REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION

[BAC 416404]

Request for Steering Committee Nominations

ACTION: Request for nominations to the Steering Committee for the Foundation's PredicTox project.

SUMMARY: The Reagan-Udall Foundation (RUF) for the Food and Drug Administration (FDA), which was created by Title VI of the Food and Drug Amendments of 2007, is requesting nominations for its PredicTox Steering Committee. The Steering Committee will provide oversight and guidance for the PredicTox project, and will report to the Reagan-Udall Foundation for the FDA's Board of Directors. This is a resubmission of FR Doc. 2015–18123, Published July 24, 2015. This resubmission includes hyperlinks that were not present in the earlier notice.

DATES: All nominations must be submitted to the Reagan-Udall Foundation for the FDA by August 28, 2015. The PredicTox Steering Committee members will be selected by the Reagan-Udall Foundation for the FDA's Board of Directors; those selected will be notified by September 30 regarding the Board's decision. See the **SUPPLEMENTARY INFORMATION** section for Steering Committee responsibilities, selection criteria and nomination instructions.

ADDRESSES: The Reagan-Udall Foundation for the FDA is located at 1025 Connecticut Ave. NW., Suite 1000, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Questions should be sent to The Reagan-Udall Foundation for the FDA, 202–828–1205, *PredicTox@ReaganUdall.org.*

SUPPLEMENTARY INFORMATION:

I. Background

The Reagan-Udall Foundation for the FDA (the Foundation) is an independent 501(c)(3) not-for-profit organization created by Congress to advance the mission of FDA to modernize medical, veterinary, food, food ingredient, and cosmetic product development; accelerate innovation; and enhance product safety. The Foundation acts as a neutral third party to establish novel, scientific collaborations. With the ultimate goal of improving public health, the Foundation provides a unique opportunity for different sectors (FDA, patient groups, academia, other government entities, and industry) to work together in a transparent way to create exciting new research projects to advance regulatory science.

PredicTox is a public-private partnership led by the Foundation, which brings together multiple stakeholder groups to leverage collective knowledge, technical expertise, data, funding, and other resources to explore systems pharmacology approaches to better understand and predict adverse events (AEs). Developing new tools and approaches for mechanism-based drug safety assessment and prediction is a priority for the FDA, as highlighted in the Agency's 2011 Strategic Plan for Advancing Regulatory Science (*http://goo.gl/BPemhh*). This project aims to harness scientific and technological knowledge, data and computational capacity across various sectors and disciplines to develop and apply systems-based approaches and multi-scales models to drug safety assessment in a coordinated manner.

While systems-based approaches can be applied to the development of predictive models for any class of drug or AE, the PredicTox pilot seeks to first provide a proof of concept pilot by focusing on large and small molecule tyrosine kinase inhibitors (TKIs) and cardiac AEs, specifically left ventricular dysfunction. TKIs are a rapidly growing treatment for oncology and select other therapeutic areas, making them an area of intense importance for patients, the FDA, and pharmaceutical manufacturers. Learnings from the PredicTox pilot will then be applied to other drug classes and/or other toxicities.

The primary objective of PredicTox is to advance systems-based science and tools necessary to support mechanism-based drug safety assessment and prediction. To accomplish this objective, the PredicTox pilot project will be conducted in an iterative, phased manner over the course of several years. The first phase will center on building and populating a knowledge management platform for molecular data, preclinical in vivo pharmacologic and toxicologic data as well as clinical data from both public and private sources.

The PredicTox platform will enable integration, mining, and analysis of highly heterogeneous data not typically combined. Future phases of the project will focus on data mining and development of analytic and visualization tools along with development of multi-scale predictive models capable of linking events at the molecular level with events at the clinical level (AEs) for improved safety assessment. For additional project information, see the Reagan-Udall Foundation Web site: *http://goo.gl/ubXMbJ.*

II. PredicTox Steering Committee Roles and Responsibilities

The PredicTox Steering Committee will provide guidance on the operation of PredicTox, in conjunction with the RUF Board, project staff, and others. The Steering Committee will provide overall programmatic oversight to ensure a focus on the long-term vision of the project, while the Scientific Advisory Committee will provide highly specialized technical expertise.

The PredicTox Steering Committee will be charged with several responsibilities, including:

- Reviewing and approving the PredicTox Charter
- Monitoring adherence to the PredicTox mission and operational principles in the Charter
- Developing metrics and evaluating the project at various milestones
- Reviewing and approving the PredicTox Research Agenda
- Reviewing proposals and contracts submitted to the project

The PredicTox Steering Committee Chair must be able to complete additional responsibilities, including:

- Defining the Steering Committee's meeting agendas and facilitating those meetings
- Recommending for termination, as necessary, any PredicTox Steering Committee members demonstrating dereliction of duties as specified in the PredicTox Charter
- Other responsibilities as required upon implementation of PredicTox

A full list of Steering Committee responsibilities, as well as responsibilities of the Chair, may be found on the Reagan-Udall Foundation Web site: *http://goo.gl/00HtQL.*

III. PredicTox Steering Committee Positions and Selection Criteria

RUF is seeking nominations for 7 voting members of the PredicTox Steering Committee, comprised of the following 5 categories:

- Patient Advocate: 1 member
- Pharmaceutical sector: 2 members
- Technology sector: 1 members
- Academia/Research Institute: 2 members
- At Large: 1 member

The Steering Committee will also have 2 members from the FDA (appointed by the FDA) and 1 member from the National Institutes of Health (appointed by the National Institutes of Health). These 3 individuals will be non-voting members.

