Regulatory Drug Approval Puzzle

1. Crossword Clues

Across

2. The phase in which a drug is tested on animals for efficacy and safety (10 letters)
5. The application submitted to the FDA to market a new drug (3 letters)
6. Regulatory body in the United States (5 letters)
7. The tragic event in 1962 that led to modern drug regulation (10 letters)

Down

1. Document summarizing all data about an investigational product, used in clinical trials (2 words, 19 letters)
2. Type of drug application for generic drugs (4 letters)
3. Tests conducted at doses not far from clinical dose to detect undesirable effects (2 words, 15 letters)

Answers Key (revealed only on request!)

2. Match the Term Activity

Match each term on the left with its correct description on the right.

Term	Description Letter
1. IND Application	a
2. ANDA	b
3. Safety Pharmacology	c

4. NDA	d
5. Investigator's Brochure	e
6. Bioequivalence	f

Descriptions:

a) Application to FDA to begin clinical trials in humans

b) Application for approval of a generic drug

c) Studies to detect undesired drug effects on major organs

d) Application to FDA for marketing a new drug

e) Compilation of all clinical/non-clinical data about an investigational product

f) Ensures that different products with the same active ingredient act similarly in the body

3. True or False

State whether the following statements are true or false:

- The FDA reviews New Drug Applications within 30 days.
- Bioequivalence studies are only required for new chemical entities, not generics.
- The Elixir Sulfonamide incident led directly to new regulations for drug approval in the US.
- Good Laboratory Practice (GLP) is mandatory for non-clinical animal studies.

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1. regulatory_approvals_for_new_drugs.pdf