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Protecting the public from unsafe compounded drug products: USFDA

13 January 2015 | News | By BioSpectrum Bureau

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In 2012, a devastating outbreak of fungal meningitis linked to a contaminated compounded drug product tragically resulted in the loss of 64 lives and caused more than 751 illnesses, many of which were very serious. These events were a powerful reminder of the potential harm that could be caused by unsafe compounding products.

FDA is moving aggressively on many fronts to protect the public from such threats.

For example, we have conducted more than 175 inspections of compounding facilities in the past two years. Some of these inspections were for cause and were performed after we received reports of serious adverse events related to drugs made by compounding pharmacies or when states requested our assistance. Other inspections were proactive, targeted at facilities identified through a risk-based model. Our proactive inspections were conducted in coordination with state officials from around the country and focused on each firm's sterile drug production, because drugs labeled as sterile are used in ways that could greatly compromise patient care and safety if they aren't actually sterile.

Our findings uncovered a variety of problems with sterile drug production practices at these facilities. As a result of these inspections, numerous firms stopped making sterile drugs and many recalled drug products that had been made under substandard conditions. In some cases, we worked with state officials to revoke or suspend pharmacy licenses. We also issued warning letters to firms that were producing drugs under inadequate conditions, notifying them of violations of the law and the need to take steps to correct the violations and prevent their recurrence.

We have also worked with the Department of Justice (DOJ) to hold facilities accountable if they harm patients or engage in serious violations of federal requirements that put patient safety at risk. Working with DOJ, FDA has initiated investigations and enforcement actions against compounding facilities that violate federal law - and we intend to continue this work with DOJ.

In addition to our inspection and enforcement efforts, FDA has taken many steps to implement the compounding provisions of the Drug Quality and Security Act (DQSA) - legislation enacted by Congress last year in response to the fungal meningitis outbreak.

To implement the compounding statutory provisions, FDA is establishing a policy framework to address compounding by state-licensed pharmacies as well as the new category of outsourcing facilities, which was created under the DQSA. Among other things, outsourcing facilities are facilities that compound sterile drugs and choose to register with FDA as outsourcing facilities, and they must comply with current good manufacturing practice requirements and are subject to FDA inspection on a risk-based schedule.

Two years after the fungal meningitis outbreak our hearts continue to go out to the victims of the tragedy and their families. Our work on behalf of all patients who want and deserve medicines that do not subject them to undue risk is far from being done. FDA will continue to work with the states, the Department of Justice and others to enable Americans to have greater confidence in their compounded drugs.