U.S. FOOD & DRUG ADMINISTRATION

MAUDE
Manufacturer and User Facility Device Experience

FAERS
FDA Adverse Event Reporting System

- **FAERS (FDA Adverse Event Reporting System)**:
  - Purpose: Tracks adverse events and medication errors associated with drugs and biologics (e.g., epinephrine in Racellet or EpiDri pellets, if classified as a drug component).
  - Data: Collects voluntary reports from healthcare providers, patients, and manufacturers, including serious side effects, allergic reactions, or unexpected outcomes.
  - Relevance to Dentistry: Since epinephrine is a pharmaceutical agent, any systemic reactions (e.g., tachycardia, hypertension) from dental hemostatic pellets would likely be reported here.
  - Access: Publicly available via the FDA's website, with quarterly data updates.
- **MAUDE (Manufacturer and User Facility Device Experience)**:
  - Purpose: Monitors adverse events related to medical devices (e.g., dental tools, delivery systems, or potentially the pellet applicators if classified as devices).
  - Data: Includes mandatory reports from manufacturers and voluntary reports from clinicians or users about device malfunctions, injuries, or deaths.
  - Access: Publicly accessible via the FDA's website, updated monthly.

190,538,600 pellets sold

Complaint Record:

Zero reported complaints or adverse incidents with any epinephrine pellets over a 62-year span.

U.S. FOOD & DRUG ADMINISTRATION

MAUDE
Manufacturer and User Facility Device Experience

FAERS
FDA Adverse Event Reporting System

- **FAERS (FDA Adverse Event Reporting System)**:
  - Purpose: Tracks adverse events and medication errors associated with drugs and biologics (e.g., epinephrine in Racellet or EpiDri pellets, if classified as a drug component).
  - Data: Collects voluntary reports from healthcare providers, patients, and manufacturers, including serious side effects, allergic reactions, or unexpected outcomes.
  - Relevance to Dentistry: Since epinephrine is a pharmaceutical agent, any systemic reactions (e.g., tachycardia, hypertension) from dental hemostatic pellets would likely be reported here.
  - Access: Publicly available via the FDA's website, with quarterly data updates.
- **MAUDE (Manufacturer and User Facility Device Experience)**:
  - Purpose: Monitors adverse events related to medical devices (e.g., dental tools, delivery systems, or potentially the pellet applicators if classified as devices).
  - Data: Includes mandatory reports from manufacturers and voluntary reports from clinicians or users about device malfunctions, injuries, or deaths.
  - Access: Publicly accessible via the FDA's website, updated monthly.

Pascal Epinephrine Retraction Cords Safety

67,734,720 Application

One potential incident