

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

REAGAN-UDALL FOUNDATION

The Reagan-Udall Foundation Bylaws

ACTION: Notice; request for comments.

SUMMARY: The Reagan-Udall Foundation, which was created by Title VI of the Food and Drug Administration Amendments of 2007, is publishing the bylaws that were adopted by its Board of Directors, for public comment.

DATES: Submit e-mail comments to: Comments@ReaganUdall.org on or before January 21, 2010.

FOR FURTHER INFORMATION CONTACT: Jane Reese-Coulbourne, The Reagan-Udall Foundation, (202) 783-7877, JRCoulbourne@ReaganUdall.org.

SUPPLEMENTARY INFORMATION:

I. Background

On September 27, 2007, the President signed into law the Food and Drug Administration Amendments Act of 2007 (FDAAA). Title VI of the law creates the Reagan-Udall Foundation, the purpose of which is to “advance the mission of the Food and Drug Administration to modernize medical, veterinary, food, food ingredient and cosmetic products development, accelerate innovation, and enhance product safety.” See section 770(b) of the act (21 U.S.C. 379dd (b)). The duties of the Foundation include the identification of unmet needs in the development, manufacture, and evaluation (including postmarket evaluation) of the safety and effectiveness of Food and Drug Administration (FDA)-regulated products, and the establishment of scientific and other projects and programs to meet those needs. See section 770(c) (21 U.S.C. 379dd(c)).

Among the areas where experts inside and outside the FDA believe the Foundation can support better science are:

- Scientific fellowships and programs to improve the scientific capacity of the FDA;
- Public-private collaboration to enhance the capacity and techniques for monitoring the safety of medical products on the market;
- Development of methods and analyses to promote the safety and effectiveness of medical products and foods; and
- Improvements in the science and technical capabilities of food safety.

The Foundation’s Board of Directors has adopted an initial set of bylaws, an important step toward its initiation of activity as a nonprofit organization. Pursuant to section 770(d)(2) of the act (21 U.S.C. 379dd(d)(2)), these bylaws are being published in the **Federal Register** for public comment. The bylaws include provisions on conflicts of interest and the acceptance of donations and grants. The Foundation is committed to the highest standards of science in support of FDA’s mission. As the Foundation develops additional information regarding the types of donations and grants (referred to in the bylaws as “gifts”) it may receive and the types of projects it will undertake and fund, it will adopt additional policies regarding conflicts of interest and other issues. In addition, as the Foundation gains more experience, it will develop detailed policies and procedures regarding gift review and acceptance policies. The Foundation will make these policies and procedures available to the public. Until that time, the Foundation will not accept donations or grants from entities subject to FDA regulation or trade associations of industries subject to FDA regulation. The Board will also monitor the terms of any individual donation or grant.

II. Bylaws of Reagan-Udall Foundation, Inc., for the Food and Drug Administration (Adopted by the Board of Directors on October 3, 2009)

Article I

Offices

Section 1. Principal Office. The principal office of the Foundation shall be at such location as the Board of Directors designates, however, such location shall, if practicable be located not more than 20 miles from the District of Columbia.

Section 2. Other Offices. The Foundation may also have an office or offices other than said principal office at such place or places as the Board of Directors shall from time to time determine or the business of the Foundation may require. Such other offices shall also, if practicable, be located not more than 20 miles from the District of Columbia.

Article II

Mission

Section 1. Mission. The Foundation is organized as a non-profit organization exclusively for charitable, scientific and educational purpose as specified in section 501(c)(3) of the Internal Revenue Code of 1986 and Section 770 of the Federal Food Drug and Cosmetic Act (21 U.S.C. 379dd). The purpose of the Foundation shall be to advance the mission of the Food and Drug Administration to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety.

Article III

Members

The Foundation shall have no members. All authority that would otherwise be vested in or exercised by members shall be vested in the Board of Directors of the Foundation. Nothing in these bylaws shall be interpreted as requiring the Board of Directors to meet, vote, or otherwise act separately as members of the Foundation in order to exercise powers that would, if there were members of the Foundation, be vested in the members.

Article IV

Board of Directors

Section 1. General Powers. The business and affairs of the Foundation shall be managed under the direction of the Board of Directors. The Board of Directors may exercise all such authority and powers of the Foundation and do all such lawful acts and things as provided by statute or the Articles of Incorporation.