Nominees for the voting positions will be evaluated by the RUF Board based on

the following required criteria for each of the 7 positions:

- Ability to complete Steering Committee responsibilities, listed above
- Currently employed by/volunteering for stakeholder field (*e.g.,* pharmaceutical, academia, patient advocate, etc.) with several years of relevant experience
- Leading expert in their relevant field (based on position, publications, or other experience)
- Working knowledge of at least one of the following areas: Risk assessment; drug safety profiling; pharmacology or systems pharmacology; toxicology or systems toxicology; biostatistics; cardiology; oncology; bioinformatics; ontology; multi-scale modeling; knowledge management platforms; software development; or data sharing
- Prior experience serving on a related or similar governance body
- Understanding of the landscape and the impact on impact on the stakeholder group they are representing with their seat

IV. Terms of Service

• The PredicTox Steering Committee meets in-person at least twice per year, with teleconferences in between meetings as deemed necessary by the Chair.

• Members will serve two or three year, staggered terms, as determined by the RUF Board.

• Members do not receive compensation from RUF.

• Members can be reimbursed by RUF for actual and reasonable expenses incurred in support of PredicTox in accordance with applicable law and their specific institutional policies.

• Members are subject to the PredicTox Conflict of Interest policies (additional information can be accessed on the Reagan-Udall Foundation Web site at: *http://goo.gl/00HtQL*).

V. Nomination Instructions

• The nomination form can be accessed on the Reagan-Udall Foundation Web site: *http://goo.gl/00HtQL.*

• Individuals may be nominated for 1 or more of the 5 stakeholder categories.

• Individuals may nominate themselves or others.

• The nomination deadline is August 28, 2015.

Dated: July 24, 2015.

Nancy Beck,

Manager, Program Development, Reagan-Udall Foundation for the FDA.

[FR Doc. 2015–18637 Filed 7–29–15; 8:45 am]

BILLING CODE 4164–04–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75518; File No. SR–BATS–2015–55

Self-Regulatory Organizations; BATS Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Extend the Pilot Period of the BATS Exchange, Inc. Supplemental Competitive Liquidity Provider Program

July 24, 2015.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 23, 2015, BATS Exchange, Inc. (the ''Exchange'' or ''BATS'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange has designated this proposal as a ''non-controversial'' proposed rule change pursuant to section 19(b)(3)(A) of the Act[3] and Rule 19b–4(f)(6)(iii) thereunder,[4] which renders it effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is proposing to extend the pilot period for the Exchange's Supplemental Competitive Liquidity Provider Program (the ''Program''), which is currently set to expire on July 28, 2015, for 3 months, to expire on October 28, 2015.

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Background

On August 30, 2011, the Exchange received approval of rules applicable to the qualification, listing and delisting of securities of issuers on the Exchange.[5] More recently, the Exchange received approval to operate a pilot program that is designed to incentivize certain Market Makers[6] registered with the Exchange as ETP CLPs, as defined in Interpretation and Policy .03 to Rule 11.8, to enhance liquidity on the Exchange in certain ETPs[7] listed on the Exchange and thereby qualify to receive part of a daily rebate as part of the Program under Interpretation and Policy .03 to Rule 11.8.[8]

The Program was approved by the Commission on a pilot basis running one-year from the date of implementation.[9] The Commission approved the Program on July 28, 2014.[10] The Exchange implemented the Program on July 28, 2014 and the pilot period for the Program is scheduled to end on July 28, 2015.

Proposal To Extend the Operation of the Program

The Exchange established the Program in order to enhance liquidity on the Exchange in certain ETPs listed on the Exchange (and thereby enhance the Exchange's ability to compete as a listing venue) by providing a mechanism by which ETP CLPs compete for part of a daily quoting incentive on the basis of providing the most aggressive quotes with the greatest amount of size. Such competition has the ability to reduce spreads, facilitate the price discovery process, and reduce costs for investors trading in such securities, thereby promoting capital formation and helping the Exchange to compete as a listing venue. The

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6)(iii).

[5] *See* Securities Exchange Act Release No. 65225 (August 30, 2011), 76 FR 55148 (September 6, 2011) (SR–BATS–2011–018).

[6] As defined in BATS Rules, the term ''Market Maker'' means a Member that acts a as a market maker pursuant to chapter XI of BATS Rules.

[7] ETP is defined in Interpretation and Policy .03(b)(4) to Rule 11.8.

[8] *See* Securities Exchange Act Release No. 72692 (July 28, 2014), 79 FR 44908 (August 1, 2014) (SR–BATS–2014–022) (''CLP Approval Order'').

[9] *See id* at 44909.

[10] *Id.*