

INTERNATIONAL PHARMACEUTICAL EXCIPIENTS
COUNCIL OF THE AMERICAS FOUNDATION

GUIDELINES AND CRITERIA FOR AWARDS AND GRADUATE STUDENT SCHOLARSHIPS

The International Pharmaceutical Excipients Council of the Americas Foundation ("Foundation") has approved the following criteria and guidelines to be used in selecting recipients of its annual awards and scholarship grants for 2010. These guidelines shall be followed when selecting recipients of these IPEC Foundation awards.

PURPOSE

The IPEC Foundation has approved the creation of various awards to reward and encourage innovation and research into excipients, *i.e.*, inactive pharmaceutical ingredients. The Foundation has also created Graduate Student Awards (scholarships).

ADMINISTRATION

The Foundation intends to review these guidelines annually. The Foundation will retain records of all expenditures distributed along with the application for the award. The Board of Directors of the Foundation will determine each year how many awards it intends to distribute. The Foundation will not grant the monetary portions of these AWARDS to disqualified individuals (as defined in the U.S. tax code for 501(c)(3) organizations).

Nominations for recipients of these awards shall be open to the public, and the Foundation will solicit the opinion of trade associates, pharmacy schools, companies, professional organizations, and others to help select worthy nominees.

In 2010, the Foundation will participate in Annual Award ceremonies of the American Association of Pharmaceutical Scientists (AAPS) and of the American College of Toxicology (ACT) where members of the Board of Directors will present the awards to the winners. The Foundation established an Internet website that will provide information to the public regarding the awards, the nomination procedure, and the past winners. (www.ipecfoundation.org)

GENERAL GUIDELINES

The Foundation intends to grant awards annually. As the Foundation grows, the Foundation may establish more awards.

Proposed award recipients may be nominated by professors; counselors; faculty members at institutions of higher learning; members of the Foundation; and officials in the pharmaceutical, chemical, food, or excipient industry.

The Foundation will establish for each award the amount (if any), the criteria for selection, the nomination process, and the selection process. All awards may not be offered every year as determined by the Foundation.

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ESTABLISHED AWARDS

The Foundation has established four major awards: (1) the Louis Blecher Outstanding Lifetime Achievement Award, (2) the Ralph Shangraw Memorial Award, (3) the Marshall Steinberg Memorial Award, and (4) the Strategic Initiatives Award. The foundation also established six (6) Excipient Graduate Student Awards (scholarships) in 2010.

NOMINATION AND ELIGIBILITY REQUIREMENTS

Individuals that want to apply for the awards discussed in this document should submit a completed nomination form, obtained at the Foundation website: www.ipecfoundation.org. (Do not send the nomination form to this e-mail address). Applications should submit a summary of their accomplishments and research efforts. Applicants should also submit a current curriculum vitae in their application.

The nomination form and supporting documents should be submitted as a single PDF file to ipecfoundation@aol.com by May 31, 2010. A single Microsoft Word file will be accepted if PDF capability is not available. The award name must be shown in the subject line of the email. Faxed or mailed nominations will be accepted if sent to: IPEC Foundation, 1655 N. Fort Myer Drive, Suite #700, Arlington, VA 22209, Fax# (703) 525-5157.

Louis Blecher Memorial Outstanding Lifetime Achievement Award

Amount of Award - To Be Determined

IPEC Foundation has established the Louis Blecher Outstanding Lifetime Achievement Award to reward those individuals who, during their lifetime, have made substantial intellectual contributions to the field of excipients, *i.e.*, inactive pharmaceutical ingredients. Recipients of this award will receive recognition and possibly a monetary amount from the IPEC Foundation as a reward for their long dedication to understanding excipients.

Nominations for this award shall be submitted directly to the Board of Directors ("Board") of IPEC Foundation. The Board shall consider any nominations that was submitted to it and may consider any other nomination made by a member of the Board. An appropriate nominee is any individual who has conducted research or has been involved in improving the safety or effectiveness of excipients for a substantial period of time.

The Board will decide the winner of the award by majority vote of members of the Board after the Board has discussed the nominees. This award will be granted periodically, but not more than once a year, to those individuals that the Board decides have substantially contributed to the understanding of excipients through a lifetime of work.

At this time, this award is only eligible to residents of the United States. In the future, IPEC Foundation may expand the eligibility pool to residents of other countries. All applicants should complete the Foundation's Award Application to be considered for this award.

