ANTIBACTERIALS LABELED FOR SECONDARY INFECTIONS

In the early 1950s, apparent success in reducing mortality in an unfamiliar turkey disease referred to as mud fever, blue comb, or transmissible enteritis, led researchers to believe that antibiotics and other drugs had a beneficial effect on the causative agent. Several drug products were subsequently approved with claims for prevention and treatment of the disease. Studies on the etiology of the disease extended over a 20-year period. In the early 1970s, the cause of the disease was determined to be a virus which is now generally recognized as a coronavirus.

Because of the above information and the fact that antibacterials are not known generally to affect virus infections, any beneficial effect is believed to result from reducing death loss from secondary bacterial infections caused by bacteria sensitive to the drug. Generally, there is little or no effect on the morbidity of the primary infection. This principle can be applied to all drug products labeled with the indications for use against viral infections or "associated" secondary infections.

1. Purpose:

   The purpose of this guide is to provide guidance for review of products intended to control secondary bacterial infections.

2. Policy:

   Labeling of antibacterials intended for use against secondary infections should not directly or by implication claim benefit, or appear to claim benefit against viral infections. Preferably viral infections need not be mentioned unless the effectiveness studies were specifically designed to assess efficacy under clinical conditions where both the viral agent and the bacterial agent are present.

3. Statutory Authority:

   Federal Food, Drug, and Cosmetic Act (FFDCA).

   1. Section 502(a). A drug shall be deemed to be misbranded if its labeling is false or misleading in any particular.

   2. Section 512(d)(1)(G). False and misleading labeling is a basis for refusing to approve an application.

4. Discussion:

For consistency, antibacterials, including antibiotics, should be indicated for specific infections caused by specific bacteria, as for example, mastitis infusion products are now labeled. However, based on the then state-of-the-art, CVM has approved many antibacterials indicated for bacterial infections caused by "organisms sensitive to the drug." This would include, by inference, any bacterial infections which might be considered as "secondary" to either another primary bacterial infection or to a viral infection. Scientifically, if any antibacterial is effective against a sensitive organism, it would make little difference if that organism were the cause of a primary infection, or if it were the cause of a so-called secondary infection. In the latter case, the mention of the primary disease is meaningless and superfluous, and may be more misleading than informative or helpful. Nevertheless, considering that early on, there was some basis for believing there might be some beneficial effect on otherwise untreatable disease, and that labels were approved, thusly, we have continued to approve products indicated for secondary infections "associated with" viral infections.

In order not to be false or misleading in any particular, the wording in the label should reflect clearly that the beneficial effect is only on the secondary infections and not on a viral infection. Any direct or implied claim of benefit against a viral infection would be false or misleading, unless supported by substantial evidence.

5. Examples:

a. Acceptable - For control of secondary bacterial infections such as (name(s) of pathogen(s)) associated with (name of viral agent or disease complex).

b. Unacceptable - For control of (viral disease) complicated by bacterial infections.

6. Implementation:

a. Labeling for new original applications, or supplements, should be in accord with this policy.

b. The Office of Surveillance and Compliance (HFV-200) will initiate action as feasible to correct labeling for previously approved products if it is not in accord with this policy.