://www.ffiec.gov/nic/).

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than November 17, 2008.

**A. Federal Reserve Bank of New York** (Ivan Hurwitz, Bank Applications Officer) 33 Liberty Street, New York, New York 10045-0001:

1. *Banco Santander S.A.*, Boadilla, Spain, to acquire 75.1 percent of the voting shares of Sovereign Bancorp, Inc., Philadelphia, Pennsylvania, and thereby indirectly acquire Sovereign Bank, Wyomissing, Pennsylvania, and thereby engage in operating a savings and loan association pursuant to section 225.28(b)(4)(ii) of Regulation Y.

Board of Governors of the Federal Reserve System, October 20, 2008.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Toxicology Program (NTP); NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); Availability of the Biennial Progress Report of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM): NIH Publication No. 08-6529

**AGENCY:** National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

**ACTION:** Availability of the ICCVAM Biennial Progress Report.

**SUMMARY:** NICEATM announces the availability of the "Biennial Progress Report: Interagency Coordinating Committee on the Validation of Alternative Methods: 2006-2007." In accordance with requirements of the ICCVAM Authorization Act of 2000 (42 U.S.C. 285l-3), this report describes progress and activities during 2006-2007 by ICCVAM and NICEATM. The report is available on the NICEATM-ICCVAM Web site at <http://iccvam.niehs.nih.gov/about/ICCVAMrpts.htm>. Copies can also be requested from NICEATM at the address given below.

**ADDRESSES:** Requests for copies of the report should be sent by mail, fax, or email to Dr. William S. Stokes, NICEATM Director, NIEHS, P.O. Box 12233, MD EC-17, Research Triangle Park, NC 27709, (phone) 919-541-2384, (fax) 919-541-0947, (e-mail) [niceatm@niehs.nih.gov](mailto:niceatm@niehs.nih.gov). Courier address: NICEATM, 79 T.W. Alexander Drive, Building 4401, Room 3128, Research Triangle Park, NC 27709.

**FOR FURTHER INFORMATION CONTACT:** Dr. William S. Stokes, NICEATM Director (919-541-2384 or [niceatm@niehs.nih.gov](mailto:niceatm@niehs.nih.gov)).

#### SUPPLEMENTARY INFORMATION:

#### Background Information on ICCVAM, NICEATM, and SACATM

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that use, generate, or disseminate toxicological information. ICCVAM conducts technical evaluations of new, revised, and alternative methods with regulatory applicability. ICCVAM also promotes scientific validation, regulatory acceptance, and national and international harmonization of toxicological test methods that more accurately assess safety and hazards of chemicals and products and that refine, reduce, and replace animal use. The ICCVAM Authorization Act of 2000 (42 U.S.C. 285l-3, available at [http://iccvam.niehs.nih.gov/docs/about\\_docs/PL106545.pdf](http://iccvam.niehs.nih.gov/docs/about_docs/PL106545.pdf)) established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM. NICEATM administers ICCVAM and provides scientific and operational support for ICCVAM-related activities. NICEATM and ICCVAM collaborate in evaluating new and improved test methods applicable to the needs of Federal agencies. Additional information about ICCVAM and NICEATM can be found at

the NICEATM-ICCVAM Web site (<http://iccvam.niehs.nih.gov>).

ICCVAM, NICEATM, and the Director of the NIEHS receive advice regarding statutorily mandated duties of ICCVAM and activities of NICEATM from the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM), a Federally chartered advisory committee. Additional information about SACATM, including the charter, roster, and records of past meetings, can be found at <http://ntp.niehs.nih.gov/go/167>.

Dated: October 8, 2008.

**Samuel H. Wilson,**

*Acting Director, National Institute of Environmental Health Sciences and National Toxicology Program.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Final Guidance on Engagement of Institutions in Human Subjects Research

**AGENCY:** Office for Human Research Protections, Office of Public Health and Science, Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** The Office for Human Research Protections (OHRP), Office of Public Health and Science, is announcing the availability of a guidance document entitled, "OHRP Guidance on Engagement of Institutions in Human Subjects Research." The guidance document describes: (1) Scenarios that, in general, would result in an institution being considered engaged in a human subjects research project; (2) scenarios that would result in an institution being considered not engaged in a human subjects research project; and (3) IRB review considerations for cooperative research in which multiple institutions are engaged in the same non-exempt human subjects research project. The guidance document is intended primarily for institutional review boards (IRBs), research administrators and other relevant institutional officials, investigators, and funding agencies that may be responsible for the conduct, review and oversight of human subject research that is conducted or supported by the Department of Health and Human Services (HHS).

The guidance document announced in this notice finalizes the draft guidance with the same title that was made available for public comment in the **Federal Register** on December 8,