
Medical Devices

A White Paper on Medical Devices in Equine Medicine

Developed by the
Biological and Therapeutic
Agents Committee



Medical devices are used in human and veterinary medicine for diagnosis and treatment of diseases. Understanding the appropriate use of medical devices is important for the treatment of horses in veterinary practices. This paper defines what constitutes a medical device and the associated approval/registration requirements and the use of these products by practitioners in relation to the product label. There are differences between medical devices used in human medicine and those devices used exclusively within veterinary medicine. Obvious veterinary devices such as lasers, syringes, ultrasound equipment, surgical implants and other “mechanical” devices will not be discussed; rather emphasis will be placed on devices which are produced in liquid form, are used as barriers or protectants, or those that support structure or function but are not defined as drugs.

What is a medical device?

Medical device as defined by the Food and Drug Administration in the Food Drug and Cosmetic Act, Section 210(h): “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part, or accessory, which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or animals and which does not achieve any *of its principal intended purposes through chemical action within or on the body of man or other animals and is not dependent upon being metabolized for the achievement of any of its principal intended purposes.*” (Examples include needles, syringes, prosthetic devices, x-ray equipment, MRI unit, pacemakers, stents, surgical lasers, shock-wave unit, and barriers in the form of sheets or solutions, etc.)

Medical device summary:

- Diagnose, cure, mitigate, treat or prevent disease or condition
- Affects the structure and function of the body
- Does not achieve intended purpose through chemical reaction
- Is not metabolized to achieve intended purpose

Medical devices (for human medicine) are classified into three categories

(Regulatory control increases from Class I to Class III):

Class I Devices are defined as non-life sustaining. These products are the least complicated and their failure poses little risk.

Class II Devices are more complicated and present more risk than Class I, though are non-life sustaining. These may be subject to specific performance standards.

Class III Devices sustain or support life, so that their failure is life threatening. These products are subject to specific performance standards.

Who is responsible for oversight of medical devices?

The FDA’s Center for Devices and Radiological Health (CDRH) has responsibility for the registration/approval and monitoring of medical devices.

What is the approval process for a human medical device?

The device classification defines the regulatory requirements for a device type. Depending upon the device classification, approval requirements can vary significantly. (The following requirements do not apply to those devices, which are intended for use exclusively within veterinary medicine).

- There is a formal establishment/facility registration process for businesses, which are involved in the production of medical devices. These facilities are required to register annually with the FDA.
- Medical devices are required to be listed with the FDA.
- Many devices (most Class I and some Class II) are exempt from Good Manufacturing Practices (GMP), **as long as the device is not labeled or otherwise represented as sterile.**
- Most Class I (and some Class II) devices are exempt from Premarket Notification requirements.
- Most Class II devices do require Premarket Notification submission to FDA before they can be marketed.
- Most Class III devices require Premarket Approval submission and approval before they can be marketed. This would entail safety and effectiveness evaluation, product development, manufacturing and market support requirements.
- Adverse events in which a device may have caused or contributed to a death or serious injury must be reported to the FDA under the Medical Device Reporting Program. (Veterinary adverse events can be reported at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/AnimalDrugForms/UCM048817> or by contacting the manufacturer directly.)

Is there a distinction between medical devices for human use and medical devices (veterinary devices) used exclusively within veterinary medicine?

Though the FDA regulates “medical devices” there is no formal approval of “veterinary devices.” The Center for Veterinary Medicine (CVM) refers to those medical devices used exclusively for animals, as veterinary devices and these are subject to the general provisions of the Federal Food Drug and Cosmetic Act (FFDCA) that relates to misbranding, mislabeling and adulteration. Example: A veterinary device is considered misbranded and mislabeled if the labeling is false or misleading. A veterinary device is misbranded if it is promoted or makes claims, which are not consistent with the labeling. Stated another way: though there is no approval process for veterinary devices, the FDA/CVM does have regulatory oversight with respect to how the products are promoted and marketed.

Summary of distinctions between medical devices and “veterinary” devices:

- Device manufacturers who make or distribute devices used exclusively within veterinary medicine are not required to register their establishments or list their devices with the FDA/CVM.
- There are no Premarket Notification requirements.
- There are no Premarket Approval requirements.
- There are no mandatory adverse event reporting requirements.
- There are no **registered/approved veterinary medical devices.**

Use of Medical Devices

Along with more traditional device products such as radiographic and shock-wave machines, there are other devices which are generally perceived, or appear to be, similar to pharmaceutical products used for treatment of animals and labeled for indications such as cryopreservation, topical wound treatment, prevention of adhesions, joint lavage and similar indications.

Veterinarians have the professional purview to use products in a manner which may not be consistent with labeling. Extra-label use specifically applies to pharmaceuticals (drugs) and is delineated in the Animal Medicinal Drug Use Clarification Act (AMDUCA). The extra-label use as described in AMDUCA pertains to FDA approved pharmaceutical products. **For human medical devices or veterinary devices, as described here, there is no reference document regarding extra-label use.** Therefore, extra-label drug use does not apply to veterinary devices. The primary concern regarding veterinary devices, labeled for local or systemic administration, is their use as pharmaceuticals. An example would be the IV administration of any medical device which acts chemically to cause an effect. This concern is warranted because veterinary devices have not been evaluated to determine their suitability, safety or efficacy as a drug.

How can a practitioner determine if the product he or she is using is a veterinary device?

Unfortunately, this is not as easy as would be reasonably assumed. Veterinary devices which are liquids, gels or sheets may have labeling which appears similar to that found on pharmaceutical products (FDA-approved drugs) falsely suggesting that the device is an approved pharmaceutical. All FDA-approved veterinary pharmaceutical products carry a six-digit New Animal Drug Application (NADA) or Abbreviated New Animal Drug Application (ANADA—for generics) number on the label. The labeling of medical devices used within veterinary medicine does not contain label verbiage identifying the product as a device. If the practitioner has questions regarding the status of a product, he or she should ask the manufacturer or their representative for clarification.

