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Federal Communications Commission.

Bulah P. Wheeler,

*Deputy Manager, Office of the Secretary,
Office of Managing Director.*

[FR Doc. 2012-3590 Filed 2-10-12; 4:15 pm]

BILLING CODE 6712-01-P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting Notice

AGENCY: Federal Election Commission.

DATE AND TIME: Monday, February 13, 2012 at 2 p.m.

PLACE: 999 E Street NW., Washington, DC.

STATUS: This Meeting Will Be Closed to the Public.

ITEMS TO BE DISCUSSED:

Investigatory records compiled for law enforcement purposes, or information which if written would be contained in such records

Information the premature disclosure of which would be likely to have a considerable adverse effect on the implementation of a proposed Commission action.

Internal personnel rules and procedures or matters affecting a particular employee.

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PERSON TO CONTACT FOR INFORMATION:

Judith Ingram, Press Officer, *Telephone:* (202) 694-1220.

Shawn Woodhead Werth,

Secretary and Clerk of the Commission.

[FR Doc. 2012-3532 Filed 2-10-12; 4:15 pm]

BILLING CODE 6715-01-P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than February 29, 2012.

A. Federal Reserve Bank of Atlanta (Chapelle Davis, Assistant Vice President) 1000 Peachtree Street NE., Atlanta, Georgia 30309:

1. *Moishe Gubin, Hillside, Illinois, and Mark Orenstein, Chicago, Illinois;* to collectively acquire voting shares of OptimumBank Holdings, Inc., Ft. Lauderdale, Florida, and thereby indirectly acquire voting shares of OptimumBank, Plantation, Florida.

Board of Governors of the Federal Reserve System, February 9, 2012.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 2012-3358 Filed 2-13-12; 8:45 am]

BILLING CODE 6210-01-P

FEDERAL RESERVE SYSTEM

Notice of Proposals To Engage in or To Acquire Companies Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 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.

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 February 29, 2012.

A. Federal Reserve Bank of Atlanta (Chapelle Davis, Assistant Vice President) 1000 Peachtree Street NE., Atlanta, Georgia 30309:

1. *Gateway Financial Holdings of Florida, Inc., Daytona Beach, Florida;* to engage through its subsidiary, Gateway Asset Holdings, Daytona Beach, Florida, in making, acquiring, brokering, or servicing loans, or other extensions of credit, pursuant to section 225.28(b)(1), and activities related to extending credit, pursuant to section 225.28(b)(2).
2. *Certus Holdings, Inc., Atlanta, Georgia;* through its newly formed wholly owned subsidiary, Certus Investment Advisors, LLC, Atlanta, Georgia, to engage in investment advisory activities, pursuant to section 225.28(b)(6)(i).

Board of Governors of the Federal Reserve System.

Dated: February 9, 2012.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 2012-3357 Filed 2-13-12; 8:45 am]

BILLING CODE: P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Availability of ICCVAM Evaluation Report and Recommendations on the Usefulness and Limitations of the LUMI-CELL® ER (BG1Luc ER TA) Test Method, An In Vitro Assay for Identifying Human Estrogen Receptor Agonist and Antagonist Activity of Chemicals

AGENCY: Division of the National Toxicology Program (DNTP), National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), HHS.

ACTION: Availability of report and recommendations; Notice of Transmittal.

SUMMARY: The NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) announces availability of an Interagency Coordinating Committee on the

Validation of Alternative Methods (ICCVAM) test method evaluation report (TMER) that includes recommendations on the usefulness and limitations of the LUMI-CELL® estrogen receptor (ER) transcriptional activation (TA) test method (hereafter referred to as the BG1Luc ER TA test method) to identify human ER agonist and antagonist activity of chemicals. The report also provides (1) performance standards that can be used to evaluate functionally and mechanistically similar test methods, (2) recommended test method protocols, (3) a final background review document (BRD) describing the current validation status of this test method, and (4) recommendations for future studies.

ICCVAM recommends that the BG1Luc ER TA test method can be used as a screening test to identify substances with *in vitro* estrogen agonist and antagonist activity. This use is based on an evaluation of results from an international validation study and corresponding accuracy and reliability.

The report and recommendations have been transmitted to Federal agencies to review and respond to ICCVAM in accordance with the provisions of the ICCVAM Authorization Act of 2000 (42 U.S.C. 2851–2).

