



POLICY & ACTION FROM CONSUMER REPORTS

Comments of Consumers Union

On

California Department of Food and Agriculture

Notice of Modifications to the Text of Proposed Regulations on Title 3 Food and Agriculture Division 5 Livestock Drugs, Chapter 1. Sales of Restricted Livestock Drugs and Chapter 2. Sales of California Prescription Drugs

By

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Consumers Union (CU), the policy and mobilization arm of Consumer Reports,¹ appreciates the chance to comment on California Department of Food and Agriculture (CDFA) Notice of Modifications to the Text of Proposed Regulations on Title 3 Food and Agriculture Division 5 Livestock Drugs, Chapter 1. Sales of Restricted Livestock Drugs and Chapter 2. Sales of California Prescription Drugs. These proposed regulations are part of the implementation of SB 27 on use of antimicrobial drugs in livestock. We support the proposed text modifications in Chapter 1 on sales of restricted livestock drugs which serve to strengthen the regulations by making the licensing procedures more stringent. We also support the suggested text modification in both Chapters 1 and 2 which clarify when a warning notice will be issued upon the finding of a violation, and remove the possibility of contesting any fines that result from those violations.

¹ Consumers Union is the policy and mobilization arm of Consumer Reports. Consumers Union is an expert, independent, nonprofit organization whose mission is to work for a fair, just, and safe marketplace for all consumers and to empower consumers to protect themselves. It conducts this work in the areas of food and product safety, telecommunications reform, health reform, financial reform, and other areas. Consumer Reports is the world's largest independent product-testing organization. Using more than 50 labs, auto test center, and survey research center, the nonprofit organization rates thousands of products and services annually. Founded in 1936, Consumer Reports has over 7 million subscribers to its magazine, website, and other publications

Detailed comments

Chapter 1. Sales of Restricted Livestock Drugs

In Article 3 Licensing, §5002 License Application, CDFA's proposed modifications to the text clarify the conditions which lead to denial of a restricted livestock drug license application. The proposed regulations state that a license is needed to sell restricted livestock drugs, which are defined as drugs which may cause harm to human health or animal health if misused. Such drugs include antimicrobial preparations including medically important antibiotics.

Presently, §5002(f) states, "A restricted livestock drug application may be denied if prior enforcement actions have been taken against the applicant, owner(s) listed, parent company, or the location to be licensed," which leaves it unclear what kind of enforcement actions would lead to denial of a license. CDFA proposes to strengthen the language by making it clear that the restricted livestock drug application will be denied if the applicant has been issued two or more violations in the last 12 months, "A restricted livestock drug application ~~may~~ *shall* be denied if ~~prior enforcement actions have been taken against~~ *two or more violations has been issued to* the applicant, owner(s) listed, parent company, or the location to be licensed *within the previous twelve (12) months*" deletions in ~~strike through~~, additions in *italics*. We support these changes to §5002(f) since they strengthen the law by removing ambiguity over what actions will result in a license being denied.

In Article 3 Licensing, §5003 License Renewal, CDFA has made similar changes. Proposed modifications to the text clarify the conditions which lead to denial of a renewal of a restricted livestock drug license application. Presently, §5003(f) states, "A restricted livestock drug renewal application may be denied if prior enforcement actions have been taken against the applicant, owner(s) listed, parent company, or the location to be licensed," which leaves it unclear what kind of enforcement actions would lead to denial of a license renewal. CDFA proposes to strengthen the language by making it clear that the restricted livestock drug application will be denied if the applicant has been issued two or more violations in the last 12 months, "A restricted livestock drug renewal application ~~may~~ *shall* be denied if ~~if prior enforcement actions have been taken against~~ *two or more violations has been issued to* the applicant, owner(s) listed, parent company, or the location to be licensed *within the previous twelve (12) months*" deletions in ~~strike through~~, additions in *italics*. We support these changes to §5003(f) since they strengthen the law by removing ambiguity over what actions will result in a license being denied.

In Article 5, Violations and Penalties, §5006 Penalties, CDFA's proposed modifications to the text make clearer when a notice of warning will be issued upon the finding of a violation, and remove the possibility of contesting any fines that result from the violation. Presently, the proposed text of §5006(a) simply states that CDFA may issue a notice of warning, while

CDFA's proposed modifications to the text makes clear that a violation will automatically result in a notice of warning: "Upon finding a violation, the ~~Secretary-Department may~~*shall* issue a notice of warning *in accordance with Section 14382 Food and Agricultural Code*" deletions in ~~strike~~*through*, additions in *italics*. Present text of §5006(b) and §5006(c) state that a first violation of this chapter leads to a fine of \$400, while subsequent violations lead to a fine of \$1,000, but CFDA proposes no changes to this text. Present text of §5006(d) states that a person may contest a fine for any violations by requesting an informal hearing at CDFA within thirty days of when the notice of fine was signed, while CDFA proposes to delete all of §5006(d) so that fines for violations cannot be contested. We support CDFA's proposed changes to §5006(a) and 5006(d), since these changes will strengthen the regulation by removing ambiguity over what actions will result in a warning notice and remove the possibility of contesting any fines associated with a violation.

Chapter 2. Sales of California Prescription Drugs

In Article 4, Violations and Penalties, §5015 Penalties, CDFA's proposed modifications to the text clarify when a notice of warning will be issued upon the finding of a violation, and remove the possibility of contesting any fines that result from the violation. Presently, the proposed text of §5015(a) simply states that CDFA may issue a notice of warning, while CDFA's proposed modifications to the text makes clear that a violation will automatically result in a notice of warning: "Upon finding a violation, the ~~Secretary-Department may~~*shall* issue a notice of warning *in accordance with Section 14408 Food and Agricultural Code*" deletions in ~~strike~~*through*, additions in *italics*. Present text of §5015(b) and §5015(c) state that a first violation of this chapter leads to a fine of \$250 per day, while subsequent violations lead to a fine of \$500 per day, respectively, but CFDA proposes no changes to this text. Present text of §5015(d) states that a person may contest a fine for any violation by requesting an informal hearing at CDFA within thirty days of when the notice of fine was signed, along with a written statement supporting the need for the hearing. CDFA proposes to delete all of §5006(d) so that fines for violations cannot be contested. We support CDFA's proposed changes to §5015(a) and 5015(d), since these changes will strengthen the regulation by removing ambiguity about what actions trigger a notice of warning and removing the possibility of contesting fines associated with violations of the law.

In sum, we support the proposed text modifications in Chapter 1 on sales of restricted livestock drugs (e.g., §5002(f), §5003(f),) which serve to strengthen the regulations by removing ambiguity over what actions result in a license or license renewal being denied. We also support the suggested text modification in both Chapters 1 (e.g., §5006(a), §5006(d)) and 2 (e.g., §515(a), §515(b)) which clarify when a warning notice will be issued upon the finding of a violation, and remove the possibility of contesting any fines that result from those violations.

These changes strengthen the regulation and hopefully signal that CDFA intends to enforce these regulations.

Respectfully submitted,

A handwritten signature in black ink that reads "Michael Hansen". The signature is written in a cursive style with a large, prominent "M" and "H".

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