Exotic Snake
Antivenoms and FDA

ACMT Annual Scientific Meeting
March 29, 2014
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“My comments are an informal communication and represent my own best judgment. These comments do not bind or obligate FDA.”
Exotic Antivenoms

- Unlikely to be licensed in U.S. (clinical studies challenging; no economic incentive)
- Needed “on hand” for institutions and individuals that maintain exotic venomous animals
- FDA instructions on how to obtain an INVESTIGATIONAL NEW DRUG application (IND) to use exotic antivenoms:
  
  http://www.fda.gov/biologicsbloodvaccines/developmentapprovalprocess/investigationalnewdrugindordeviceexemptionideprocess/ucm094321.htm

OR google "FDA information use of antivenoms"
“How to”

- Go to the FDA website on antivenoms for step-by-step instructions on
  - How to apply for an IND for antivenom
  - How to import antivenom
- IND information
  - Product information (form 1571), package insert
  - Certificate of analysis when lot arrives should be sent to IND to confirm sterility/safety
  - Identification of medically responsible individual (form 1572)
  - Statement that product will not be resold (commercially – not to be confused with cost recovery)
For Antivenom IND Holders

- **Annual reports should be submitted and include:**
  - Antivenom use; brief case reports
    - include observations of allergic events or other adverse events possibly due to antivenom (WHY?) ; patient recovered/died; sequelae if any
  - changes in product manufacturing, if known
  - CoA for new lots received
  - If no changes/no cases, brief letter so stating

- **Send an amendment if**
  - Changes in medically responsible individuals (new 1572 forms)
  - Addition of a new antivenom product to stock
Emergency IND

- FDA can authorize shipment of a drug *in advance* of an IND submission
  - Administration of product can proceed without IRB approval but must be reported to IRB within 5 days
- Request is normally to FDA by telephone (24/7)
- Authorization conditioned on appropriate IND submission as soon as practicable.
- Code of Federal Regulations: 21 CFR 312.36*

Emergency IND

The investigator will:
- Obtain manufacturer’s or zoo’s agreement
- Arrange for delivery of product
- Submit IND as soon as practicable
- Report to [local] IRB within 5 days

FDA will:
- Assign IND number
- Contact field offices (who can contact customs), if necessary
- Assist IND holder with submission instructions during normal business hours (Regulatory Project Managers, Office of Blood Research and Review)
Emergency IND “how to”

- contact FDA during business hours
  - Office of Blood Research and Review, CBER
    - 301-827-2000 or 301-827-1800
- Nights and weekends call
  - Office of Crisis Management and Emergency Operations Center
    - 301-796-8240 or 866-300-4374
  - Tell the staffer who answers that the product you need is a CBER (Center for Biologics) product so that they contact the correct medical officer
Charging for an Investigational Drug

- Ongoing challenge for zoos and other institutions
  - Giving antivenom out for members of the public depletes antivenom stocks meant to treat staff who work with venomous animals; replacing antivenoms can take weeks to months.
  - Financial costs

- IND holders, such as zoos, may apply for cost recovery in advance, under recent FDA guidance on charging for “expanded access use”
What FDA can and cannot do

- **We CAN**
  - Grant cost recovery
  - Assist in IND development and respond to questions
  - Evaluate possible safety signals when antivenoms are used

- **We CAN NOT**
  - Stock antivenoms (FDA does not maintain stockpiles)
  - Pay for antivenoms
  - Enforce cost recovery
What you can do

- Submit annual reports, even if very brief
  - So that we can identification safety signals across IND’s
  - Supply CoA’s for new lots
- Report unexpected fatal or life-threatening suspected adverse events to FDA within 7 days
- Let us know what would be helpful to the antivenom community
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Thank You!