FOR FURTHER INFORMATION CONTACT: Dr. William S. Stokes, Director, NICEATM, NIEHS, P.O. Box 12233, Mail Stop: K2–16, Research Triangle Park, NC, 27709, (telephone) 919–541–2384, (fax) 919–541–0947, (email) niceatm@niehs.nih.gov. Courier address: NICEATM, NIEHS, Room 2034, 530 Davis Drive, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Background

In January 2004, Xenobiotic Detection Systems, Inc. (XDS, Durham, NC) nominated the BG1Luc ER TA test method for an interlaboratory validation study. ICCVAM and the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) recommended a high priority for the nominated study, based on the lack of adequately validated test methods and the regulatory and public health need for such test methods. NICEATM subsequently led and coordinated an international validation study with its counterparts in Japan (Japanese Center for the Validation of Alternative Methods) and Europe (European Centre for the Validation of Alternative Methods) in laboratories sponsored by each validation organization. ICCVAM also proposed the development of BG1Luc ER TA test method performance standards. ICCVAM assigned the

activities a high priority after considering comments from the public and endorsement from SACATM.

ICCVAM established an interagency Endocrine Disruptor Working Group (EDWG) composed of scientists from the 15 Federal agencies represented on ICCVAM to work with NICEATM to carry out the relevant evaluation activities. Following completion of the validation study, NICEATM, ICCVAM, and the EDWG prepared a draft BRD and draft test method recommendations. NICEATM released the ICCVAM draft documents to the public for comment and convened an international independent scientific peer review panel (hereafter referred to as the Panel) in public session on March 29–30, 2011, to provide their conclusions on the draft BRD and draft ICCVAM test method recommendations (76 FR 4113). Stakeholders from the public were provided opportunities to comment throughout the review process, including the opportunity for oral comments at the Panel meeting. The Panel considered these comments, as well as public comments submitted prior to the meeting, before concluding its deliberations. The Panel report was published and made available to the public for review and comment (76 FR 28781). The draft test method recommendations, the draft BRD, the draft Panel report, and all public comments were made available to SACATM, which provided comments at its public meeting on June 16–17, 2011 (76 FR 23323).

ICCVAM considered the peer review panel report and all public and SACATM comments in preparing the ICCVAM final test method recommendations. Detailed ICCVAM recommendations are provided in the ICCVAM TMER, *The LUMI-CELL® ER (BG1Luc ER TA) Test Method: An In Vitro Assay for Identifying Human Estrogen Receptor Agonist and Antagonist Activity of Chemicals* (NIH Publication No. 11–7850, available at <http://iccvam.niehs.nih.gov/methods/endocrine/ERTA-TMER.htm>). ICCVAM recommends that the BG1Luc ER TA test method can be used as a screening test to identify substances with *in vitro* estrogen agonist activity. This use is based on an evaluation of available validation study data and corresponding accuracy and reliability. ICCVAM recommends that the accuracy of this assay is at least equivalent to the current ER TA assay included in regulatory testing guidance. The ICCVAM TMER also includes the updated ICCVAM-recommended BG1Luc ER TA test method protocol, performance standards that are applicable to functionally and

mechanistically similar test methods, the final BRD, relevant endocrine disruptor testing regulations and testing guidelines, applicable **Federal Register** notices, the Panel report, public comments, and SACATM meeting minutes.

Background Information on ICCVAM, NICEATM, and SACATM

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that require, use, generate, or disseminate toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative safety testing methods with regulatory applicability and promotes the scientific validation and regulatory acceptance of toxicological and safety testing methods that more accurately assess the safety and hazards of chemicals and products and that reduce, refine (decrease or eliminate pain and distress), or replace animal use. The ICCVAM Authorization Act of 2000 (42 U.S.C. 2851–3) established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM. NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts independent validation studies to assess the usefulness and limitations of new, revised, and alternative test methods and strategies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative test methods and strategies applicable to the needs of Federal agencies. Additional information about NICEATM and ICCVAM can be found on the NICEATM–ICCVAM Web site (<http://iccvam.niehs.nih.gov>).

SACATM was established in response to the ICCVAM Authorization Act (Section 2851–3[d]) and is composed of scientists from the public and private sectors (67 FR 11358). SACATM advises ICCVAM, NICEATM, and the Director of the NIEHS and NTP regarding statutorily mandated duties of ICCVAM and activities of NICEATM. SACATM provides advice on priorities and activities related to the development, validation, scientific review, regulatory acceptance, implementation, and national and international harmonization of new, revised, and alternative toxicological test methods. Additional information about SACATM, including the charter, roster, and records of past meetings, can be found at <http://ntp.niehs.nih.gov/go/167>.

References

EPA. 2009. Endocrine Disruptor Screening Program Test Guidelines. OPPTS 890.1300: Estrogen Receptor Transcriptional Activation (Human Cell Line (HeLa-9903)). Washington, DC: U.S. Environmental Protection Agency. Available: <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0576-0006>.

