NEUTERSOL® FROM LABORATORY TO MARKET— LESSONS LEARNED

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Even though there is worldwide human and pet overpopulation, it is difficult to secure enough research funding to support development of male contraceptive medicines and devices. The reality is that research funding in general is limited and development of a product from laboratory to market is lengthy and expensive. Neutersol®, an injectable solution for sterilization of male dogs, is the first product approved by the Food and Drug Administration (FDA) for animal sterilization and was marketed in the United States in 2003. The Research and Development (R&D) process used for Neutersol® may serve as a typical model for most male contraceptive medicines and devices developed with limited resources in the United States and worldwide. R&D of the product was done at the University of Missouri-Columbia and was sponsored by a small business venture capital company. The Neutersol® experience with the following questions offers lessons that are applicable to R&D of most male contraceptive medicines and devices.

1. How long is the R&D process from laboratory to market?
2. How is the process for the new product started?
3. What major procedures are required for the product?
4. What are the claims and liability?
5. How is the laboratory data transferred to manufacturing?
6. What is the appropriate procedure for responding to the FDA?

7. How is the labeling technical section finalized?
8. How is the exclusivity of the marketed product extended?