Section 2. Composition, Number and Appointment. The Board of Directors of the Foundation shall be composed of 16 members, two ex officio members (non-voting) and 14 appointed (voting) members. The ex officio members shall

be the following individuals or their designees: The Commissioner of Food and Drugs and the Director of the National Institutes of Health. Of the fourteen appointed (voting) members, no more than four members shall be representatives of the general pharmaceutical, device, food, cosmetic and biotechnology industries; three shall be representatives of academic research organizations; two shall be representatives of patient or consumer advocacy organizations, one shall be a representative of health care providers; and four or more shall be at large members with expertise or experience relevant to the purpose of the Foundation. No employee of the Federal Government shall be appointed as a member of the Board.

Section 3. Terms of Office. The term of office of each appointed member of the Board shall be four years except that the terms of offices for the initial appointed members of the Board shall expire on a staggered basis as follows: one industry representative, one academic research representative, and one at-large representative each shall have an initial appointment of two years; two industry representatives, one at-large representative, one academic research representative, and one patient/consumer representative each shall have an initial term of three years; and one industry representative, two at-large representatives, one academic research representative, one patient/consumer representative, and the one health care provider representative each shall have an initial term of four years. A member of the Board of Directors may continue to serve after the expiration of his or her term until a successor is appointed. A member of the Board of Directors may be reappointed for a subsequent term or terms. If a member of the Board does not serve the full term, described herein, the individual appointed, pursuant to section 10, to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

Section 4. Annual Meeting and Annual Reporting. (a) The annual meeting of the Board of Directors shall be held at such time, but in no event later than the end of the fifth month following the end of the fiscal year of the Foundation, and at such place as shall be specified in a notice thereof given as hereinafter provided in section 7 of this Article IV or waiver of notice. (b) The annual meeting shall be open to the public. (c) At the annual meeting the Foundation shall publish a report for the preceding fiscal year, which shall include a comprehensive statement of the operations, activities, financial

condition and accomplishments of the Foundation. (d) The Foundation shall make copies of each report submitted under this section 4 of Article IV available to any person for a charge not exceeding the cost of providing such copy.

Section 5. Regular Meeting. Regular meetings of the Board of Directors shall be held at such time and place as the Board of Directors may fix.

Section 6. Special Meetings. Special meetings of the Board of Directors may be called at any time or at the request of the Chair of the Board or the Executive Director. The person or persons authorized to call special meetings of the Board may fix the time and place for holding such special meeting.

Section 7. Notice. Annual and special meetings of the Board of Directors shall be held on notice to the directors. Notice shall state the time and place of the meeting and, in the case of a special meeting, the purpose or purposes for holding such meeting. Notice of each such meeting shall be sent by electronic mail or mailed, postage prepaid, to each director, addressed to him or her at his or her address as shown by the records of the Foundation, at least ten days before the day on which such meeting is to be held, or under extraordinary circumstances be delivered to him or her personally or be given to him or her by telephone, or other similar means, at least twenty-four hours before the time at which such meeting is to be held. Notice of any such meeting need not be given to any director who submits a signed waiver of notice before the meeting or who attends such meeting without protesting, prior to or at its commencement, the lack of notice to him or her.

Section 8. Quorum. A majority of the voting members of the entire Board of Directors shall constitute a quorum for purposes of conducting the business at any meeting of the Board of Directors; but if less than a majority of the voting directors are present at said meeting, a majority of the voting directors present may adjourn the meeting from time to time without further notice. The Chair may, under extraordinary circumstances, in his or her discretion, require the vote of the full Board (all voting members) on a particular matter, provided the Chair discloses to the Board the basis for requiring such a vote. When the vote of the full Board is required, voting members will be permitted to vote at a meeting of the Board or by submitting his or her vote to the Chair in writing.

Section 9. Manner of Acting. The act of a majority of the voting directors

present at a meeting at which a quorum is present shall be the act of the Board of Directors, unless the act of a greater number is required by law or these Bylaws.

Section 10. Vacancies. Any vacancy in the membership of the Board shall not affect the power of the remaining directors to execute the duties of the Board and any such vacancy shall be filled promptly by appointment by the appointed directors by majority vote.

Section 11. Resignations. Any appointed member of the Board of Directors may resign at any time by giving written notice of his or her resignation to the Board of Directors, the Chair of the Board, the Executive Director or the Secretary. Any such resignation shall take effect at the time specified therein if later than the date of its receipt, or if the time when it shall become effective is not specified therein, immediately upon its receipt. Unless otherwise specified therein, the acceptance of such resignation shall not be necessary to make it effective.

Section 12. Removal of Directors. Except as otherwise provided by statute, any director may be removed for cause by the vote of a majority of the voting members of the Board of Directors then in office. The failure to participate in at least half of the meetings and calls scheduled over a one year period shall be a basis for such removal.

