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- As defined in Federal Food, Drug, and Cosmetic Act (FD&C Act):

  articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; articles intended to affect the structure or any function of the body of man or other animals.

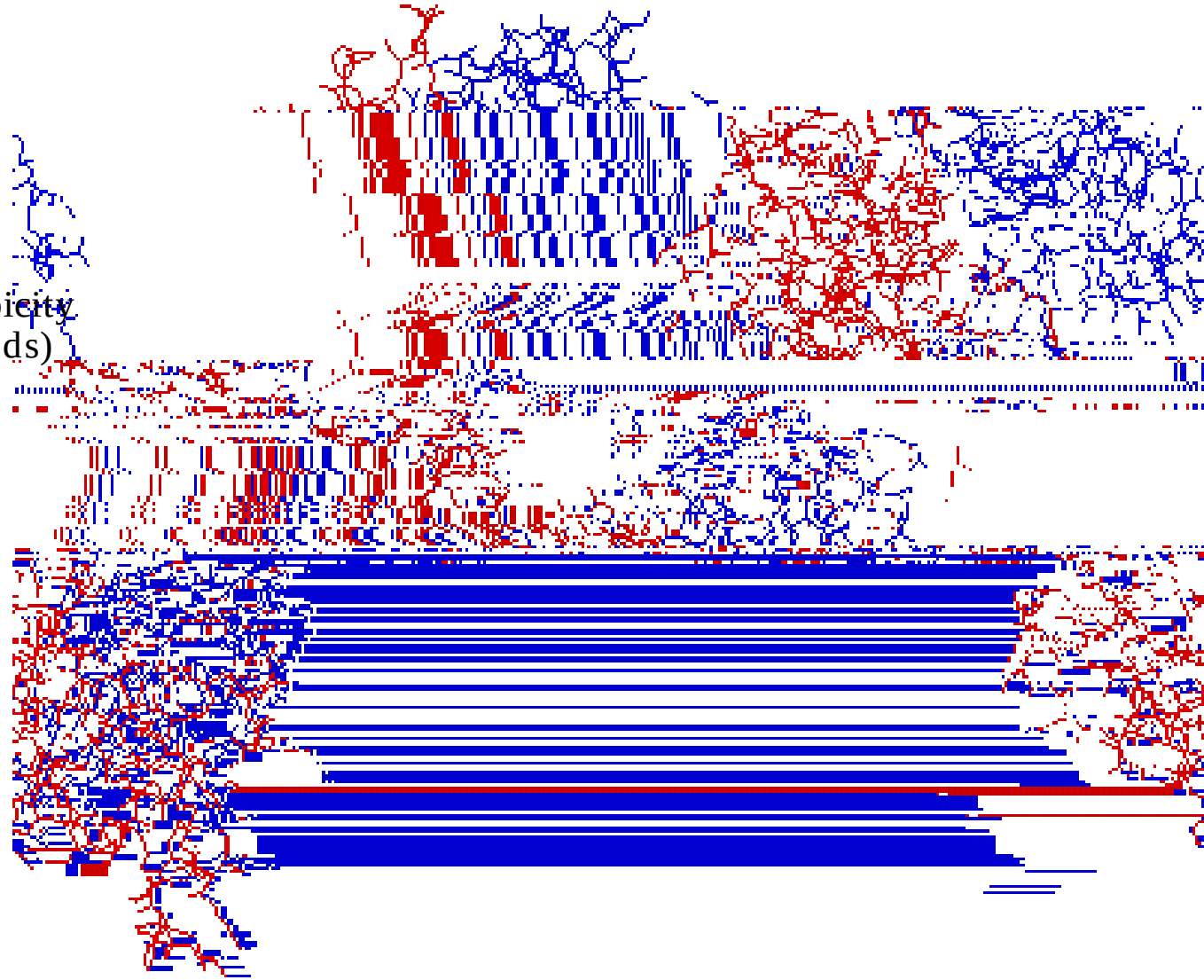
- As defined in Section 351(i) of the Public Health Service Act (PHS Act):

  “…a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound…)”

Proteins have expected:

- Size, charge, hydrophobicity
- Correct folding (S-S bonds)
- Subunits
- Glycosylation
- Bioactivity

& Unexpected:



- One that relies, to at least some extent, on the Agency's conclusions about the safety and effectiveness (or safety, purity, and potency) of an approved (or unlicensed) product

- Under the PHS Act – no explicit pathway

- Under the FD&C Act – two pathways
  - 505(j)
  - 505(b)(2)

Pharmaceutical Equivalents

Drug products in identical dosage forms that contain identical amounts of the identical active drug ingredient or (e.g., for modified

- ***Comparability***

  The comparison by the manufacturer of a biological product before and after a manufacturing change to demonstrate that the safety, identify, purity, and potency remain unchanged http://www.fda.gov/cder/Guidance/compare.htm

- ***Follow-on***

  Informal term, referring to products intended to be

- Is the product sufficiently similar to a licensed product to allow reliance on existing scientific knowledge about