Veterinary Medicine Case Study:

Dorothy McAdams, Supervisory Veterinary Medical Officer, Center for Veterinary Medicine, U.S. Food and Drug Administration

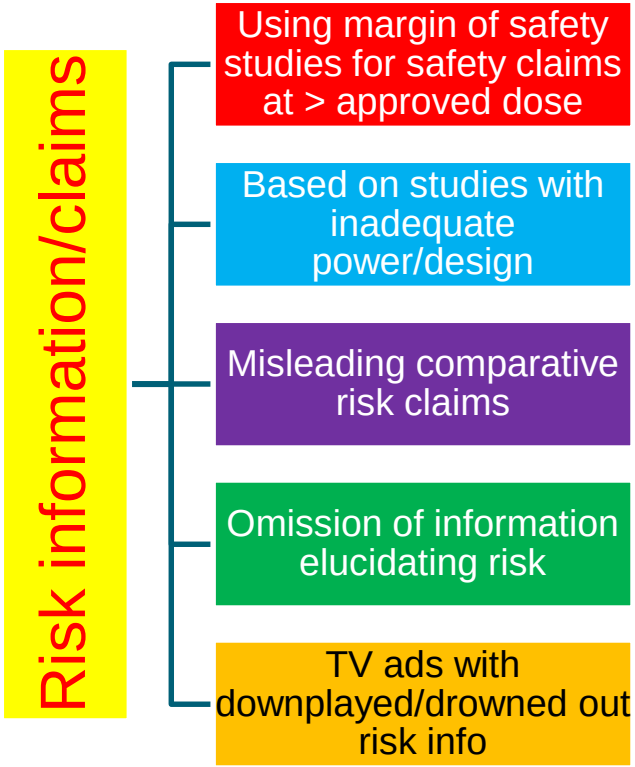
Jeannie Perron, Partner, Covington & Burling LLP