Section 13. Compensation. Members of the Board may not receive compensation for service on the Board. Directors may be reimbursed for travel, the reasonable cost of meals and lodging, and other necessary expenses incurred in carrying out the duties of the Board, as set forth in these Bylaws.

Section 14. Informal Action by Board of Directors. Any action required or permitted by law to be taken at a meeting of the Board of Directors may be taken without a meeting if a unanimous written consent, which sets forth the action to be taken, shall be signed by each voting member of the Board and filed with the minutes of proceedings of the Board.

Section 15. Telephonic Meeting. Members of the Board may participate in a meeting by means of a telephone conference or similar communications equipment if all persons participating in the meeting can hear each other at the same time.

Section 16. Emeritus Directors. The Board of Directors may from time to time appoint a former director to the honorary position of "Director Emeritus." Unless otherwise determined by the Board of Directors, the appointment of a Director Emeritus shall continue in effect for the

remainder of the person's life. A former director holding such honorary position shall be entitled to receive notice of, and to attend meetings or portions of meetings of the Board of Directors, but shall have no voting or other rights of a director.

Article V

Committees

Section 1. Committees. The Board of Directors, by resolution adopted by a majority of the voting directors in office, shall designate and appoint an Executive Committee, a Governance Committee and a Finance Committee, and may designate and appoint one or more other committees each of which shall consist of two or more directors, and delegate to such committees any of the powers of the Board of Directors, except the power to amend, alter, and repeal the Bylaws; to elect, appoint or remove any member of such committee or any member of the Board or any officer of the Foundation; to amend or restate the Articles of Incorporation; or to adopt a plan of merger or consolidation with another corporation. The appointment of any committee, the delegation of authority to it, or action by it under that authority shall not operate to relieve the Board of Directors, or any individual member of the Board, of any responsibility imposed upon it or upon him or her by law.

Section 2. Executive Committee. The Executive Committee shall carry out the responsibilities of the Board of Directors between meetings of the Board of Directors.

The Chair of the Board shall be chair of the Executive Committee and the Secretary of the Foundation shall act as secretary thereof. The Chairs of the Governance and Finance Committees shall be members of the Executive Committee. The Executive Director shall be an ex officio, non-voting member of the Executive Committee. In the absence of the Chair, Executive Director or Secretary at any meeting of the Executive Committee, the committee shall appoint a chair or secretary of the meeting as the case may be.

Section 3. Governance Committee. The Governance Committee shall be responsible for making recommendations to the Board on all matters affecting governance, reviewing the Board's performance policies and these Bylaws, and making recommendations to the Board for director nominees and Officer appointments. The Vice Chair of the Board shall chair the Governance Committee.

Section 4. Finance Committee. The Finance Committee shall be responsible for developing and reviewing fiscal procedures and shall make recommendations to the Board regarding the budget and other financial matters. The Treasurer of the Foundation shall chair the Finance Committee.

Section 5. Term of Office. All committees of the Board of Directors shall serve at the pleasure of the Board of Directors. Members of committees who are designated by the Board of Directors shall serve at the pleasure of the Board of Directors. Each chair of a committee shall hold such office for one year and until his or her death, resignation or removal, whichever occurs first. A chair of a committee may continue to serve as chair after the expiration of his or her term until a successor is appointed.

Section 6. Organization, Meetings of Committees. The Board of Directors shall appoint one member of each of the other committees that may be created to be the chair of such committee. All committees may adopt rules governing the time, or the method of call or holding their meetings, and the conduct of their affairs. All committees shall keep a record of their acts and proceedings and shall report thereon to the Board of Directors.

Section 7. Vacancies. A vacancy in the membership of any committee may be filled by appointments made in the same manner as provided in the case of the original appointments.

Section 8. Quorum. Unless otherwise provided in the resolution of the Board of Directors designating a committee, a majority of the whole committee shall constitute a quorum and the act of a majority of the members present at a meeting at which a quorum is present shall be the act of the committee.

Article VI

Officers, Employees, Agents and Contractors

Section 1. Number and Qualifications of Officers. The Officers of the Foundation (except for the initial Chair, which shall be appointed by the ex-officio directors) shall be elected by the Board of Directors and shall include the Chair and Vice Chair of the Board, the Secretary, the Treasurer, and any other officers as may be necessary or desirable for the business of the Foundation.

Section 2. Election and Term of Office. The officers of the Foundation, except the Chair of the Board, shall be elected annually by the members of the Board of Directors at its annual meeting. Each such officer shall hold office until

death, resignation, removal or until the next annual meeting of the Board of Directors and until his or her successor shall be duly elected. The members of the Board of Directors shall elect a member of the Board to serve as the Chair of the Board, who shall serve through the end of his or her term. An officer may be re-elected for subsequent terms.