Should a veterinarian choose to use a veterinary device as a pharmaceutical, he or she should consider the following:

- The care and welfare of the horse should be foremost for all treatment decisions.
- The medical devices manufactured solely for use in veterinary medicine have not gone through any type of approval process, as such, *there is no requirement for safety or efficacy evaluation.*
- The manufacturing process of these devices is not required to meet specific, uniform standards. For example, there is no regulatory oversight process to assure quality control of purity, potency, stability and sterility.
- There are no mandatory requirements for reporting or cataloging an adverse event.
- It is AAEP's position that if there are FDA-approved products available and formulated in the appropriate dosage for the disease indication of the patient, those products should be used in preference to a medical device used as a pharmaceutical.

- Before a veterinarian uses a medical device as a pharmaceutical, he or she should consider consulting with their liability insurance provider.
- Veterinarians should inform clients when a medical device is used as a pharmaceutical.
- It is unethical for a veterinarian to promote or represent a medical device as equivalent to an approved pharmaceutical product.
- It is illegal for a manufacturer to promote or represent a medical device as a pharmaceutical.

Summary

Medical devices are designed and manufactured for a specific use. These products may be useful tools to the equine practitioner for those intended purposes. Should a practitioner choose to use a device as a pharmaceutical, he or she should be aware that these products have not been evaluated to determine their suitability for that usage by any regulatory agency. The final decision as to whether to use these products should be based upon what is in the best interest of the equine patient.

Regarding the use of injectable medical devices, the AAEP supports the guidelines provided in AMDUCA regarding the extra-label use of pharmaceuticals and reminds practitioners these guidelines do not apply to medical devices.

The FDA has considerable resource information available on medical devices and the practitioner is encouraged to review this material. Several web sites have been included in the reference section of this document for that purpose.

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Glossary

Adulterated A regulatory term used to describe a product which has not met any aspect of approval, manufacturing, marketing or any other mandatory requirements as described in the code of federal regulations which governs that specific product classification.

AMDUCA The Animal Medicinal Drug Use Clarification Act was passed into law in 1994 and took effect in 1996. This legislation legalized extra label drug use for veterinarians and set the parameters for this use within veterinary medicine.

ANADA Abbreviated New Animal Drug Application is the FDA/CVM required submission process which is necessary to receive approval of a generic veterinary drug.

CDRH The **Center for Devices and Radiological Health** is the branch of the United States Food and Drug Administration responsible for the premarket approval of all medical devices, as well as overseeing the manufacturing, performance and safety of these devices. The CDRH also oversees the radiation safety performance of non-medical devices which emit certain types of electromagnetic radiation, such as cellular phones and microwave ovens.

CVM The Center for Veterinary Medicine is a branch of the U.S. Food and Drug Administration (FDA) that regulates the manufacture and distribution of food, food additives, and drugs that will be given to animals.

GMP Good manufacturing practice or "GMP" is part of a quality system covering the manufacture and testing of active pharmaceutical ingredients, diagnostics, foods, pharmaceutical products, and medical devices. GMPs are guidelines, and in some countries such as the USA regulations, that outline the aspects of production and testing that can impact the quality of a product.

FDA Food and Drug Administration (FDA or USFDA) is a government agency of the United States Department of Health and Human Services. The FDA is responsible for regulating and supervising the safety of foods, tobacco products, dietary supplements, prescription and non-prescription medication, vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), veterinary products, and cosmetics.

FFDCA The Federal Food, Drug, and Cosmetic Act (abbreviated as FFDCA, FDCA, or FD&C) is a set of laws passed by Congress in 1938 giving authority to the U.S. Food and Drug Administration (FDA) to oversee the safety of food, drugs, and cosmetics. These laws have been updated and expanded since that time.

Misbranded To brand or label misleadingly or fraudulently or in violation of statutory requirements. A device is considered misbranded if the company did not notify FDA of its intent to introduce the device into commercial distribution.

Mislabeled Labeled falsely and in violation of statutory requirements.

NADA New Animal Drug Application; this is the FDA/CVM required submission process which is necessary to receive approval of a veterinary drug.

Pharmaceutical For the purposes of this paper, pharmaceutical shall mean an FDA-approved drug product.

Premarket Notification A premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective; that is, substantially equivalent to a legally marketed device that is not subject to a premarket approval process (PMA). This is also referred to as a 501(k) submission—which alludes to the section of the Code of Federal Regulations Title 21 which specifies the submission requirements.

Premarket Approval The FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices and is significantly different from the Premarket Notification process known as 510 (k). Due to the level of risk associated with Class III devices, FDA has determined that general and special controls alone are insufficient to assure the safety and effectiveness of class III devices.

Veterinary Device Used to describe a medical device manufactured for exclusive use within veterinary medicine. It is acknowledged there is no specific medical device classification recognized by FDA/CVM as “veterinary device.”

References

<http://www.nrsp-7.org/Legislation/AMDUCA.pdf>
(AMDUCA)

<http://www.fda.gov/AnimalVeterinary/ResourcesforYou/ucm047117.htm>
(veterinary devices)

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm>
(device classification)

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm>
(Is the product a medical device?)

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051549.htm>
(medical device class I and II exemptions)

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm>
(submission process)

<http://www.fda.gov/AnimalVeterinary/ResourcesforYou/FDAandtheVeterinarian/default.htm>
(excellent general resource regarding CVM)

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm#list>
(overview of device regulation)

<http://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm>
(search engine for medical devices)

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm>
(data bases, includes medical devices)