



April 15, 2011

The Honorable Margaret A. Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Hamburg:

The Endocrine Society (Society) is writing in support of the “Draft Guidance for Industry and FDA Staff: Artificial Pancreas Systems – Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications” that was submitted to the U.S. Food and Drug Administration (FDA) by the Juvenile Diabetes Research Foundation on March 10. The Society represents more than 14,000 physicians and scientists engaged in the treatment and research of endocrine disorders, such as osteoporosis, diabetes, hypertension, infertility, obesity, and thyroid disease. Our members strongly believe that the FDA should adopt the proposed guidance to enable researchers to study the effectiveness of the artificial pancreas on the treatment of type 1 diabetes in an outpatient setting.

Type 1 diabetes is a particularly complex and taxing disease in need of dedicated research to improve technology for insulin delivery and glucose monitoring. Individuals living with the disease must repeatedly measure and stabilize their blood sugar by taking insulin. Improper dosage can result in seizures, heart damage, coma, or death. The artificial pancreas can automatically control blood sugar, reducing these complications and easing the burden of living with this disease. Numerous inpatient studies have shown that the use of an artificial pancreas greatly reduced dangerously high and low blood sugars and researchers are now ready to study the safety and effectiveness of this technology in an outpatient setting.

Before this can occur, however, the FDA must issue directives regarding the scope of these studies. The “Draft Guidance for Industry and FDA Staff: Artificial Pancreas Systems – Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications” provides exemplary recommendations for these directives and should be given immediate consideration to ensure the advancement of this technology and to improve the lives of millions of Americans living with this disease. If the Society can be of any assistance during this process, please do not hesitate to contact Stephanie Kutler, Director of Government Affairs, at skutler@endo-society.org.

Sincerely,

Kelly E. Mayo, Ph.D.
President, The Endocrine Society.