Section 3. Resignations. Any officer of the Foundation may resign at any time by giving written notice of his or her resignation to the Board of Directors, the Chair of the Board, the Executive Director or the Secretary. Any such resignation shall take effect at the time specified therein or, if the time when it shall become effective is not specified therein, immediately upon its receipt. Unless otherwise specified therein, the acceptance of any such resignation shall not be necessary to make it effective.

Section 4. Removal. Any officer of the Foundation elected or appointed by the Board of Directors may be removed by an affirmative vote of a majority of the then incumbent voting members of the Board of Directors whenever in its judgment the best interests of the Foundation would be served thereby, but such removal shall be without prejudice to the contract rights, if any, of the officer so removed.

Section 5. Vacancies. A vacancy in any office because of death, resignation, removal, disqualification or otherwise shall be filled by the vote of a majority of the voting members of the Board of Directors for the unexpired portion of the term.

Section 6. Chair of the Board. The Chair of the Board shall be a member of the Board, an officer of the Foundation and, if present, shall preside at each meeting of the Board of Directors. He or she shall advise and counsel with the Executive Director and in his or her absence with the other officers of the Foundation, and shall perform such other duties as may from time to time be assigned to him or her by the Board of Directors.

Section 7. Vice-Chair of the Board. The Vice-Chair of the Board shall be a member of the Board, an officer of the Foundation and, if present, shall preside at each meeting of the Board of Directors at which the Chair of the Board is not present, and shall perform the other duties of the Chair of the Board during such times as the Chair of the Board is unavailable to perform such duties.

Section 8. Treasurer. The Treasurer shall be a member of the Board and shall (a) have charge and custody of, and be responsible for, all the funds and securities of the Foundation; (b) keep or cause to be kept full and accurate

accounts of receipts and disbursements in books belonging to the Foundation; (c) deposit or cause to be deposited all moneys and other valuables to the credit of the Foundation in such depositories as may be designated by the Board of Directors or pursuant to its direction; (d) receive, and give receipts for, moneys due and payable to the Foundation from any source whatsoever; (e) disburse the funds of the Foundation; (f) render to the Board of Directors, whenever the Board of Directors may require, an account of the financial condition of the Foundation; and (g) in general, perform all duties incident to the office of Treasurer and such other duties as from time to time may be assigned to him or her by the Board of Directors.

Section 9. Secretary. The Secretary shall be a member of the Board and shall (a) Keep or cause to be kept the minutes of all meetings of the Board of Directors; (b) see that all notices are duly given in accordance with the provisions of these Bylaws and as required by law; (c) be custodian of the records and the seal of the Foundation and affix and attest the seal to all other documents to be executed on behalf of the Foundation under its seal; (d) see that the books, reports, statements, certificates, and other documents and records required by law to be kept and filed are properly kept and filed; (e) in general, perform all duties incident to the office of Secretary and such other duties as from time to time may be assigned to him or her by the Board of Directors.

Section 10. Executive Director. The Board of Directors shall appoint an Executive Director who shall serve at the pleasure of the Board of Directors. The Executive Director shall be the chief executive officer of the Foundation who shall be responsible for the day-to-day operations of the Foundation. If the Board of Directors has not elected a Chair or Vice Chair of the Board or if the Chair and Vice Chair of the Board are absent, the Executive Director shall preside at such meeting of the Board of Directors. He or she shall perform all duties incident to the office of the Executive Director and such other duties as may from time to time be assigned to him or her by the Board of Directors.

Section 11. Compensation. The Foundation may pay reasonable compensation for services rendered by employees of the Foundation. All amounts paid as compensation by the Foundation to any employee shall be approved by the Board of Directors. The compensation of the Executive Officer shall not be greater than the

compensation of the Commissioner of the Food and Drug Administration.

Section 12. Agents and Contractors. The Executive Director shall be responsible for hiring, promoting, and discharging all other employees and agents of the Foundation. The Executive Director shall also be responsible for defining the duties of such employees and agents and determining the compensation to be paid to such employees.

Article VII

Conflicts of Interest

Section 1. General Policy. No director, officer, employee, fellow or trainee of the Foundation (hereinafter "Interested Persons") shall take any action on or participate in the consideration or determination of any Foundation matter in which he or she, his or her spouse, minor child, general partner, non-federal organization in which he or she is serving as an officer, director, trustee, general partner or employee, or any person or nonfederal organization with whom he or she is negotiating or has any arrangement concerning potential employment, has a financial interest.

