ISPE AND FDA RECEIVE VICE PRESIDENT AL GORE'S "HAMMER AWARD"

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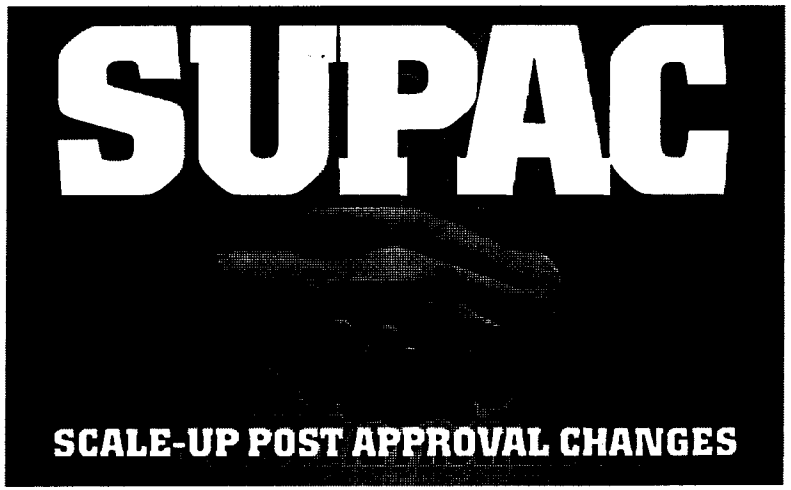

ISPE The Society for Pharmaceutical and Medical Device Professionals

FDA

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In June 1996, the Food and Drug Administration (FDA) approached the leadership of the International Society for Pharmaceutical Engineering (ISPE) with a request for technical assistance that could save the Pharmaceutical Industry millions of dollars – savings that could benefit consumers in the long run. ISPE agreed, quickly developed a plan with the FDA, and put a management team in place. Just four months later, ISPE and FDA presented a first draft of the document known as the "Similar Equipment List" during an open industry forum.

In recognition of this unique partnership, ISPE, the FDA's Center for Drug Evaluation and Research (CDER) and Office of Regulatory Affairs (ORA) Central Region will receive Vice President Al Gore's "Hammer Award" in a ceremony during today's Executive Series. The Hammer Award is given to federal employees and their partners who have advanced the Vice President's National Performance Review (NPR) goals of cutting red tape, improving service to customers, and helping build a better and more cost effective government.

The NPR committee cited the collaborative effort on the part of ISPE and FDA staff from CDER and ORA in developing a listing of "similar equipment" needed for efficient implementation of Scale-Up and Post-Approval Change (SUPAC) guidance for immediate release-solid oral dosage form products. SUPAC guidance and this associated "Similar Equipment List" provide substantive regulatory relief in filing of change information. The Similar Equipment List is expected to save industry millions of dollars in developing and implementing change procedures. It has been published in the Federal Register and is now available through the FDA Internet home page (http://www.fda.gov).

On hand to present the award on behalf of the Vice President's National Performance Review will be Marie A. Urban, Coordinator of Regulatory Affairs for the FDA and a representative of the National Performance Review. To accept on behalf of CDER will be Roger Williams, MD, Deputy Director, Pharmaceutical Science. Williams and his staff were prominently involved in the original creation of the SUPAC guidance. Several additional documents are being prepared under Williams' leadership.

Joseph X. Phillips, Deputy Regional Food and Drug Director, Mid-Atlantic Region, will accept for ORA. Phillips had been working closely in another cost-saving partnership with ISPE known as the "Baseline™ Pharmaceutical Engineering Guides for New Facilities." He and his Mid-Atlantic group were the primary facilitators with ISPE on the technical aspects of the Similar Equipment List.

Larry Kranking, ISPE President, and Vice President, Production Operations for Eisai, Inc., will accept on behalf of the Society. Kranking developed the ISPE management plan, recruited the project team and became its first chairperson, and established the format for the document. He passed the chairmanship reins to Russ Somma, Assistant Director, Process Development Solids, Novartis Pharmaceuticals, whose Steering Committee and Task Teams completed the work.

"We turned to ISPE because they have a worldwide network of 10,000 engineers with broad-based experience with manufacturing equipment," said Phillips. "We have had an excellent relationship with ISPE over the years and had proven we could accomplish important tasks together through the Baseline™ Guide series. The SUPAC Similar Equipment List is another tangible example of how the consumer can benefit when industry and government collaborate."

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