

**CVM's Helpful Hints on Labeling Submissions**

## Comments on Labeling Supplements

1. Rather than indicating that 'format' changes were made, it is helpful to indicate what specific changes have been made.
2. Please send in the Type B and C labels when needed (need if no Volume 0 created yet or if changes to the A precipitate changes to B/C).
3. Follow current AAFCO guidelines for creating new Type B and C labeling.
4. The Indications on Type B and C labels should exactly match that on the Type A labeling.
5. Please check the calculations in Mixing Directions for Type B and C feeds. We sometimes see math errors.
6. Use established names in title of blue birds rather than trade names (see AAFCO manual).
7. Give unique names to Blue Birds for a particular product (e.g., several bluebirds called swine ration so can't distinguish).
8. Sponsors have been submitting FPL to HFV-140 instead of to the target animal review division. FPL should always be submitted to the target animal review division and not to HFV-140, even if the labeling was approved in a CMC supplement.
9. Sponsors unnecessarily incorporate labeling in some CMC supplemental applications. If a CMC change requires a change in labeling, e.g., storage condition, change in manufacturing site (not in all cases), etc., then updated labeling should be included. If there is no CMC impact on labeling, no labeling should be submitted.
10. Need a 356V. Fill out FDA 356V correctly, particularly the proprietary name and established name.
11. Need a categorical exclusion request.
12. Helpful if you include the letter from OSC if making changes in response to their letter
13. Clearly mark "supplement—labeling changes being effected" Don't call it a CBE-30.
14. Update horse labels with the current food consumption statement (Do not use in horses intended for human consumption).
15. Helpful if you indicate in the cover letter which container size(s) or concentration(s) (if Type A) is currently being marketed.

16. Helpful if sponsor can identify the last submission to CVM that contained approved labeling, whether it was to an NADA submission or to the DER file. Include date and submission code. This will help CVM searching the files.
17. Helpful if sponsor is aware of and points out any discrepancies between the label and the CFR citation for their drug product.
18. Environmental assessment must be included with the manufacturing submissions along with 356V. Cover letter should include information regarding what you are trying to do (i.e. if you have labeling changes, etc.). Heavy focus on 356V.