Section 2. Responsibilities of Interested Persons. In addition to actual conflicts of interest, Interested Persons are also obliged to avoid actions that could be perceived or interpreted to be in conflict with the Foundation's best interests. Interested Persons shall disclose their financial interest in entities doing business with the Foundation and refrain from participating in decisions affecting transactions between the Foundation and those other entities without approval by the Board of Directors.

Section 3. Additional Conflict of Interest Policies and Procedures. Appendix A to these Bylaws includes more detailed policies and procedures for identifying and managing conflicts of interest.

Section 4. Oversight Responsibilities. The Chair of the Board shall be responsible for the application of the Foundation's conflicts of interest policies and procedures to Board Members, committee members, and the Executive Director. The Executive Director shall be responsible for the application and interpretation of this policy as it relates to all other employees, fellows, and trainees.

Section 5. Project Specific Conflicts Policies. The Foundation shall, as appropriate, develop conflicts of interest policies and procedures specific to an individual project and/or consortium developed to carry out the goals of the Foundation. Such policies and

procedures shall be made available to the public.

Article VIII

Acceptance of Donations and Grants

Section 1. General Policy. It shall be the policy of the Foundation to accept donations and grants (hereinafter "Gifts") that further its missions, supporting the Food and Drug Administration. This mission is realized through Gifts that support the programs and projects of the Foundation, Gifts that secure the operation and future growth of the Foundation, or Gifts that otherwise facilitate the Foundation in providing services to the Food and Drug Administration. The Board of Directors shall develop and adopt detailed Gift review and acceptance policies and procedures that define what constitutes acceptable Gifts. Such policies and procedures shall be made available to the public. The Board of Directors shall be responsible for ensuring that the requirements of this Article VIII and the Foundation's Gift policies and procedures are met.

Section 2. Review of Gifts. The Board of Directors has the discretion to accept or refuse all Gifts and is charged with the responsibility of reviewing and properly screening all Gifts made to the Foundation. The Board of Directors shall determine whether acceptance of a gift will reflect unfavorably on, or compromise the integrity of the Foundation. The Board of Directors shall have the discretion to refuse any Gift that is deemed inappropriate for any reason, such as the appearance of, or an actual conflict of interest, unreasonable or burdensome restrictions, costs to the Foundation in fulfilling the terms of, or administering the Gift, or any other reason. The Board of Directors shall make decisions regarding acceptance or refusal of gifts by a majority of voting members present at a regularly scheduled meeting of the Board or by a majority of all voting members if the decision is made between regularly scheduled meetings. If a vote is taken between regularly scheduled meetings, members may vote in writing by regular mail or e-mail.

Section 3. Restrictions on Gifts. The Foundation will accept unrestricted Gifts. The Foundation may also accept Gifts for specific programs and purposes, provided such Gifts are not inconsistent with its mission, purposes, and priorities. The Foundation will not accept Gifts that are too restrictive in purpose or otherwise inappropriate.

Section 4. Availability of Information on Gift Acceptance. Information about

the Foundation's acceptance of Gifts shall be made available to the public.

Article IX

Grants and Contracts

Section 1. Grantee/Contractor Selection and Award Principles. The selection and award of grants and/or contracts by the Foundation will be conducted to ensure fairness, impartiality, and inclusiveness. All grant and contract awards shall be approved by the Board of Directors.

Section 2. Solicitation. The Foundation will take reasonable steps to make each solicitation widely known to the public.

Section 3. Peer Review. An objective peer-review process will be used to assess responses to solicitations and provide recommendations to the Board of Directors.

Section 4. Objectivity. All reviews and assessments shall be made objectively and shall not be based on commercial or proprietary interests.

Section 5. Conflicts of Interest. All participants involved in the development, review, and selection process shall abide by the Foundation's Conflict of Interest policies.

Section 6. Administrative Expenses Cap. Grants, contracts and cooperative agreements shall provide that the administrative expenses allocable to funds provided by the Foundation not exceed 25%.

Section 7. Exclusions. This Article shall not apply to the selection and award of grants and contracts related to running the day-to-day operations of the Foundation.

Article X

Information and Inventions

Section 1. Information and Data. All information and data developed by the Foundation or with Foundation funds shall be released and published, to the extent practicable, to maximize their use by the Food and Drug Administration, nonprofit organizations and academic and industrial researchers to further the goals and priorities of the Foundation. The Foundation may charge cost-based fees for published materials produced by the Foundation.