FDLI

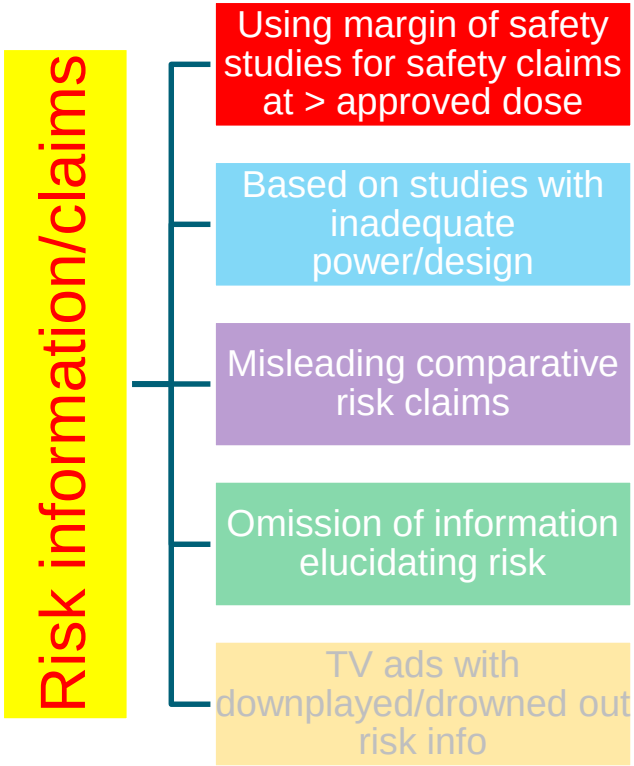
Animal Drugs Breakout

Jeannie Perron, JD, DVM

FDA Enforcement



FDA Enforcement



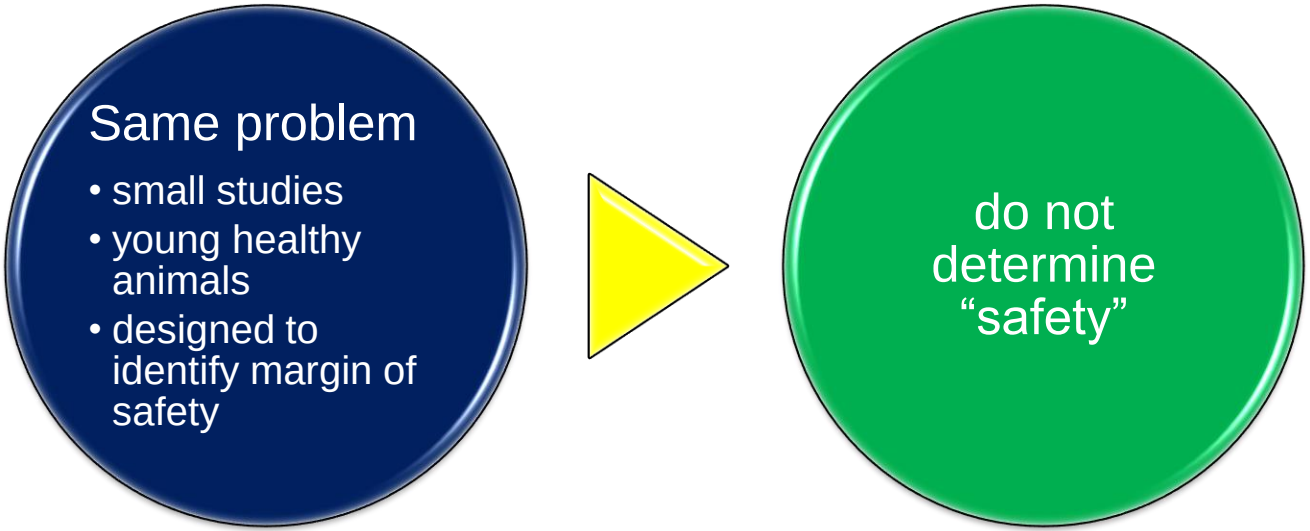
Margin of safety

"Proven safe in a 9-month safety study at up to approximately 15X the recommended therapeutic dose in healthy dogs."

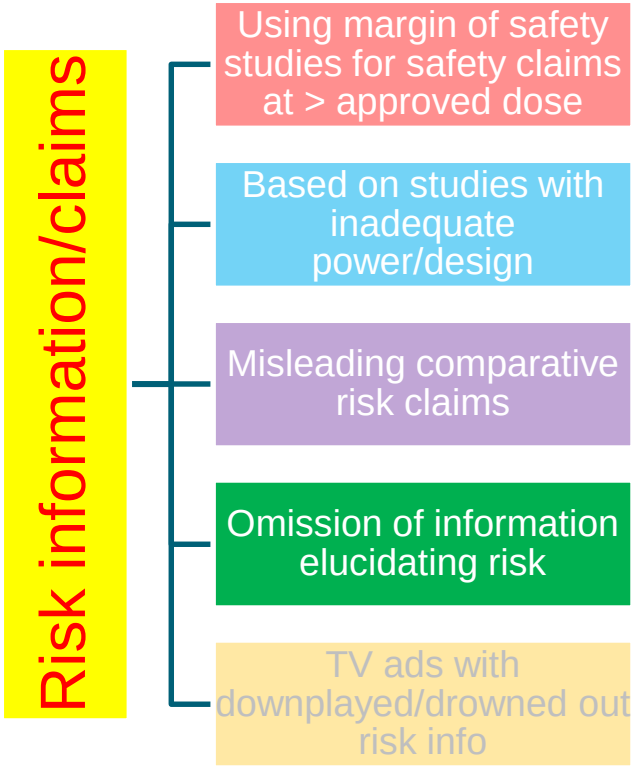
Untitled letter: "these statements suggest that administration of GALLIPRANT is 'safe' at up to 15X the approved dose."

