U.S. FOOD & DRUG ADMINISTRATION

Office of Global Policy and Strategy

OGPS STATEMENT

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FDA Expands Mutual Recognition Agreement with European Union

Today, the U.S. Food and Drug Administration (FDA) and the European Union (EU) are announcing their decision to expand the scope of the U.S.-EU Mutual Recognition Agreement (MRA) Sectoral Annex for Pharmaceutical Good Manufacturing Practices (GMP) to include inspections of veterinary pharmaceuticals (also called “animal drugs”). This MRA entered into force on November 1, 2017, but initially included only pharmaceuticals intended for human use. Today’s action to include animal drugs in the MRA is an important step in ensuring the safety and quality of animal drug products and will enhance efficiencies for the U.S. and EU regulatory systems.

For FDA, an MRA is an agreement between two or more countries to recognize an inspection by the other country, and this is the first step toward strengthening use of each other’s animal drug inspection expertise and resources. The overall goal of the MRA is to produce greater efficiencies for both regulatory systems and provide a more practical means for both the FDA and the EU to oversee the facilities that manufacture animal drugs.

By utilizing each other’s inspection reports and related information, an MRA can ultimately enable the FDA and the EU to avoid duplication of some animal drug inspections and enable regulators to devote more resources to other parts of the world where there may be greater risk.

Over the past several months, the FDA has taken numerous steps to prepare for expanding and implementing the MRA’s coverage to include animal drugs. Among other things, this has included sharing information with the EU about FDA’s Center for Veterinary Medicine’s oversight of animal drug manufacturing in the United States; observing EU audits of individual member states including observations of inspections conducted by EU member state inspectors; and conducting assessments of some EU member states’ regulatory frameworks, which found that these member states have the capability, capacity, and procedures to carry out routine GMP surveillance inspections that meet FDA requirements for animal drugs.

FDA currently has confirmed that 16 European Union Member States have the capability of carrying out GMP inspections for certain veterinary products at a level equivalent to the United States. The 16 Member States include: Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Greece, Hungary, Ireland, Luxembourg, Netherlands, Poland, Portugal, Slovenia, and Spain.

With this expanded MRA, FDA can rely on GMP inspections of veterinary product facilities of these 16 Member States and the European Union will rely on inspections conducted by the FDA.

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Additional Resources:
Mutual Recognition Agreement
Mutual Recognition Agreement / Frequently Asked Questions and Answers