Section 2. Inventions. The Foundation shall ensure that (a) Action is taken to obtain patents for inventions developed by the Foundation or with funds from the Foundation; (b) action is taken to enable the licensing of such inventions; and (c) executed licenses, memoranda of understanding, material transfer agreements, contracts and other such instruments promote, to the maximum extent practicable, the broadest

conversion to commercial and noncommercial applications of licensed and patented inventions of the Foundation to further the goals and priorities of the Foundation. The Foundation may, consistent with the policy to support the widest and least restrictive use of inventions, charge a reasonable royalty for the use of such inventions.

Article XI

Training Fellowships

The Foundation will establish fellowships for: Scientists, doctors and other professionals, who are not employees of any FDA-regulated industry; FDA professionals to obtain training outside the agency; and non-FDA professionals to obtain training at the Foundation, academic or scientific institutions or the FDA. The purpose of such fellowships shall be to foster greater understanding of and expertise in new scientific tools, diagnostics, manufacturing techniques, and potential barriers to translating basic research into clinical and regulatory practice, train scientific or regulatory professionals in regulatory science and policy, and increase the exchange of scientific information between FDA and external entities.

Article XII

Memoranda of Understanding and Cooperative Agreements

Section 1. Review. All memoranda of understanding and cooperative agreements between the Foundation and other entities, including the Food and Drug Administration, shall promote the goals and priorities of the Foundation, shall comply with the Foundation's Conflict of Interest policies and shall be reviewed and approved by the Board of Directors to ensure that such requirements are met.

Section 2. Execution. All memoranda of understanding and cooperative agreements between the Foundation and other entities, including the Food and Drug Administration, shall be signed by the Executive Director, after obtaining appropriate approval of the Board of Directors.

Article XIII

Indemnification

Section 1. Officers and Directors. To the maximum extent permitted by the laws of the State of Maryland in effect from time to time, and subject to compliance with any procedures and other requirements prescribed by said laws and by such rules and regulations, non inconsistent with said laws, as the

Board of Directors may in its discretion impose in general or particular cases or classes of cases, any person who is threatened to be made a party to any threatened, pending or completed action, suit, or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that he or she is or was a Director or officer of the Foundation shall be indemnified by the Foundation against judgments, penalties, fines, settlements, and reasonable expenses, including attorney's fees, actually and necessarily incurred by him or her in connection with such action, suit or proceeding, or in connection with any appeal therein (which reasonable expenses may be paid or reimbursed in advance of final disposition of any such suit, action, or proceeding subject to the receipt of a written undertaking to repay such expenses in the event that such person is determined not to be entitled to be indemnified).

Section 2. Employees and Agents. To the maximum extent permitted by the laws of the State of Maryland in effect from time to time, and subject to compliance with any procedures and other requirements prescribed by said laws and by such rules and regulations, not inconsistent with said laws, as the Board of Directors may in its discretion impose in general or particular cases or classes of cases, any person who is threatened to be made a party to any threatened, pending or completed action, suit, or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that he or she is or was an employee or agent of the Foundation may (but need not) be indemnified by the Foundation against judgments, penalties, fines, settlements, and reasonable expenses, including attorney's fees, actually and necessarily incurred by him or her in connection with such action, suit or proceeding, or in connection with any appeal therein (which reasonable expenses may be paid or reimbursed in advance of final disposition of any such suit, action, or proceeding subject to the receipt of a written undertaking to repay such expenses in the event that such person is determined not to be entitled to be indemnified).

Article XIV

General Provisions

Section 1. Seal. The seal of the Foundation shall be in such form as shall be approved by the Board of Directors.

Section 2. Fiscal Year. The fiscal year of the Foundation shall end on December 31 of each year or on such

other date as may be fixed by resolution of the Board of Directors.

Section 3. Checks, Notes, Drafts, Etc. All checks, notes, drafts, or other orders for the payment of money of the Foundation shall be signed endorsed, or accepted in the name of the Foundation by such officer, person or persons as from time to time may be designated by the Board of Directors or by an officer or officers authorized by the Board of Directors to make such designation.

Section 4. Execution of Contracts, Deeds, Etc. The Board of Directors may authorize any officer or officers, the Executive Director, or any agent or agents, in the name and on behalf of the Foundation to enter into or execute and deliver any and all deeds, bonds, mortgages, contracts and other obligations or instruments, and such authority may be general or confined to specific instances.

Section 5. Deposits. All funds of the Foundation shall be deposited from time to time to the credit of the Foundation in such banks, trust companies or other depositories as the Board of Directors may select.

Article XV

Amendments

These Bylaws may be amended, altered or repealed or new Bylaws may be adopted by a majority of the voting directors present at any regular meeting or at any special meeting, if at least two days written notice is given of intention to alter, amend, repeal or adopt new bylaws at such meeting.