May 2, 2018 Galliprant® untitled letter

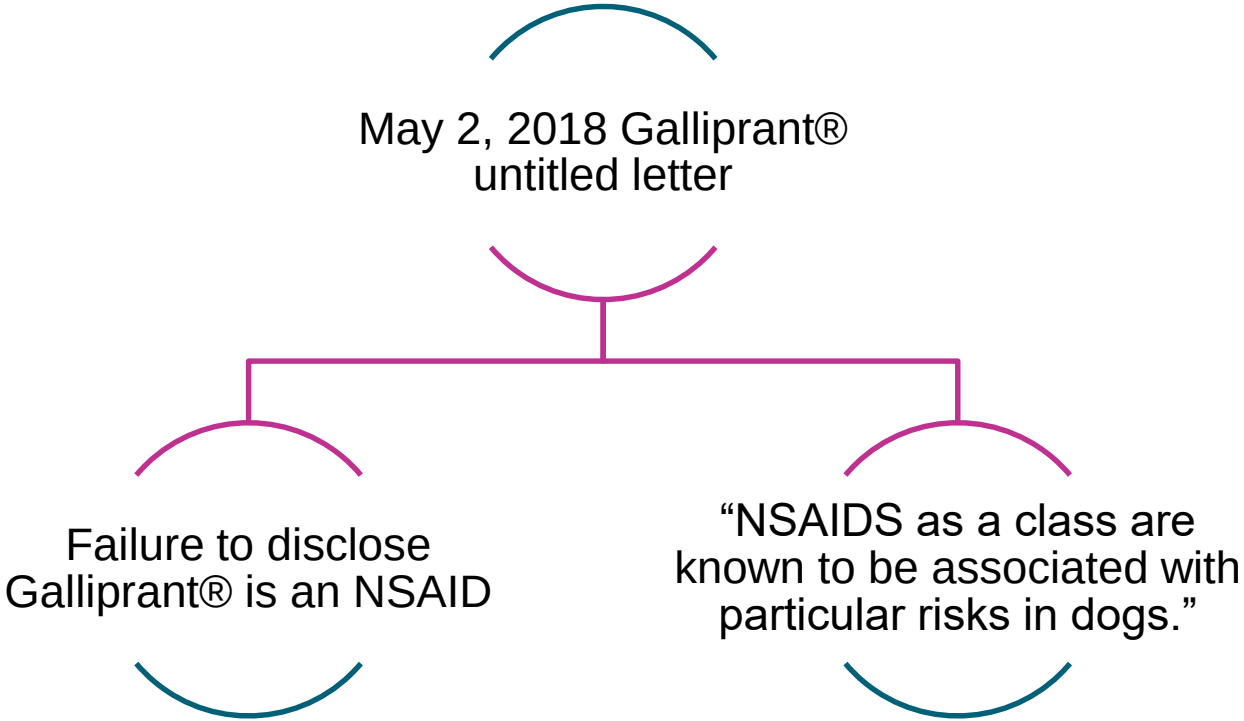
Safety


Same problem
• small studies
• young healthy animals
• designed to identify margin of safety
do not determine "safety"

