IkariaÃ,® Issues Notice of Completed Remediation for INOMAXÃ,® DS Drug-delivery System

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HAMPTON, N.J., Dec. 22, 2011 /PRNewswire/ -- Ikaria, Inc. announced today that it has completed a remediation action for its INOMAX® DS drug-delivery systems related to a fretting corrosion. This class I recall notice is being issued at the direction of the U.S. Food and Drug Administration (FDA). No further action is necessary.

There is a reasonable likelihood of serious adverse health consequences or death associated with the type of malfunction addressed in this recall. The associated health risks may include hypoxia, hypotension, bradycardia, cardiac arrest, organ damage, ARDS, and neurological deficits.

In an investigation conducted by Ikaria in April 2010, it was determined that fretting corrosion, or micro-movement at the electrical contact interface of non-noble metals, such as tin, was the root cause for erratic nitric oxide (NO) monitoring readings which were reported when the INOMAX DS was used for NO delivery to patients. As a result, Ikaria implemented a service process change involving application of DeoxIT®, an anti-corrosion lubricant specifically formulated to prevent fretting corrosion, to the flex cable/connector of the monitoring circuit board of the INOMAX DS to effectively mitigate the observed erratic readings of NO monitoring. Specifically, replacement of the ribbon cable with application of DeoxIT was added to the preventive maintenance plan for all INOMAX DS drug-delivery systems and was performed when the systems rotated through Ikaria's Regional Service Centers for any routine service activity. This issue did not affect the INOvent® or INOMAX DSIR drug-delivery systems.

Ikaria sent a communications to healthcare professionals on December 22, 2011 informing them of the completion of this action, and that no further action is necessary. This notice is available at www.inomax.com [1] or www.ikaria '/>"/> [2]

SOURCE [3]

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http://www.mdtmag.com/news/2011/12/ikaria%C3%A3%E2%80%9A%C2%AE-issues-notice-completed-remediation-inomax%C3%A3%E2%80%9A%C2%AE-ds-drug-delivery-system?qt-video_of_the_day=0

Links:

[1] http://www.inomax.com/
[2] http://www.ikaria.com/
[3] http://www.bio-medicine.org/medicine-technology-1/Ikaria-AE-Issues-Notice-of-Completed-Remediation-for-INOMAX-AE-DS-Drug-delivery-System-23116-1/