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From: **Board of Pharmacy** <pharmacy.subscriberlist@dca.ca.gov>

Date: Mon, Feb 27, 2017 at 8:21 AM

Subject: Avella Specialty Pharmacy Unexpired Sterile Injectable Products Labeled “Latex Free”: Recall - Products May Contain Synthetic or Natural Latex

To: PHARM-GENERAL@dcalists.ca.gov

AUDIENCE: Pharmacy, Risk Manager

ISSUE: Advanced Pharma, Inc. d/b/a Avella of Houston, is conducting a voluntary recall of all unexpired sterile injectable products labeled "latex free" that were produced at Advanced Pharma, Inc.'s Houston location between September 1, 2016 and February 16, 2017 to the user level (hospitals and institutions) because such products may contain synthetic latex and/or natural latex.

Avella and Advanced Pharma have been unable to confirm with clarity whether its “latex free” label statements are accurate in all cases. The risk of potential adverse events related to a latex allergy, while rare, can range from local site reactions including swelling and inflammation, to allergic reactions which could be life-threatening to users who are sensitive to latex.

BACKGROUND: These products were distributed directly to healthcare facilities (hospitals and institutions).

RECOMMENDATION: Customers in AL, AZ, CA, CO, CT, DE, FL, GA, MS, NC, NJ, OH, OK, OR, PA, SC, TN, TX, UT, or VA that have any of the affected medications labeled with “latex free” that are being recalled should immediately discontinue use and return the unused portion to Avella Specialty Pharmacy. For a full list of Advanced Pharma products, please visit www.AdvancedPharma.com.

Patients and healthcare providers with questions regarding this recall can contact the Advanced Pharma recall line at [\(877\) 292-4323](tel:8772924323), Monday through Friday, between 6am and 6pm Pacific Standard Time or via e-mail at ProductRecall@avella.com. Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to the use of these products.

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
- [Download form](#) or call [1-800-332-1088](tel:18003321088) 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

Read the MedWatch safety alert, including a link to the press release, at:

<https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm543251.htm>

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