

## A COMPARISON OF THE UNITED STATES' FDA APPROVAL PROCESS AND EUROPEAN EMA APPROVAL PROCESS

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**Introduction:** In the Past, no regulations existed to protect the public from dangerous drugs. Medications that were ineffective, potentially harmful were sold to the public. This is a drastically different reality from what exists today in the United States and Europe.

**Objectives:** The approval processes of the FDA and EMA are complex. It is a process difficult to understand for patients. It is information that Clinicians should be familiar with. What does the FDA or EMA approval processes actually entail? What does it mean?

**Aims:** To describe the FDA and EMA as well as their approval processes for new medications.

**Methods:** A review of the literature as published by the EMA, as well as the FDA Orange Book from 1995-2012 to compare the FDA and EMA central approval processes.

**Results:** The public trust the FDA and EMA to determine what medications are safe and effective, making the FDA and EMA approval a meaningful title to patients. Review of the literature and medication approvals in EU and US shows two of the world's most rigorous drug review processes.

**Conclusions:** In an increasingly expanding environment of global healthcare, we attempt to stimulate discussion about the challenges of cross cultural medicine. Some of these challenges are elucidated by the drug approval process of the EMA that tries to incorporate all member nations of the E.U under one regulatory agency. This is a theme that will continue to emerge as we look at world in which information and medicine become intertwined.