Altuzan (bevacizumab): Counterfeit Product - Contains no Active Ingredient

ISSUE: FDA lab tests have confirmed that a counterfeit version of Roche's Altuzan 400mg/16ml (bevacizumab),an injectable cancer medication, found in the U.S. contains no active ingredient. Even if the identified drugs were not counterfeit, Altuzan is not approved by FDA for use in the United States (it is an approved drug in Turkey).

BACKGROUND: Medical practices obtained the counterfeit Altuzan and other unapproved products through foreign sources, in particular from Richards Pharma, also known as Richards Services, Warwick Healthcare Solutions, or Ban Dune Marketing Inc (BDMI). Many, if not all, of the products sold and distributed through this distributor have not been approved by the FDA. Pictures of the counterfeit version of Altuzan are shown in the FDA statement. Packaging or vials found in the U.S. that claim to be Roche's Altuzan with lot number B6021 should be considered counterfeit.

RECOMMENDATION: Any medical practice that has obtained unapproved products, in particular from Richards Pharma, Richards Services, Warwick Healthcare Solutions, or Ban Dune Marketing Inc (BDMI), should stop using them and contact the FDA. The products should be retained and securely stored until further notice by the FDA.

FDA is asking the public to report suspect counterfeit products and other suspect products obtained from Richards Pharma, Richards Services, Warwick Healthcare Solutions, Ban Dune Marketing Inc (BDMI), or other sources:
Call FDA's Office of Criminal Investigations (OCI) at 800-551-3989, or
Visit OCI's Web site (www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm[1]), or
Email - DrugSupplyChainIntegrity@fda.hhs.gov

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm[2]
- Download form[3] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

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FDA
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
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