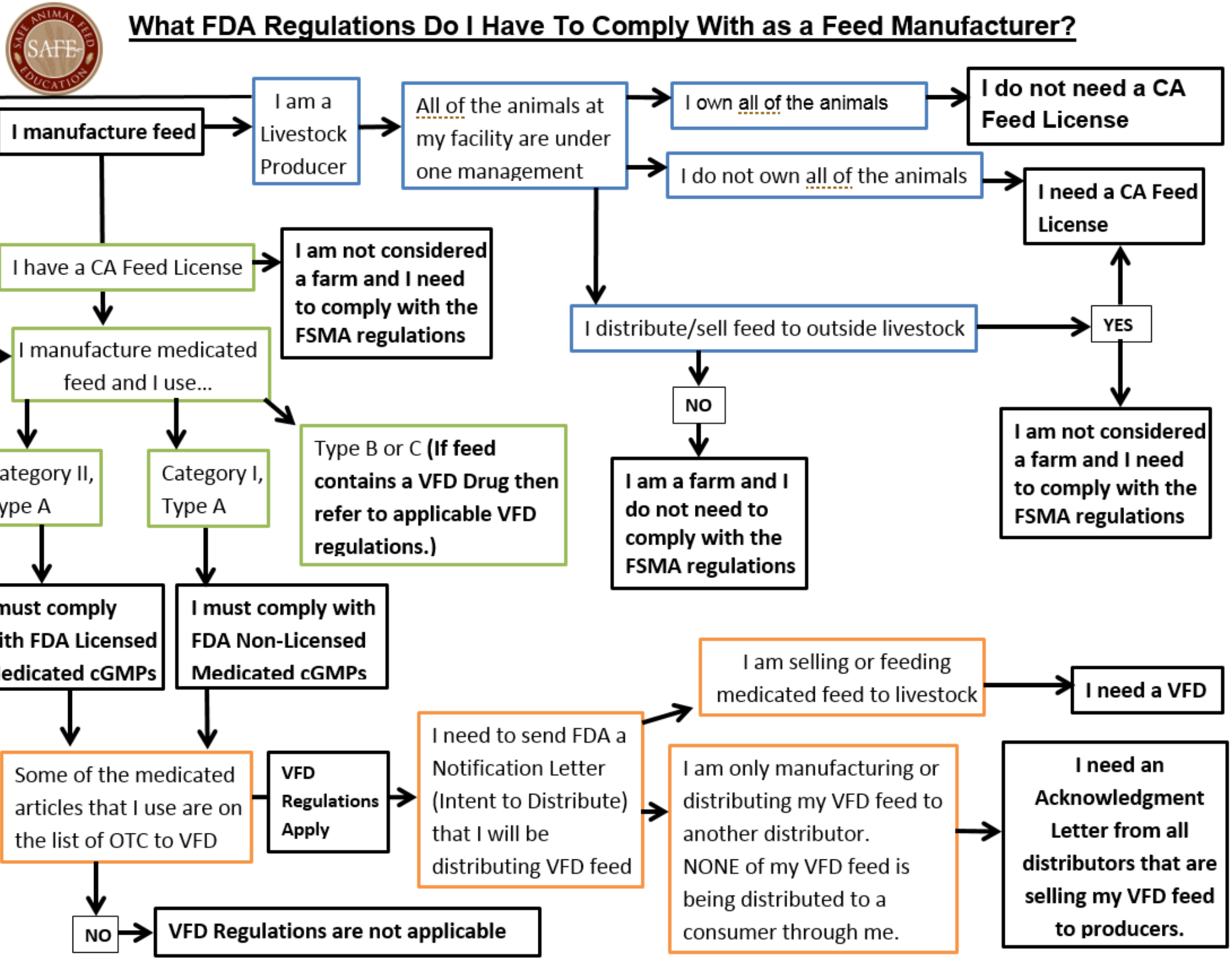
What FDA Regulations Do I Have To Comply With as a Feed Manufacturer?