The award for 2008 has been given to Louis Blecher, founder of the International Pharmaceutical Excipients Council of the Americas in 1991 and the person responsible for the creation of the Regional

IPECs in America, Europe, and Japan. Mr. Blecher's strong commitment and efforts to build an excipient global trade association and to set high standards of global self-regulation and harmonization of excipients over the last seventeen years have been a credit to the entire international pharmaceutical industry. To honor Louis Blecher's outstanding lifetime efforts the Foundation has made him the first recipient of this award and renamed this award in his honor. Mr. Blecher died in 2008.

Ralph Shangraw Memorial Award

Amount of award - \$10,000

The Ralph Shangraw Memorial Award is to be given to any person that has provided an outstanding research in the study of excipients or excipient-related technology.

Before his death in 1998, Professor Shangraw, former Chair, Department of Pharmaceutics, had spent over 38 years teaching and conducting research on improving the safety and functionality of excipients at the University of Maryland School of Pharmacy, along with many years of service at the U. S. Pharmacopeia. In addition, Professor Shangraw was one of the founding members of the American Association of Pharmaceutical Scientists (AAPS).

This award recognizes research achievements broadly in the field of pharmaceutical excipients, including but not limited to, research that contributes to: (1) an understanding of the basic science underlying excipient functionality, (2) excipient safety, including the development of test methods and standards, (3) the development of new excipients or novel use of existing excipients in new applications, and (4), the development of rational compendial/regulatory standards for excipients. Recipients of this award will receive \$10,000 from IPEC Foundation as a reward for their efforts.

Nominations for this award shall be submitted to the Foundation's Scientific Advisory Committee ("SAC"). The SAC will initially screen the applicants based on the Foundation's criteria, and the top (3) nominees will be referred to Foundation Board of Directors for final selection. The Board will decide the winner by a majority vote of the Board of Directors after discussing the various nominees and the recommendations of the SAC. The Board of Directors will rank the award applicants by order of merit, to ensure a qualified recipient is readily available, in case the top-ranked selection declines the grant. All applicants must complete the Foundation's Award Application to be considered for this award.

The award will be given out by the Foundation annually unless there are no worthy applicants that year. This award is open to any individual who has contributed to the research of excipients regardless of nationality. The winner will be expected to attend the 2010 Annual Meeting of the American Association of Pharmaceutical Scientists (AAPS) in New Orleans, LA. The recipient will also be awarded a complimentary AAPS Annual Meeting registration. Employees of IPEC-Americas and IPEC Federation member companies are not eligible for monetary compensation if selected for this award.

Marshall Steinberg Memorial Award

Amount of Award - \$10,000

IPEC Foundation has established the Marshall Steinberg Memorial Award to reward those individuals who have made outstanding contributions in the area of safety and toxicology for excipients, *i.e.*, inactive pharmaceutical ingredients. Recipients of this award will receive \$10,000 from IPEC Foundation as a reward for their research. This award is offered in coordination with the American College of Toxicology (ACT).

Marshall Steinberg, Ph.D. (Toxicology and Pharmacology), former Chairman of IPEC, died in 2003. Marshall retired from a distinguished career in the U.S. Army in 1976 and, among other subsequent positions, was Vice President of Health and Environment at Hercules. He was President of the American College of Toxicology and a fellow of the Academy of Toxicological Sciences. Marshall directed creation of IPEC's Safety Guidelines which are held in high regard by Food and Drug Administration as a basis for testing new excipients.

Nominations for this award shall be submitted to the Foundation. The Foundation will then send these nominations to representatives of the American College of Toxicology ("ACT"). The Board will decide the winner after reviewing the recommendations from the ACT Awards Committee.

This award recognizes achievements in the field of pharmaceutical excipients that includes but is not limited to: (1) research that contributes to the safety of excipients; (2) investigations that establish test methods and standards that enhance the safety of excipients; (3) studies that support the development of new excipients or novel uses for existing excipients that provide or assure greater safety in their use in pharmaceuticals; and (4) toxicology research that improves the overall safety of excipients and/or finished pharmaceuticals.

The winner will be expected to attend the Annual Meeting of the 2010 American College of Toxicology in Baltimore, MD. The recipient will also be awarded a complimentary ACT Annual Meeting registration.

