

Synopsis of Procedure to Acquire Foreign Anti-venom

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Purpose: The purpose of this paper is to aid those keepers in the acquisition of their own supply of Anti-venom to alleviate the burden on zoo and other institutional supplies. The process of obtaining foreign A/V is often avoided because of the perception that there is a voluminous amount of paperwork involved, which is not the case. After wading through the process, it was found to be less painful than 'ripping off a band-aid' and the rewards of having a ready supply of A/V in hand will save hours of time in initiating treatment, which can mean the difference between life and death. Partaking in this hobby means accepting risks and responsibilities to ourselves as well as other keepers—Keeping a supply of anti-venom is one of those responsibilities!

I. Overview:

- a. Acquiring foreign manufactured anti-venom requires two basic permits: 1) BB-IND # from US Food and Drug Administration and 2) Import Permit from USDA.
- b. **BB-IND** (Investigational New Drug) is a number/permit issued by the US Food and Drug Administration(FDA) Center for Biologic Research and Evaluation(CBER). This is the authority that oversees the clinical trial/testing of new drugs in the US. Foreign A/V is considered to be an "experimental drug" in the US.
 - **Time for issue:** usually about 30-60 days from receipt of application.
- c. **Import Permit.** This is simply that. Much like an import permit is required for animals since the A/V is a biologic serum derivative, the USDA Animal and Plant Health Inspection Service (APHIS) is the authority that issues these permits.
 - **Time for issue:** usually about 30 days from receipt of application.
 - **Note:** You can apply for the BB-IND and Import Permit simultaneously to save time.
- d. Once you have the A/V, you will need the supplier to fax or mail you a certificate of compliance or "Quality Control" certification stating that the A/V has been tested for quality assurance. A copy of this is then sent to FDA/CBER.
- e. Each year you must submit a report to FDA/CBER stating if any (or none) A/V was used.

II. Steps to acquire BB-IND.

The following items will be needed prior to submitting the application (Forms may be downloaded from the file library at www.venomousreptiles.org) :

- Completed Form 1571 (IND Application filled out by Sponsor, i.e., YOU)
- Completed Form 1572 (IND Application filled out by Investigator, i.e. your Primary Care Physician[PCP])
- (2) Original A/V package inserts

- Copy of physicians Curriculum Vitae
 - Additional human experience with A/V (optional, but recommended)
- 1) Contact A/V supplier/manufacturer and request that they send you **2 A/V package inserts** (must be originals NOT photocopies). These are required for submission with the application.
Note: when you contact them, it's easy to have them fax you an invoice as well.
 - 2) Complete Form 1571. This is completed by the drug sponsor (i.e., the person who wants or needs the A/V and under whose control it will remain.)
 - 3) Have your Physician complete Form 1572. Your physician will act as the Principal Investigator under whose supervision OR direction--if administered by another physician--the A/V will be administered.
 - 4) Get a copy of your personal physicians Curriculum Vitae (professional resume).
 - 5) If you can find info on previous use of the A/V in humans as clinical data, do so (e.g., I found articles on bushmaster envenomation and treatment in a 1998 Chicago Herpetological Society bulletin for obtaining Costa Rican Polyvalent A/V)
 - 6) Make 3 copies of the submission. The original and 2 copies will go to FDA/CBER. Keep one for your records.

III. Steps to acquire USDA Veterinary Import Permit.

Pretty simple, complete the form VS 16-3 and enclose a check.

IV. Getting the A/V

Once you have the IND and Import Permit, Fax a copy of the permit to the Supplier. Wire the money to them through your bank. You may or may not need a customs broker to clear it. It's usually not necessary if for personal use but this also depends on the price (as long as it's under \$2500). Check with the manufacturer on who they will use as a carrier. It usually arrives Overnight Courier.

V. Contacts for A/V

- SAIMR Polyvalent (*Bitis, Naja, Dendroaspis*)
South African Vaccine Producers Ltd (SAVP)
<http://www.savp.co.za/>
- Costa Rican Polyvalent Anti-Botropico, Lacquetico, Crotalico (*Lachesis stenophrys, Bothrops asper, Crotalus d. durissus, Bothreichis, Atropoides*) Instituto Clodomiro Picado
- USDA Animal and Plant Health Inspection (APHIS)
<http://www.aphis.usda.gov/>
- USFDA Center for Biologics Research and Evaluation (CBER)
<http://www.fda.gov/cber/ind/ind.htm>
- WCH Clinical Toxinology Resources
www.toxinology.com