July 22, 2010
Dear Colleague,

The U.S. Food and Drug Administration (FDA or the Agency) is seeking your help in communicating an important woman's health safety message to your members. We hope you will share this information with your members to ensure that they are obtaining and using only FDA-approved products.

The FDA has become aware of the purchase, use, and distribution of unapproved intrauterine devices (IUD) and intrauterine systems (IUS) by some medical practices throughout the United States. The violative products include unapproved versions of FDA-approved products such as Mirena, Implanon, Copper-T, and ParaGard; as well as products not approved for use in the United States, such as T-Safe.

The FDA's major concerns with the use of unapproved IUD/IUS's are (1) the potential lack of safety and efficacy, and especially the risk of reduced efficacy for preventing pregnancy; (2) the negative public health impact from the import and use of unapproved IUD/IUS's that can be from unknown sources or foreign locations, and may not have been manufactured, transported or stored under conditions required as part of the FDA approval process; and (3) the use of and subsequent billing for unapproved medical products, which raises the possibility of insurance fraud, particularly Medicaid fraud.

To reduce the chance of receiving an unapproved or adulterated medical product, your internet purchases should be made from state-licensed distributors or pharmacies located in the U.S. Health care providers should be aware that purchasing medical products from web sites that are outside of the U.S. may be illegal and may increase the risk of receiving a potentially harmful product, since many web sites sell products that are not FDA-approved and could be manufactured in other countries. These products may or may not have been approved by regulatory agencies in other countries or may be counterfeit. For example, FDA is aware of several web sites that appear to be Canadian web sites but ship products from countries other than Canada. For this reason, the Agency does not recommend inserting IUD/IUS's furnished by a patient who may have purchased the product on the internet, without first properly verifying that it is an FDA-approved product that was purchased from a licensed pharmaceutical or device supplier in the U.S.

Federal law requires that IUD/IUS's be FDA-approved prior to marketing. This law is designed to protect patients from products that are unsafe and ineffective. The recent issue with patients in Rhode Island unknowingly receiving imported, unapproved IUD/IUS's highlights the unacceptable risk patients may be exposed to when a product's identity, purity, source, handling, and storage cannot be verified. Health care providers should be reassured, however, that FDA-approved IUD/IUS's have gone through rigorous testing and review for safety and efficacy, and must meet specified storage and manufacturing practices. Providers can continue to use these FDA-approved IUD/IUS's with confidence in their safety and efficacy.

The FDA is asking that you communicate this information to your members so that appropriate steps can be taken, if necessary, to ensure that they are obtaining and using only FDA-approved products. Patients who may have received an unapproved IUD/IUS have been instructed to consult with their providers regarding next steps, including whether or not their IUD or IUS should be removed. So far, the FDA has been made aware of the use of these unapproved products in several states; however, as the investigation continues, this issue may impact other states nationwide. Information regarding the distribution of unapproved IUD/IUS products can be reported to FDA's Office of Criminal Investigations at http://www.fda.gov/ICECI/CriminalInvestigations/default.htm, under "Report Suspected Criminal Activity."

The FDA and other public health organizations continue to look into this situation, and will update the medical community as new information of public health importance becomes available. The Agency is committed to promoting and protecting the public health by ensuring that only safe and effective products are available to the American public. We appreciate your hard work and willingness in support of this effort.

Sincerely,
Theresa Toigo, RPh, MBA
Director, Office of Special Health Issues
Food and Drug Administration