Appendix A to Bylaws

Ethical Guidelines for Identifying and Managing Conflicts of Interest

Congress created the Reagan-Udall Foundation (Foundation) to support the mission of the FDA by identifying, funding, and supporting projects and programs that will help equip FDA staff with the highest caliber science and technology to enhance the safety and effectiveness of FDA regulated products. The Foundation will not participate in regulatory matters nor will it offer advice to FDA on policy matters. In addition, to support its independence and to maximize its scientific impact, the Foundation is implementing specific guidelines and procedures that identify and avoid potential bias—and appearances of such bias—and that provide a transparent process for individual and institutional decisions.

I. Individual Conflicts

Article VII of the Bylaws describes an individual's obligations with respect to conflicts of interest as follows: "No

director, officer, employee, fellow or trainee of the Foundation (hereinafter 'Interested Persons') shall take any action on or participate in the consideration or determination of any Foundation matter in which he or she, his or her spouse, minor child, general partner, non-federal organization in which he or she is serving as an officer, director, trustee, general partner or employee, or any person or nonfederal organization with whom he or she is negotiating or has any arrangement concerning potential employment, has a financial interest. In addition to actual conflicts of interest, Interested Persons are also obliged to avoid actions that could be perceived or interpreted to be in conflict with the Foundation's best interests. Interested Persons shall disclose their financial interest in entities doing business with the Foundation and refrain from participating in decisions affecting transactions between the Foundation and those other entities without approval by the Board of Directors."

Staff

Goal: To ensure that issues involving conflicts of interest are addressed when staff are hired and on an ongoing, annual basis.

(1) *Data Gathering.*

The following FDA Financial Disclosure form is to be filled out by prospective employees prior to being hired and filled out annually by Foundation Employees: FDA's form for Senior FDA Employees at http://www.oge.gov/forms/form_450.aspx.

(2) *Process for Review.*

The completed form is to be reviewed by the Foundation's General Counsel (hereinafter General Counsel), who will be responsible for identifying conflicts and determining what actions would be necessary to ensure that a prospective or current employee does not participate in matters in which such a conflict would or could exist. The General Counsel will advise the Executive Committee regarding such conflicts and necessary actions.

(3) *Process for Addressing Conflicts of Interest.*

The General Counsel will advise the Executive Committee and the Board regarding a prospective or current employee for whom conflicts have been identified. With respect to a prospective employee, the Executive Committee will recommend whether a particular person should be hired in light of conflicts, and if so, how such conflicts should be addressed. If conflicts arise after a person has been hired, then the Executive Committee will advise the Board regarding appropriate steps to be

taken, including divesting holdings causing the conflict, recusing the employee from particular matters and terminating the employee. The Board will receive all pertinent documents relating to any conflicts and will make the final decision with respect to hiring a person for whom a conflict has been identified and with respect to addressing conflicts that have arisen after an employee has been hired.

Board

Goal: To ensure that the potential for, or the appearance of, conflicts are identified, so appropriate steps can be taken to ensure that the principles in the Bylaws are met.

(1) *Data Gathering.*

Upon appointment, and annually thereafter, each Board member must provide the General Counsel a signed statement that lists any interest, financial or otherwise, that the member, his or her spouse, minor child, general partner or employee has in any company that is regulated by FDA. The statement will also disclose the identity of any FDA regulated firm for whom any adult children of the Board member works and the nature of any business that such children have before the Foundation. Such statement must describe the nature of the interest but need not list its monetary value.

(2) *Process for Review.*

The statement described above will be reviewed by the Foundation's General Counsel, who will be responsible for identifying conflicts and Foundation matters from which such Board member must recuse him or herself from on the basis of such conflicts. The General Counsel will advise the Board member regarding such conflicts and necessary recusals.

(3) *Process for Addressing Conflicts of Interest.*

If it has been determined by the General Counsel that recusal is necessary, then the recused Board member shall not participate in any discussions or votes regarding the matter or matters on which he or she has been recused. Among other things, a recused Board member shall not participate in discussions or votes regarding whether a particular project should be undertaken by the Foundation or to whom a project grant or contract funded by the Foundation may be awarded.

II. Review of Reagan-Udall Foundation Projects

Goal: Strictly guard against conflicts of interest and undue influence while raising funds for worthwhile Foundation projects.

Guidelines: Prior to initiation all specific projects must be reviewed and approved:

(1) By the Reagan-Udall Board of Directors.

Before granting its final approval to a project, the Board shall submit the project to independent review. In selecting reviewers, the Board shall insure that:

- Reviewers are qualified experts on the relevant topics.
- Each reviewer has certified that he or she meets the conflict of interest standard in Article VII.

