

# Does It Require FDA Approval?

First, what is your product?

## Food

No. FDA does not approve food, beverages, or dietary supplements.

## OTC Drug

Does your drug conform to an Over-The-Counter Monograph?

### If Yes:

No. Drugs that conform to an OTC monograph may be marketed without FDA approval.

### If No:

Yes. FDA requires approval of new drugs.

## Medical Device

Is your device Class III?

### If Yes:

Yes. Class III devices require FDA premarket approval.

### If No:

No. However, your product may be subject to *premarket notification*.

## Cosmetic

No. FDA does not require approval of cosmetic products and their ingredients before marketing.

*\*\* Please note: FDA approval is required for new food additives and for color additives used in food, drugs, cosmetics, and some medical devices.*

**Registrar Corp** 