

# Non-FDA Approved Drugs



The term “FDA Approved Drug” has caused some confusion in the marketplace. FDA approved drugs go through an approval process that can often take many years and millions of dollars to complete. Only the final product consisting of specific ingredient(s) at specified strength(s) and a dosage form for a defined indication are considered FDA approved.

The individual Active Pharmaceutical Ingredients (APIs) used by FDA approved products or even in compounds, by their very nature, are not FDA approved. Recently, some insurance companies have taken the stance that they will not reimburse for a compounded medication because either the compound or the API is not FDA approved. While FDA approved medication(s) make up the majority of the drugs that are commercially available in the market today, it may be surprising to some that there are drugs that are commercially manufactured that did not go through the FDA approval process.

These drugs are critically important to patients and practitioners and are still prescribed frequently. Insurance companies may be applying an inconsistent policy if they reimburse for any of the drugs listed and not for compounded medications.

PCCA only purchases APIs from FDA-registered and GMP-certified manufacturers and every chemical goes through a 14-step checks and analyses program before being repacked for member pharmacies. For more information on PCCA quality, check out [www.pccarx.com/quality](http://www.pccarx.com/quality).



## Non-FDA Approved Drugs Currently Available in the US Market\*

DRUG	DOSAGE FORM
Amyl nitrate	Inhalant
Antipyrine and benzocaine	Otic solution
ASA and codeine phosphate	Tablets
Chloral hydrate	Suppository
Ephedrine sulfate	Capsules
Ephedrine sulfate	Injection
Ergonovine maleate	Tablets
Hydromorphone hydrochloride	Suppositories
Mephobarbital	Tablets
Methenamine mandelate	Tablets
Opium	Tincture
Pancrelipase	Capsules (non-DR)
Paregoric	Liquid
Phenazopyridine hydrochloride	Tablets
Phenobarbital	Elixir
Phenobarbital	Tablets
Phenobarbital sodium	Injection
Potassium bicarbonate	Effervescent tablets
Potassium bicarbonate and potassium chloride	Effervescent tablets
Potassium chloride	Oral solution
Potassium gluconate	Tablets
Potassium iodide	Oral solution
Potassium phosphate	Tablets
Potassium phosphate	IV solution
Sodium fluoride	Oral Solution
Sodium fluoride	Tablets
Thyroid	Tablets

\* Current list as of June 2013.