NEXUS
PHARMACEUTICALS, INC.

Nexus Pharmaceuticals Inc. Issues Voluntary Nationwide Recall of Benztropine Mesylate Injection, USP 2 mg/2 mL (1 mg/mL), in 2 mL Single Dose Vials

Vernon Hills, Ill. – August 1st, 2013 – Nexus Pharmaceuticals Inc. is voluntarily recalling two lots of Benztropine Mesylate Injection, USP, 2 mg/2mL (1mg/mL) in 2 mL single dose vials due to the potential presence of visible particulate matter in the vials. This recall is being conducted at the hospital user level. The product is manufactured by Allergy Laboratories, Inc. and was distributed by Nexus Pharmaceuticals Inc. The recalled lots are:

Product Name/ Strength/Size	Benztropine Mesylate Injection, USP 2 mg/2 mL (1 mg/mL), 2 mL Single Dose Vial	
NDC Number	14789-300-02	
Label	Nexus	Nexus
Product Code	1478930002	
Lot Number	030712	112911
Expiration Date	03/2014	11/2013
First Ship Date	03/26/2012	12/15/2011
Last Ship Date	05/17/2012	3/26/2012

No adverse events, patient reactions or customer complaints have been reported to date.

Nexus Pharmaceuticals is notifying its distributors and is arranging for return of all recalled products. Any questions about returning unused products should be directed to the customer call center at 888-806-4606 Monday through Friday, Between the hours of 8 a.m. and 6 p.m. (Central Time)

The administration of particulate, if present in a parenteral drug, poses a potential safety risk to patients. Case reports suggest that sequelae of thromboembolism, some life-threatening (such as pulmonary emboli), may occur. There have also been reports in the literature of particulate possibly causing phlebitis, mechanical block of the capillaries or arterioles, activation of platelets, subsequent generation of microthrombi, and emboli. Patients with preexisting condition of trauma or other medical condition that adversely affects the microvascular blood supply are at an

175 E. Hawthorn Parkway, Suite 155 • Vernon Hills, IL 60061 • Web: www.nexuspharma.net
Phone: (847) 996-3790 • Fax: (847) 996-3799

NEXUS
PHARMACEUTICALS, INC.

increased risk. Administration of a particulate can also lead to formation of granulomas, which represent a protective local inflammatory response to the foreign material and are typically non-serious. The defect discovered in this product was noted as visible particulate using higher magnification.

Benztropine Mesylate is used as an adjunct in the therapy of all forms of Parkinsonism. It is useful also in the control of extrapyramidal disorders due to neuroleptic drugs, except tardive dyskinesia.

To report adverse events or quality problems experienced with the use of this product, call Nexus Pharmaceuticals Inc. Medical Affairs at 1-877-913-2720, Monday through Friday, between the hours of 8 a.m. and 5 p.m. (Central Time), or by e-mail at sales@nexuspharma.net.

Any adverse reactions or quality problems experienced with the use of these products may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Online: http://www.fda.gov/MedWatch/report.htm
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: http://www.fda.gov/MedWatch/getforms.htm. Mail to address on the pre-addressed form.
- Fax: 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Media Contact
Omair Ahmed
Vice President Sales and Marketing
Nexus Pharmaceuticals Inc.
847-996-3790
oahmed@nexuspharma.net