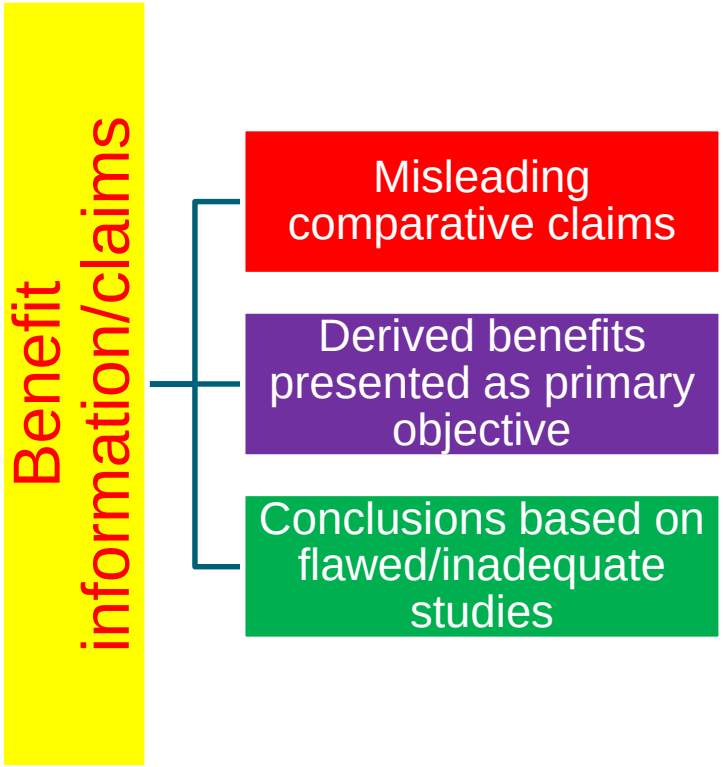
FDA Enforcement



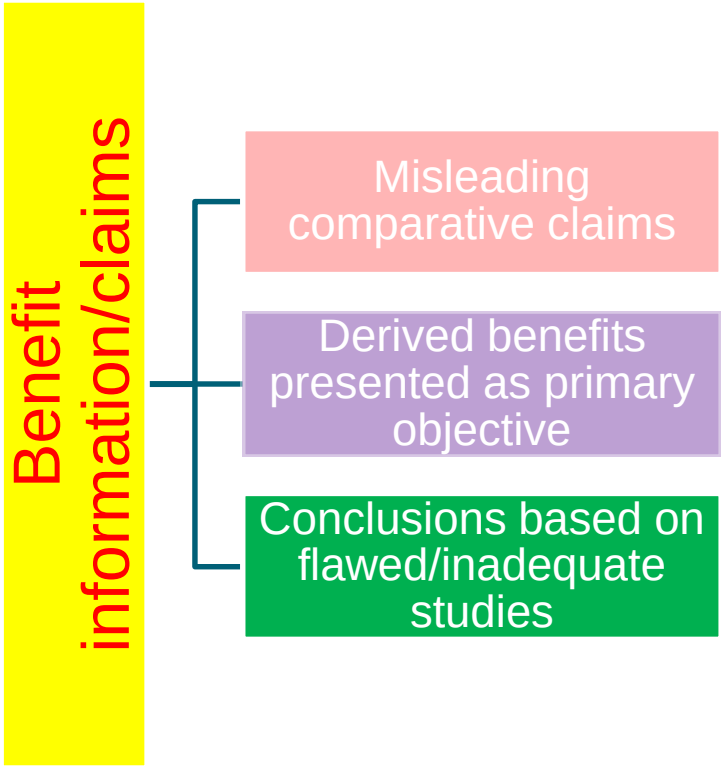
Information elucidating risk



FDA Enforcement



FDA Enforcement



March 10, 2014 Zuprevo untitled letter

"Lasts 28 days in lungs for optimal efficacy"

Untitled letter: "the authors [of the underlying study] do not conclude that duration of tildipirosin in lung tissues results in greater or optimal efficacy and … conclude that 'further research is warranted'"

Likely to get FDA's attention

High risk products

- e.g., medically important antimicrobials

Competitive and large distribution products

New and novel products

Likely to get FDA's attention

High risk products

- e.g., medically important antimicrobials

Competitive and large distribution products

New and novel products

High risk products

Oct. 22, 2015 Pulmotil® untitled letter

- “macrolide antibiotics are considered critically important to human medicine.”

High risk products

Oct. 22, 2015 Pulmotil® untitled letter

- Pulmotil® had boxed warnings and additional human safe use warnings (e.g., protective clothing during administration)
- Also, extent of use limitation to treat fewest animals possible/no refills

High risk products

Oct. 22, 2015 Pulmotil® untitled letter

- Promotional materials omitted human safety/extent of use information

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