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FDA Obtains Permanent Injunction Barring Two Companies from Manufacturing and Distributing Unapproved Drugs
Companies made and distributed adulterated, misbranded and unapproved drugs

The U.S. Food and Drug Administration today announced that it had obtained a permanent injunction barring Neilgen Pharmaceuticals Inc. of Westminster, Md., its parent company, Advent Pharmaceuticals, Inc. (Advent), of East Windsor, N.J., and two of their officers, Bharat Patel and Pragna Patel, from manufacturing and distributing any unapproved, adulterated or misbranded drugs.

Both Neilgen, which does business as Unigen Pharmaceuticals Inc. (Unigen), and Advent are contract manufacturers and distributors of more than 25 different unapproved drug products each. The more than 50 unapproved drug products primarily include prescription cough and cold products. The unapproved drugs manufactured by Unigen and/or Advent include, but are not limited to:

- RE All 12 Suspension;
- BP Allergy Junior Suspension;
- PE Tann 20 mg/CP Tann 4 mg Suspension;
- BP New Allergy DM Suspension;
- D-Tann CT Tablets;
- B-Vex D Suspension;
- Histex SR; and
- Chlorpheniramine Maleate 12 mg/Pseudoephedrine HCl 120 mg LA Tablets.

The unapproved drugs manufactured by these companies have not undergone the FDA's drug approval process, so their safety and effectiveness have not been established and the FDA has not reviewed the adequacy and accuracy of the directions for use and warnings on the labeling.

Consumers in possession of any of these products should discontinue using them and discuss FDA-approved treatments with their health care professional. Pharmacists should discontinue dispensing these products.

The defendants signed a consent decree that orders them to destroy their existing drug supply, and prohibits them from commercially manufacturing and distributing any new drugs without the FDA's approval. Further, the firms must retain outside experts who will advise them on appropriate compliance standards with U.S. current Good Manufacturing Practice (cGMP) requirements for drugs, and obtain written authorization from FDA to resume operations. The consent decree also authorizes the FDA to order the defendants to cease operations or take other corrective action in the event of future violations and further subjects the defendants to liquidated damages of \$1,000 for each violation. An additional \$5,000 per day, up to \$1 million per year, can be levied for each violation, if the defendants fail to comply with any of the provisions of the decree. The consent decree was entered by Chief Judge Benson E. Legg in the U.S. District Court of Maryland on April 9, 2009.

“The FDA's key enforcement priorities include shutting down manufacturers and distributors of unapproved drugs. Drugs not in compliance with cGMP cause great risk to public health,” said Michael Chappell, acting associate commissioner for the FDA's Office of Regulatory Affairs.

The FDA sought an injunction after the defendants failed to comply with previous warnings and continued to manufacture drugs in violation of federal law. Multiple FDA inspections of both the Unigen and Advent facilities found that the companies continued to manufacture unapproved new drugs. FDA inspections also revealed numerous and recurring violations of the cGMP requirements for drugs in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Both Unigen and Advent failed to respond adequately to issues raised by the FDA's inspection findings.

“To protect the American public, companies that continue to market unapproved drugs must be required to cease that illegal activity,” said Janet Woodcock, M.D., director, the FDA's Center for Drug Evaluation and Research. “It is critical that only drugs that are safe, effective and manufactured in accordance with good manufacturing practices be allowed into the U.S. marketplace.”

In June 2006, the FDA issued a guidance document titled, “Marketed Unapproved Drugs - Compliance Policy Guide” (CPG). The CPG makes clear that companies may not market drugs that require approval without first establishing in applications that the products are safe and effective. Among priorities in the CPG are enforcement actions against manufacturers that violate provisions of the FD&C Act.