Appendix 4

Plan for Transitioning to New Labeling by January 1, 2017

CVM's primary goal is that beginning on January 1, 2017, all affected products (medically important antimicrobials approved for use in animal feed or water) are to be used in the market in accordance with the changes outlined in GFIs #209 and #213 as part of FDA's strategy to ensure the judicious use of medically important antimicrobials in animal agriculture. This means that, as of that date, such products would no longer be used for production (i.e. growth promotion and feed efficiency) purposes and would only be used with the prior authorization of a licensed veterinarian.

The FDA sent a letter in September 2015 to each affected animal drug sponsor outlining the process of transitioning their products to remove approval for production use and to phase in veterinary oversight for the remaining therapeutic uses of these products by the end of December 2016. The letter also explained the approval process for each label change and outlined the materials sponsors need to submit to the agency in order to complete the transition.

Below are key time periods that were discussed in the letter to animal drug sponsors, and some of the different labeling you may see enter the market as animal drug sponsors manage product inventories and facilitate the transition to new labeling by the January 1, 2017, target date.

A. Between now and June 30, 2016

Transitional labeling: Between now and June 30, 2016, drug sponsors may use "transitional labels" provided with the existing product labeling and/or information that is printed on or affixed to the product labeling. If such "transitional labeling" is used, we would expect such labeling to be consistent with the following statements:

> ***Statement that applies to feed products:*** *Beginning January 1, 2017, this product will require a veterinary feed directive issued by a licensed veterinarian and will be subject to the following restriction:*
>
> "Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian." [6]
>
> ***Statement that applies to water products:*** *Beginning January 1, 2017, this product will require a prescription issued by a licensed veterinarian and will be subject to the following restriction:*
>
> "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian." [7]

[6] 21 CFR Sec. 558.6 (a) (6)

Statement that applies to all feed or water products with production indications: *Effective January 1, 2017, this product will no longer be approved for [insert all production indications as they appear on labeling] which means the use of this product for that [/these] purpose[s] will no longer be legal.*

We expect all agreements on new labeling to be in place and labeling supplement materials submitted to FDA by drug sponsors by no later than June 30, 2016. Therefore, after June 30, 2016, we have asked sponsors to use discretion in deciding whether to continue to apply "transitional labeling" to new product inventory.

Given the unique circumstances and the temporary nature of this "transitional labeling," we informed sponsors that we would not object to them immediately labeling affected product with the above information. As such, distributors may see this "transitional labeling" on the market between now and June 30, 2016, and to a more limited extent, after June 30, 2016.

B. Between June 30, 2016 and January 1, 2017

Between June 30, 2016 and January 1, 2017, we expect the drug sponsors to begin manufacturing product containing the new labeling for distribution to the marketplace on or after January 1, 2017. New labeling could utilize stickers affixed to existing product labeling and/or new printed labeling.

For medicated feed products, sponsors will also need to generate updated Blue Bird labels. We have informed sponsors that it would be helpful to make available advance copies of the updated Blue Bird labels for feed manufacturers.

New animal drug sponsors have been encouraged to manage product inventory appropriately so that new labeling will not enter the market before January 1, 2017. Product labeled with new VFD drug labeling (restricting medicated feed containing the VFD drug to use by or on the order of a licensed veterinarian) will not include a "transitional statement" indicating the implementation begins January 1, 2017, and may be confusing.

Please note: a veterinary feed directive is not required to be issued by a licensed veterinarian for affected products transitioning from OTC to VFD status until January 1, 2017.

C. After January 1, 2017

As noted above, our primary goal is that beginning on January 1, 2017, all affected products are to be used in the market in accordance with the changes outlined in GFIs #209 and #213. This means that on that date, feed manufacturers will be expected to begin labeling medicated feeds with the new GFI #213-aligned Blue Bird labels.

---

[7] 21 CFR Sec. 201.105 (a)(2)

Our expectation is that beginning on January 1, 2017, product is either 1) labeled with "new" final printed label, 2) has a sticker affixed to the product that includes the "new" final label language, or 3) is labeled with the "transitional label" statement(s) described above.

Additional Resources:

- Letter to Sponsors Regarding Implementation of GFI 213: http://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/UCM482139.pdf
- Judicious Use of Antimicrobials http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/default.htm