ICCVAM. 2011. ICCVAM Test Method Evaluation Report: The LUMI-CELL® ER (BG1Luc ER TA) Test Method: An *In Vitro* Assay for Identifying Human Estrogen Receptor Agonist and Antagonist Activity of Chemicals. Research Triangle Park, NC: National Institute of Environmental Health Sciences. Available: <http://iccvam.niehs.nih.gov/methods/endocrine/ERTA-TMER.htm>.

ICCVAM. 2006. Addendum to ICCVAM Evaluation of *In Vitro* Test Methods for Detecting Potential Endocrine Disruptors. Research Triangle Park, NC: National Institute of Environmental Health Sciences. Available: http://iccvam.niehs.nih.gov/docs/endo_docs/EDAddendFinal.pdf.

ICCVAM. 2003a. ICCVAM Evaluation of *In Vitro* Test Methods For Detecting Potential Endocrine Disruptors: Estrogen Receptor and Androgen Receptor Binding and Transcriptional Activation Assays. NIH Publication No. 03-4503. Research Triangle Park, NC: National Institute of Environmental Health Sciences. Available: http://iccvam.niehs.nih.gov/methods/endocrine/end_TMER.htm.

ICCVAM. 2002a. Background Review Document. Current Status of Test Methods for Detecting Endocrine Disruptors: *In Vitro* Estrogen Receptor Transcriptional Activation Assays. NIH Publication No. 03-4505. Research Triangle Park, NC: National Institute of Environmental Health Sciences. Available: http://iccvam.niehs.nih.gov/methods/endocrine/end_bckgnd.htm#ERTA.

ICCVAM. 2002b. Background Review Document. Current Status of Test Methods for Detecting Endocrine Disruptors: *In Vitro* Androgen Receptor Binding Assays. NIH Publication No. 03-4506. Research Triangle Park, NC: National Institute of Environmental Health Sciences. Available: http://iccvam.niehs.nih.gov/methods/endocrine/end_bckgnd.htm#ARBnd.

ICCVAM. 2002c. Background Review Document: Current Status of Test Methods for Detecting Endocrine Disruptors: *In Vitro* Estrogen Receptor Binding Assays. NIH Publication No. 03-4504. Research Triangle Park, NC: National Institute of Environmental Health Sciences. Available: http://iccvam.niehs.nih.gov/methods/endocrine/end_bckgnd.htm#ERBnd.

ICCVAM. 2002d. Background Review Document. Current Status of Test Methods for Detecting Endocrine Disruptors: *In Vitro* Androgen Receptor Transcriptional Activation Assays. NIH Publication No. 03-4507. Research Triangle Park, NC: National Institute of Environmental Health Sciences. Available: http://iccvam.niehs.nih.gov/methods/endocrine/end_bckgnd.htm#ARTA.

ICCVAM. 2002e. Expert Panel Evaluation of the Validation Status of *In Vitro* Test Methods for Detecting Endocrine Disruptors: Estrogen Receptor and Androgen Receptor

Binding and Transcriptional Activation Assays. Expert Panel Final Report. Research Triangle Park, NC: National Institute of Environmental Health Sciences. Available: http://iccvam.niehs.nih.gov/methods/endocrine/end_EPrt.htm.

OECD. 2009. Test No 455: The Stably Transfected Human Estrogen Receptor-alpha Transcriptional Activation Assay for Detection of Estrogenic Agonist-Activity of Chemicals. In: OECD Guidelines for the Testing of Chemicals, Section 4: Health Effects. Paris: OECD Publishing. Available: http://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-4-health-effects_20745788.

Rogers JM, Denison MS. 2000. Recombinant cell bioassays for endocrine disruptors: Development of a stably transfected human ovarian cell line for the detection of estrogenic and anti-estrogenic chemicals. *In Vitro Mol Toxicol* 13(1):67-82.

Dated: February 7, 2012.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. 2012-3437 Filed 2-13-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS-10421]

Agency Information Collection Activities: Proposed Collection; Comment Request

Correction

In notice document 2012-2821 appearing on pages 6123-6124 in the issue of February 7, 2012, make the following correction:

On page 6124, in the first column, in the last line, "April 9, 2012" should read "April 3, 2012".

[FR Doc. C1-2012-2821 Filed 2-13-12; 8:45 am]

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0110]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device Reporting; Manufacturer, Importer, User Facility, and Distributor Reporting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an

opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on medical device reporting (MDR); manufacturer, importer, user facility, and distributor reporting.

DATES: Submit either electronic or written comments on the collection of information by April 16, 2012.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, Daniel.Gittleson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and