The award will be given out by the Foundation annually unless there are no worthy applicants that year. This award is open to any individual who has contributed to the research of excipients safety and toxicology regardless of nationality. All applicants must complete the Foundation's Award Application to be considered for this award. Employees of IPEC-Americas and IPEC Federation member companies are not eligible for monetary compensation if selected for this award.

Development of Strategic Excipient Initiatives Awards

IPEC Foundation has resolved to create a series of Strategic Initiative Awards to spur the development of research and new technology relating to excipients, i.e., inactive pharmaceutical ingredients. Each Strategic Initiative Award will target an issue that the Foundation has determined is the most important for furthering the safety or effectiveness of excipient products. These awards will focus on those areas where the private sector has shown to provide inadequate incentives for research and development. Each award will be accompanied by a financial reward given by IPEC Foundation. The Foundation will both contribute its own money to establish the financial reward as well as solicit third parties to contribute to the financial reward. The rules for each Strategic Initiative Award will be determined on a case-by-case basis by the Foundation.

First Strategic Initiative Award

Amount of reward - \$20,000

The Foundation has resolved that the first Strategic Initiative Award shall be given to the person or organization that develops the first low-cost portable test kit that can be used to test the quality of excipient products in the supply chain. IPEC Foundation has decided to give the winner of this award \$20,000 from the Foundation's funds along with any other money that it can raise from third parties to support this award.

There is a large global concern over ensuring the quality of pharmaceutical products against the risks associated with bioterrorism and deliberate adulteration. In the past, some of the most egregious adverse events associated with pharmaceutical products have occurred due to the use of incorrect inactive ingredients in products. For example, the inappropriate use of diethylene glycol as a solvent by the S. E. Massengill Company in their "Elixir Sulfanilamide" product in 1937 led to the deaths of over 100 people. In subsequent years this same adulteration was involved in two incidents in Haiti and one in Panama that led to many deaths. More recently it was the basis for a recall of toothpaste manufactured in China. Recently, the United States government has established the Interagency Working Group on Import Safety to specifically address problems associated with the importation of unsafe pharmaceuticals and to "improve the safety of imported products in a manner that expands global trade." The creation of a portable device that both governments and companies could use to test the excipients in imported products would be an extremely valuable innovation to ensure the safety and quality of products for American consumers.

The winning device or devices should be able to be authenticate certain excipients on-site and be able to test the most widely-used excipients. Any technology that could be eligible to win the award must be available for purchase by any manufacturer and the U.S. Government.

Nominations for this award shall be submitted to the Scientific Advisory Committee ("SAC"). This Committee will review the nominations and make recommendations to the Foundation's Board of Directors who will then decide who shall win the award. The Board will decide the winner of the award by majority vote of members of the Board after discussing the various nominees and the recommendations of the SAC. This award is open to any individual, company, or organization (governmental or private) regardless of nationality. All applicants should complete the Foundation's Award Application to be considered for this award.

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AWARD APPLICATION (2010)

1. Official Name of Nominee: _____

2. Official Address of Nominee: _____

3. Phone Number of Nominee: _____ 4. Fax number of Nominee _____

5. Email address of Nominee: _____

(IF THIS IS A SELF NOMINATION, DO NOT FILL OUT SECTION BELOW)

6. Official Name of Nominator: _____

7. Official Address of Nominator: _____

8. Phone Number of Nominator: _____ 9. Fax number of Nominator _____

10. Email address of Nominator: _____

11. State the award or award applied for: _____

12. Attach to this document the following:

- a) A resume/curriculum vitae of the nominee.
- b) A short statement describing why the award or award should be given to the nominee.
- c) If this application is for the Development of Strategic Excipient Initiatives Award, please attach a document describing the proposed solution, a statement ensuring that awardee will make the winning device available to purchase by industry and government as soon as possible, and any additional information or prototypes illustrating the innovation.
- d) Submit for as a single PDF file to ipecfoundation@aol.com by May 31, 2010. A single Microsoft Word file will be accepted if PDF compatibility is not available. The award name must be shown in the subject line of the e-mail. Faxed or mailed to:

Ms. Kimberly Beals

IPEC Foundation
1655 North Fort Myer Drive, Suite #700
Arlington, VA 22209
Telephone: (703) 875-2127

I certify that all of the information above is true and accurate. I also certify that I have read the Foundation's Guidelines and Criteria for Awards and agree to follow its requirements.

Nominee's Signature: _____ Date: _____