Single Tier Label Claim

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INTRODUCTION

For many years, the Center for Veterinary Biologics (CVB) has been interested in improving the regulatory approach to information presented on biological product labeling. A particular focus of this effort has been looking for mechanisms to improve the way information is provided to the end-user regarding product performance. It is envisioned that a change in the way information is presented will allow the end-user to make a more informed decision regarding the performance of the product.

A single label claim, or single uniform indication statement is being proposed to replace the current 4-tier label claim system described in VS Memorandum 800.202. A critical component of this single label claim is a required statement on labels referring the end-user to a website (location undetermined) where basic, yet relevant, data regarding efficacy and safety for any given product may be reviewed by the public. This information will be in a standardized tabular format with no confidential business information. The proposed single label claim will not change the manner efficacy studies are evaluated or the information on Container or Circular labels. The drivers for this regulatory action and the proposed impact on those drivers are found below. A series of potential questions and answers are also included.

DRIVERS

1. The various levels of label claims are often poorly understood in the market place. For a particular product, it may not be clear what a label claim means and often supporting data that the claim is based on is not provided.

Effect of proposed single label claim:

- Replace the current four tier system with a single claim that carries the implication that if the product is licensed, it is efficacious and meets USDA requirements.

- Rather than have more information on the label, this proposal will require a label statement referring the user to a website (location undetermined) where basic information regarding efficacy (and safety) for the product may be viewed. The user may also compare efficacy results from several firms with like products. Thus, the end-user can use personal judgment in determining which product to use to meet his/her particular circumstances/needs. End-users are encouraged to consult their veterinarian or animal health professional about the use of a particular product, as they deem appropriate.

- Product performance includes both efficacy and safety. The quantity of safety data incorporated into this proposed regulatory action is open to discussion.

2. Current label claims have sometimes been utilized as marketing tools.

Effect of proposed single label claim:

- The supporting data for each product included on the website will make the demonstration of product efficacy more transparent to the end-user.

- The supporting data provided should give a better indication of product performance than which category of label claim the product previously displayed.

3. Changing the labeling approach to a single claim has the potential to save both biologics manufacturer and agency resources.

Effect of proposed single label claim: (in addition to Driver #2)

- Changes in the efficacy data will be reflected in the data presented on the web-site, and may not have any significant changes on the container labeling itself.

- Not putting a product into a certain efficacy category may save time in terms of regulatory review required, as well as industry resources in terms of animals used, studies performed, etc.

- Provides transparency with regard to product performance across the regulated industry. High quality products/data will drive the market.

Questions and Answers:

1. What is the purpose of labeling?
   Ans: Labeling allows a lay person to be able to understand the proper need, administration, revaccination, and precautions that must be taken in order to use the product effectively and safely.

2. How will products currently with claims of a particular disease form (i.e., PRRS) be treated?
   Ans: The label claim may include "This product is effective for the control of the respiratory form of disease caused by PRRS virus", or similar language.

3. Will safety data be available in conjunction with efficacy data?
   Ans: Including safety data as part of the data set that is presented for a product on the web-site has been considered. Whether this occurs, or safety data is reflected on the label as is currently the practice is a point of interest/discussion.

4. Where will the statement referring the reader to the website be located?
   Ans: This statement may appear at the end of the current labeling requirements or it may be incorporated into the label claim (i.e., "This product is effective in

dogs/cats/swine/cattle/poultry against disease caused by (microorganism X). For efficacy data, go to proposedwebsite.com/gov.").

5. Will this proposed regulatory action include additional changes to labeling such as age of animals used, repeat vaccination, maternal antibody override, removal of the True Name?
   Ans: The proposed action includes only efficacy claims. Depending on the comments received, safety data may be incorporated. The age of animals, repeat vaccinations, and maternal antibody override issues are already addressed on labels. CVB currently has no plans to drop the requirements for including True Names on labeling materials. CVB will continue to look for ways to improve product labeling in the future.

6. How much of the efficacy study design will be made available?
   Ans: Unless subsequent study data is available (such as for a change in label claim), the data will be the original efficacy data used to license the product. Sufficient information from that data will be placed on the website so the end user can make an informed decision regarding the performance of the product.

   Information that is envisioned to be made public include: number, age, and serological status of animals; age at first vaccination; interval between vaccinations if appropriate; interval between vaccination and challenge; challenge organism (not strain) and dose (including numbers of organisms/ml or $TCID_{50}$/ml etc).

   The data itself will be presented in such a way that the numbers of animals in control and vaccinate groups exhibiting clinical signs of the disease will be listed. In cases such as lung lesion scores, a footnote may be included to provide information on how the scoring was completed. In no instance will confidential business information (CBI) be disclosed.

7. Will the firms have a chance to review the Summaries of Efficacy data and how will that process be addressed?

   Ans: CVB is still considering options related to this issue. Firms will likely have an opportunity to review data in the Summary of Efficacy data table prior to being placed onto the designated website for public viewing.

8. Will CVB's review of the study reports change with this proposed regulatory action?
   Ans: No. Review of reports will proceed as usual.

9. Given that Firm A has a current label claim of "for prevention of disease due to…". Firms B and C have claims of "aids in prevention of disease…" and "aids in control of disease…" for the exact same product. How will CVB address this issue?
   Ans: The original efficacy data from these products will be available for public review on an undetermined website. It is our intent that the efficacy data presented on the web-site will demonstrate those differences to the end-user.

10. In some cases, firms do not have the original efficacy data for products that are many decades old (i.e., leptos, IBR, distemper, etc). How will CVB address this issue?

Ans: The CVB recognizes this may be the case for some products. For these products, a statement may be inserted indicating the efficacy data for these products is not available due to the fact that it was licensed many years ago.

11. Will this regulation apply to reference qualification/requalification data? If so, will the original efficacy data be made available on the website together with the most recent reference qualification data?

Ans: Efficacy and reference qualification data, albeit linked, are different and serve a different purpose. At this time, CVB's position is that reference qualification/re-qualification data may be on the website as an addendum to the original efficacy study if it demonstrates a significantly different level of efficacy. However, the reference qualification/requalification data will not replace host animal efficacy studies.

12. Will this regulatory action replace the eFOIA initiative by CVB?

Ans: Yes.

13. The regulation proposes a website where Summaries of Efficacy data may be viewed by the public. Will firms be allowed to use these summaries in promotional and advertising materials?

Ans: Firms will be able to reference the website, as they can reference other publically available information. Firms will not be allowed to make false or misleading statements about their products, or those of their competitors, consistent with the policies currently in place.

14. How will CVB address those "parent" products having fall-out products on the website?

Ans: Original efficacy data for each fraction in the "parent" product will be made available. It is envisioned that all fall-out products will be tied to the "parent" whether by informational statement or by adding copies of the appropriate fraction to each of the fall-out products. In the latter case, an informative statement may be included to refer the reader to the "parent" product.