FDA APPROVAL PROCESS

Students will explain the drug approval process in detail.

Students will turn in:

* A typed report summarizing the information found on about the FDA new drug approval process. Directions are found below. Please use paragraphs and full sentences.
* See the homework template online at meghanlineburg-instructorwebsite.weebly.com

Drug Approval Process

1. Go to <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm090410.htm>
2. Click on *CFR Sections for INDs*
3. From this page click on *Phases of an Investigation* (under *Subpart B*).
4. Please read about the three phases of clinical investigation.
5. Read over the FDA Drug Approval Process Infographic found online at the instructor website under Courses and PH140 Classification Systems.
6. What happens before the clinical studies can occur?
7. Explain the difference between the three phases of clinical trials.
8. Do studies and trials stop completely once a medication is considered approved?