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GENERAL REVIEW AND ENFORCEMENT POLICIES

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NEW ANIMAL DRUG REGULATION

To be legally marketed in accordance with the FFDCA and CFR New animal drugs are required to be subject to approved new animal drug applications (NADA) supported by adequate safety and effectiveness data. Review of data, labeling and manufacturing controls and procedures by the Office of New Animal Drug Evaluation (ONADE) are key elements in evaluating new animal drug applications.

I. Purpose:

To provide general references and guidance to regulation of new animal drugs.

II. Authority:

Specific sections of the law and specific regulations are cited in the guides on investigational and new animal drugs, labeling and medicated animal feeds. Key regulatory authority is as follows:

A. The Federal Food, Drug, and Cosmetic Act (FFDCA):

1. Definitions: Section 201, which defines among other things labels, labeling, new drugs, new animal drugs and animal feed.
2. Prohibited Acts: Section 301 prohibits interstate commerce of any adulterated or misbranded food, drug, device or cosmetic. It also prohibits the adulteration or misbranding of these articles while in interstate commerce or while held for sale after shipment in interstate commerce. There are numerous other prohibited acts in this section of the FFDCA.
3. New Animal Drugs: Section 512 sets forth the authority for regulating new animal drugs, including generic animal drugs, and feeds containing new animal drugs. It provides an exemption for new animal drugs intended solely for investigational use.
4. Drug Registration and Listing: Section 510 sets forth the requirements for registration of facilities and listing of drug products.
5. Adulteration and Misbranding: Sections 501 and 502 set forth the authority to deem drugs (and devices) adulterated and misbranded.

- B. The rules codified under Title 21 of the Code of Federal Regulations (CFR) are intended to facilitate the enforcement of the FFDCA. Of special pertinence are:
1. Subchapter E - Animal Drugs, Feeds, and Related Products. This subchapter is the principal location of new animal drug regulations. Parts 500 and 510 set forth requirements and warnings for various drugs including Specific Administrative Rulings and Decisions. Parts 511 and 514 cover investigational new animal drugs and commercial marketing of new animal drugs. Parts 520-558 (except Part 556) list the approved new animal drugs including drugs for use in animal feeds. Part 530 lists drugs prohibited from extralabel use in animals. Part 556 lists residue tolerances.
  2. Subchapter A - General. This subchapter contains general regulations for the enforcement of the Act. It also contains sections on environmental impact considerations, color additives, and good laboratory practices.
  3. Subchapter C - Drugs: General. Regulations concerning drug labeling, drug registration/listing, good manufacturing practice and other requirements are found in this chapter.

III. Approved New Animal Drugs:

These include new animal drugs that have an approved NADA.

IV. Generic New Animal Drugs:

These include new animal drugs that have an approved abbreviated new animal drug application (ANADA). These drugs should be a duplicate of a reference listed new animal drug.

V. Investigational New Animal Drugs:

These include new animal drugs that are used under the provisions of an investigational new animal drug application (INAD).

VI. Supplemental New Animal Drug Applications:

These are applications, made by sponsors, which amend the originally approved NADA or ANADA.

VII. Unapproved New Animal Drugs:

These include new animal drugs which have not been the subject of an approved NADA, ANADA or are provided for in an INAD.

Unapproved new animal drugs are deemed unsafe under §512 of the FFDCa. As unsafe NADs they are adulterated under §501(a) (5) of the FFDCa and are misbranded under §502 of the FFDCa.