

safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

PIPRACIL (piperacillin sodium) 2-gram, 3-gram, and 4-gram vials are the subject of approved NDA 50-545 held by Lederle (part of Wyeth-Ayerst Pharmaceuticals). PIPRACIL is a broad-spectrum penicillin indicated for the treatment of serious infections and for prophylactic use in surgery. The holder of the application for PIPRACIL (piperacillin sodium) 2-gram, 3-gram, and 4-gram vials has informed FDA that the drug products have been withdrawn from sale.

The agency has determined that Wyeth-Ayerst's PIPRACIL 2-gram, 3-gram, and 4-gram vials were not withdrawn from sale for reasons of safety or effectiveness. FDA has independently evaluated relevant literature and data for possible postmarketing adverse event reports and has found no information that would indicate these products were withdrawn for reasons of safety or effectiveness.

For the reasons outlined, FDA determines that Wyeth-Ayerst's

PIPRACIL 2-gram, 3-gram, and 4-gram vials were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list PIPRACIL (piperacillin sodium) 2-gram, 3-gram, and 4-gram vials in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to PIPRACIL (piperacillin sodium) 2-gram, 3-gram, and 4-gram vials may be approved by the agency.

Dated: October 21, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: September 2003

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of September 2003, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusions is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, and all Federal Health Care programs. In addition, no program payment is made to any business or facility, *e.g.*, a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all Executive Branch procurement and non-procurement programs and activities.

OFFICE OF INVESTIGATION, OFFICE OF INSPECTOR GENERAL—DHHS CASE INVESTIGATION MANAGEMENT SYSTEM

[For press release from 09/01/2003–09/30/2003]

Subject name	Address	Effective date
Program-Related Convictions		
Arca, William	Oceanside, NY	10/20/2003
Arias, Grisel	Miami, FL	10/20/2003
Arias, Idania	Miami, FL	10/20/2003
Badalyan, Arsen	Van Nuys, CA	10/20/2003
Batiste, Vernida	Marrero, LA	10/20/2003
Benson, Kelly	North Mankato, MN	10/20/2003
Bishop, Michael	Casa Grande, AZ	10/20/2003
Boisseau, Carlene	Chester, VA	10/20/2003
Boland, C	Easley, SC	10/20/2003
Bouza, Vicente	Miami, FL	10/20/2003
Burgos, Marco	Miami Beach, FL	10/20/2003
Burgos, Suzanne	Miami Beach, FL	10/20/2003
Carter, Valarie	Los Angeles, CA	10/20/2003
Cash, Lenard	San Antonio, TX	10/20/2003
Clark, Merle	Oceanside, NY	10/20/2003
Clements, Deborah	Whitehall, OH	10/20/2003
Coppin, Leslie	Highlands Ranch, CO	10/20/2003
Cortez, Josie	Alhambra, CA	10/20/2003
Crow, Ronald	Beaver, WV	10/20/2003
Curran, Joan	Avon, OH	10/20/2003
De Jesus, Lorna	Long Beach, CA	10/20/2003
Deshields, Cynthia	Philadelphia, PA	10/20/2003
Dewan, Suman	New Orleans, LA	12/4/2002
Donaghy, Thomas	Whitehall, OH	10/20/2003
Donohue, Joseph	Sheridan, OR	10/20/2003
Edgar, Daniel	Peachtree City, GA	10/20/2003
EMA Medical Laboratory, Inc	Ridgewood, NY	10/20/2003
Exsted, Melody	Sandstone, MN	10/20/2003
Feldman, Gary	Lompoc, CA	10/20/2003
Ferran, Osmin	Miami, FL	10/20/2003
Flemons, Michael	Venus, TX	10/20/2003
Franklin, Dwonne	Minneapolis, MN	10/20/2003
Gezvkaryan, Khachik	Eloy, AZ	10/20/2003