Definitions

Category I drugs- those for which no withdrawal period is required at the lowest use level in each species for which they are approved.

Category II drugs- those (1) for which a withdrawal period is required at the lowest use level for at least one species for which they are approved, or (2) that are regulated on a “no-residue” basis or with a “zero” tolerance because of carcinogenic concern, regardless of whether a withdrawal period is required.

Type A medicated article- a product of standardized potency containing one or more new animal drugs intended for use in the manufacture of another medicated article or a medicated feed.

Type B medicated feed- An animal feed containing a new animal drug and is intended solely for manufacture into another Type B or Type C medicated feed that is produced by a drug component, a Type A medicated article or Type B medicated feed.

Type C medicated feed- a medicated feed containing a new animal drug that may be offered as a complete feed, or may be fed top dressed or offered free choice in conjunction with other animal feed to supplement the animals’ total daily ration. It is produced by substantially diluting a drug component, a Type A medicated article or a Type B or Type C medicated feed, with ingredients to a level of use that is covered by an approved new animal drug application.

OTC (Over the counter)- drugs that are available over the counter without veterinary oversight or consultation.

VFD (Veterinary Feed Directive) Drug- a drug that is intended for use in or on animal feed which is limited by an approved application and is to be used only under the professional supervision of a licensed veterinarian.

VFD (Veterinary Feed Directive)- a written (nonverbal) statement issued by a licensed veterinarian in the course of the veterinarian’s professional practice that orders the use of a VFD drug in or on an animal feed. The written statement authorizes the client (the owner of the animal or animals or other caretaker) to obtain and use animal feed bearing or containing a VFD drug or combination VFD drug to treat the client’s animals only in accordance with the conditions for use approved, conditionally approved, or indexed by the Food and Drug Administration.

Distributor- any person who distributes a medicated feed containing a VFD drug to another person. Either another distributor or the client-recipient of a VFD).

FSMA (Food Safety Modernization Act)- signed into law by President Obama in 2011, and is intended to allow FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA enables FDA to focus on preventive food safety problems rather than relying primarily on reacting to problems after they occur

Acknowledgement Letter- A written (nonverbal) communication provided to a distributor (consignor) from another distributor (consignor). An acknowledgement letter must be provided either in hardcopy or through electronic media and must affirm: (1) that the distributor will not ship such VFD feed to an animal production facility that does not have a VFD, (2) that the distributor will not ship such VFD feed to another distributor without receiving a similar written acknowledgment letter, and (3) that the distributor has complied with the distributor notification requirements.

Notice of Intent to Distribute VFD Feed- must be filed to FDA prior to distributing any VFD feed. This letter must include the distributor's complete name and business address; the distributor's signature of the distributor's authorized agent; and the date the notification was sent.

Livestock Producer- a feedlot, dairy, integrated and non-integrated poultry or swine facility, etc.

"Selling Feed" in California- any time livestock feed is sold or distributed in California.

In the case of a livestock producer,

-if a facility is managing livestock that are owned by different people and the facility charges the livestock owners on the amount of feed being consumed then that is considered selling feed and requires a CA commercial feed license.

- if a facility is managing livestock that are owned by different people and the facility is feeding the animals but charges the livestock owner a flat fee that does not vary based on the feed consumed then the facility is providing a service and it is not considered selling feed.

FDA Licensed Medicated cGMP or Medicated Feed Mill License (MFML)- feed mills that manufacture Type B or Type C medicated feeds from a Category II, Type A medicated article; liquid or free-choice feeds using a Category II drug, and liquid or free-choice feeds using a Category I drug and proprietary formula and/or specifications, must be licensed with FDA. These mills must comply with the FDA Licensed Medicated cGMP regulations.

FDA Non-Licensed Medicated cGMP or Non Licensed Medicated Feed- feed mill that manufacture Type B or Type C medicated feeds from Category I, Type A medicated articles are not required to have a license with FDA, however, they are required to comply with FDA Non-Licensed Medicated cGMP regulations.