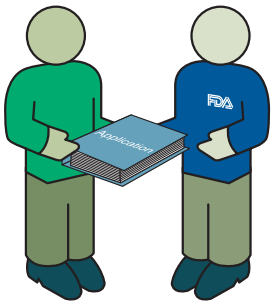
The Drug Review Process

START

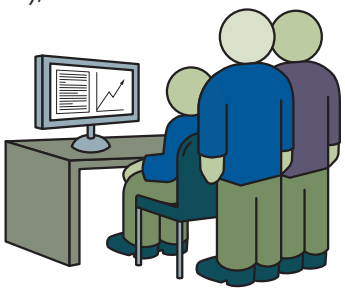
1



An application to begin human testing (clinical trials) of a drug is submitted to FDA.

2

FDA reviews the application to determine if it is safe to begin human testing. An Institutional Review Board (IRB), which is not part of FDA but is regulated by FDA, also reviews the testing plan. An IRB makes sure that the rights and welfare of participants are protected.



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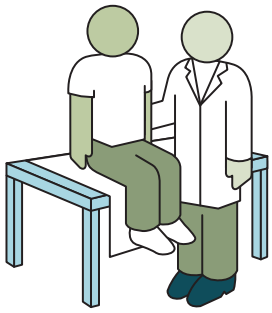
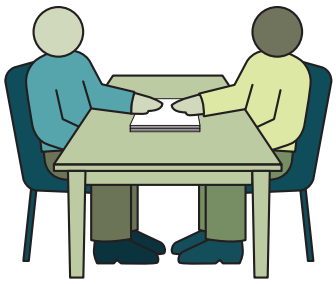


If FDA and IRB permit, human testing begins with the purpose of determining the drug's safety and effectiveness.

4

During human testing, applicant is required to submit all information about the drug. FDA and applicant may meet to discuss findings.



5

FDA is asked to consider approving the drug for sale in the United States.

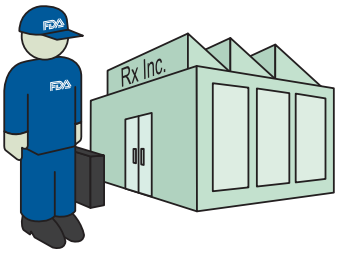
FINISH

10

FDA decides whether the drug can be approved, which would allow the drug to be sold in the U.S. If FDA does not approve the drug, FDA communicates its concerns to the applicant.

9

FDA inspects the places where the drug will be made, and how it will be made.



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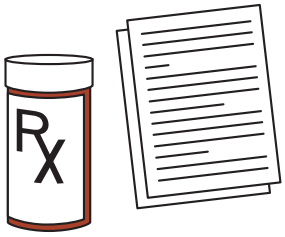
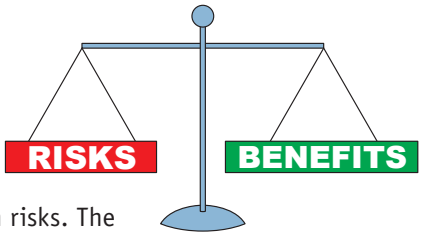


FDA reviews information that will go in the drug's labeling (instructions for, and information about, using the drug).

7

FDA reviews application to determine if the drug's benefits outweigh its known risks. The review team includes experts in



- medicine
- pharmacology
- chemistry
- biopharmaceutics
- statistics
- microbiology (as needed)

FDA may ask for additional information, and may hold advisory committee meeting to get outside expert advice.

6

FDA has 60 days to decide whether to file an application, or refuse to file an incomplete application.