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Do Compounded Medications Require FDA Approval?

The FDA approval process is intended for mass-produced drugs made by manufacturers. Because compounded medications are personalized for individual patients, it is not possible for each formulation to go through the FDA's drug approval process, which takes years to complete and is prohibitively expensive, often costing hundreds of millions of dollars.

About PCCA

PCCA is an independent compounding pharmacy's complete resource for fine chemicals, devices, equipment, training & support.

Compounding & Pharmacists

Pharmacists: Are you looking for a new direction?

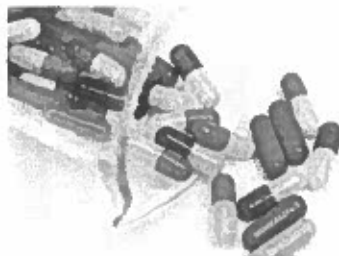


Have you ever had a patient or a prescriber report that a patient had difficulty taking a medication as directed?

Do you wish you had more ways to use your pharmacy skills, knowledge, and creativity to work with your patients and prescribers to solve their unique medication challenges?

You're not alone! Pharmacy compounding has allowed many pharmacists to find their niche as medication problem-solvers. The "one-size-fits-all" nature of many mass-

manufactured medications means that some patients' needs are not met by those products.



Many patients experience issues such as:

- Stomach upset when taking oral medication
- Reluctance to take the medication due to its taste
- Issues with the route of administration, such as difficulty swallowing pills
- Allergy, sensitivity, or other aversion to ingredients such as flavors or dyes, lactose, sugar, alcohol, gluten, or casein.
- Requiring a different dose of medication than that which is available from a manufacturer
- Difficulty keeping track of multiple medications
- Patients who need a medication that has been discontinued by the manufacturer
- Patients who don't want to take medication at all, especially children or pets

A compounding pharmacist may be able to provide solutions for challenges such as these. Working closely with the patient and the prescriber, compounding gives the pharmacist the means to customize medication to meet the individual needs of each patient.

At one time, all medications were compounded. Over the past few decades, compounding has experienced a renaissance as modern technology and innovative

techniques and research have allowed more pharmacists
to customize medications to meet specific patient needs.

Learn more about what compounding and PCCA membership can do for
your practice, your patients, and your prescribers!

Contact PCCA

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