In the unusual case where a waiver of this requirement is necessary because there is no other practical means of ensuring the necessary expertise, the name of the reviewer and the justification for the waiver will be made public and the Board must determine that the financial interest is not so substantial as to be likely to affect the integrity of the review.

Before granting its final approval to a project, the Board shall also determine that:

- Independent review was sufficient to ensure the objectivity, scientific validity, and feasibility of the proposal.
- The project is likely to advance the mission of the FDA to modernize medical, veterinary, food, food ingredient, or cosmetic product development, accelerate innovation, or enhance product safety.

(2) *By a meaningful independent review.*

- For projects with a total budget over \$250,000 ("large projects"), the Board may (i) use an existing independent review process (for example, if one of the project collaborators is an academic institution or foundation with an appropriate independent review mechanism); or (ii) utilize an ad hoc, independent panel to review the project.
- For small projects with a total budget of \$250,000 or less ("small projects"), the Board may use an abbreviated independent review process.
- A majority of reviewers must determine that the project design is objective, scientifically valid, and feasible, and that the project is likely to advance the mission of the FDA to modernize medical, veterinary, food, food ingredient, or cosmetic product development, accelerate innovation, or enhance product safety.

III. Policies for Accepting Funds

The Foundation has in place two sets of guidelines for the acceptance of funds.

(1) Core Operating Funds can be accepted from

- Federal Government appropriations process.
 - Individuals as tax deductible donations.
 - Foundations and other Not for Profit organizations.
- (2) Project Funds can be accepted from
- Federal Government appropriations process.
 - Individuals as tax deductible donations.
 - Foundations and other Not for Profit organizations.
 - Other entities.

IV. Violations of Conflicts in Interest Policy

If the Board of Directors has reason to believe that a Foundation employee or Board member has failed to disclose a conflict, it shall inform the person of the basis for such belief and afford the person an opportunity to explain the alleged failure to disclose. If, after hearing the response of such person and making further investigations as may be warranted, the Board determines that the employee or Board member has knowingly or intentionally failed to disclose a conflict of interest it shall take appropriate action, including termination of the employee or Board member.

V. Transparency

The Foundation will post the following on its Web site:

- (1) The Foundation Bylaws and Appendix A. Public comment will be sought on these bylaws and on any proposed changes prior to adoption.
- (2) A statement about RUF's commitment to transparency.
- (3) A copy of the conflict of interest form used by Foundation Staff.
- (4) Information regarding particular recusals of Board members or Staff, including the particular matters on which the Board member or staff will be recused and the basis for the recusal.
- (5) For each Board member, a list of any interest, financial or otherwise, that the member, his or her spouse, minor child, general partner or employee has in an FDA-regulated company that conducts business in areas where the Foundation is active such that the interest could pose a potential conflict. Such statement will describe the nature of the interest but need not list its monetary value.
- (6) In the unusual case when there is a waiver of the requirement that a reviewer have no direct financial interest in the outcome of a project because there is no other practical means of ensuring the necessary expertise, the name of the reviewer and the justification for the waiver.

(7) The amount of each donation and the identity of the donor, including in kind donations.

(8) Information about each project, including:

- An Executive Summary, including a summary of the review process.
- A list of organizational project participants and their role.
- The identity of all funders.
- A list of Board and/or staff members who were recused from discussion and decision making for the project.

(9) The Foundation's 990 IRS filings and annual reports (for all years).

(10) A section for questions, feedback and public input.

Dated: December 15, 2009.

Mark B. McClellan,

Chairman, Reagan-Udall Foundation Board.

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DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: Southeast Region Dealer and Interview Family of Forms.

OMB Control Number: 0648-0013.

Form Number(s): 88-12, 88-12B, 88-129, 88-30.

Type of Request: Regular submission.

Number of Respondents: 13,766.

Average Hours per Response: Shrimp and finfish interviews and dealer quota reports, 10 minutes; dealer no-purchase reports, 3 minutes; rock shrimp, golden crab and coral dealer reports, 15 minutes.

Burden Hours: 1,656.

Needs and Uses: The National Marine Fisheries Service, Southeast Fisheries Science Center uses these reporting instruments to collect landings statistics and quota monitoring data from commercial seafood dealers and to conduct interviews with fishermen for effort and fishing locations data. This family of forms includes data collection activities for monitoring fishery quotas, routine collections of monthly statistics from seafood dealers, and interviews with fishermen to collect catch/effort and biological data. Collection of information is authorized by the development of regional fishery management councils under the authority of the Magnuson-Stevens