

AMENDED IN ASSEMBLY JUNE 4, 2014

AMENDED IN SENATE MARCH 26, 2014

**SENATE BILL**

**No. 835**

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**Introduced by Senator Hill**

January 6, 2014

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An act to amend Section 14288 of, and to add Article 4.5 (commencing with Section 18770) to Chapter 4 of Part 3 of Division 9 of, the Food and Agricultural Code, relating to food and agriculture.

LEGISLATIVE COUNSEL'S DIGEST

SB 835, as amended, Hill. Food animals: medically important antimicrobial drugs.

Under existing law, the Secretary of Food and Agriculture has the responsibility of ensuring that ~~food products~~ *livestock or poultry raised for the production of human food* are not adulterated and that they are capable for use as human food. A violation of the laws and regulations relating to the adulteration of livestock or poultry products is a crime, punishable as specified. Existing law regulates the sale of livestock drugs by the secretary, and requires livestock drugs to be registered.

This bill would prohibit the secretary from registering a medically important antimicrobial drug, as defined, ~~which~~ *that* is administered to food animals, as defined, through feed or drinking water, unless prescribed requirements are met. The bill would, except as specified, provide that a medically important antimicrobial drug currently registered with the department that does not meet the prescribed requirements has until January 1, 2017, to meet the prescribed requirements and reregister with the secretary. The bill would require a veterinarian-client-patient relationship, as described, to exist prior to the use of a medically important antimicrobial drug *administered to*

*food animals through feed or drinking water.* Because a violation of the bill’s provisions would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.  
State-mandated local program: yes.

*The people of the State of California do enact as follows:*

1 SECTION 1. Section 14288 of the Food and Agricultural Code  
2 is amended to read:  
3 14288. The secretary shall refuse to register a livestock drug  
4 if he or she finds any of the following is true of the drug:  
5 (a) It is of little or no value for the purpose for which it is  
6 intended to be used.  
7 (b) It is dangerous to the health of livestock if used in accordance  
8 with the instructions.  
9 (c) The instructions for use do not contain adequate warnings  
10 against use in those conditions, whether pathological or normal,  
11 under which its use may be dangerous to the health of livestock  
12 or humans who consume products from the livestock, or against  
13 unsafe dosage, unsafe duration of use, or unsafe methods of  
14 administration.  
15 (d) If the application and the accompanying material, data, and  
16 information do not comply with the requirements of this chapter  
17 or are insufficient to permit the secretary to make the  
18 determinations that are required by this section.  
19 (e) It is a medically important antimicrobial drug, as defined in  
20 Section 18770, ~~which~~ *that* is administered to food animals, as  
21 defined in Section 4825.1 of the Business and Professions Code,  
22 through feed or drinking water, unless the drug complies with  
23 Section 18771.  
24 SEC. 2. Article 4.5 (commencing with Section 18770) is added  
25 to Chapter 4 of Part 3 of Division 9 of the Food and Agricultural  
26 Code, to read:

1 Article 4.5. Medically Important Antimicrobial Drugs

2  
3 18770. For purposes of this article, the following definitions  
4 apply:

5 (a) “FDA” means the federal Food and Drug Administration.

6 (b) “Food animal” has the same meaning as defined in  
7 subdivision (c) of Section 4825.1 of the Business and Professions  
8 Code.

9 (c) “Medically important antimicrobial drug” means an  
10 antimicrobial drug listed in Appendix A of the FDA Guidance for  
11 Industry #152, including a critically important, highly important,  
12 and important antimicrobial drug. ~~The secretary shall have the~~  
13 ~~discretion to consider any changes to this list by the FDA to~~  
14 ~~determine whether a substance is a medically important~~  
15 ~~antimicrobial drug drug, as that appendix may be amended, unless~~  
16 ~~the secretary determines that the amendment to the appendix~~  
17 ~~includes a drug that is not a critically important, highly important,~~  
18 ~~or important antimicrobial drug.~~

19 (d) “Veterinary feed directive” is the directive described in  
20 Section 354 of Title 21 of the United States Code.

21 18771. To comply with FDA Guidance for Industry #213,  
22 dated December 2013, a medically important antimicrobial drug,  
23 including a combination drug incorporating a medically important  
24 antimicrobial drug, shall meet all of the requirements in the  
25 guidance document, including, but not limited to, the following:

26 (a) To reflect the need for professional oversight by a licensed  
27 veterinarian, the manufacturer shall remove from the approved  
28 production uses on the label of the medically important  
29 antimicrobial drug or combination drug the production indications,  
30 including, but not limited to, “increased rate of weight gain” or  
31 “improved feed efficiency.”

32 (b) The manufacturer shall revise the condition of the use of the  
33 medically important antimicrobial drug or combination drug from  
34 over the counter availability to a marketing status requiring  
35 veterinary prescription, including, but not limited to, the following:

36 (1) For medicated feed products, a change from over the counter  
37 to veterinary feed directive.

38 (2) For medicated drinking water products, a change from over  
39 the counter to veterinary prescription.

1 (c) When administered through feed or drinking water, the  
2 medically important antimicrobial drug may only be used to treat,  
3 prevent, or control disease under the supervision of, or by  
4 prescription from, a licensed veterinarian.

5 18772. There shall be a veterinarian-client-patient relationship  
6 to ensure that a medically important antimicrobial drug  
7 *administered to food animals through feed or drinking water* is  
8 used in a manner that is consistent with professionally accepted  
9 best practices. For the purposes of this section, a  
10 “veterinarian-client-patient relationship” is a relationship meeting  
11 the requirements of Section 2032.1 of Title 16 of the California  
12 Code of Regulations.

13 18773. (a) (1) If a medically important antimicrobial drug,  
14 or combination drug, for use in food animals is registered with the  
15 department as of January 1, 2015, and the drug does not comply  
16 with Section 18771, the manufacturer of the medically important  
17 antimicrobial drug, or combination drug, shall have until January  
18 1, 2017, to reregister the drug with the secretary. The secretary  
19 shall refuse to reregister the drug unless it complies with Section  
20 18771.

21 (2) Notwithstanding paragraph (1), if a drug label reviewed by  
22 the FDA under the Guidance for Industry #213 is delayed beyond  
23 January 1, 2017, the secretary shall have the authority to continue  
24 registering the drug during the FDA’s review period.

25 (3) If ~~revision~~ *revisions* to the veterinary feed directive ~~causes~~  
26 *cause* the FDA to delay implementation of the Guidance for  
27 Industry #213, the secretary shall have the authority to extend the  
28 time period by which a manufacturer is required to reregister the  
29 drug pursuant to paragraph (1) to be consistent with the delay in  
30 the implementation of the ~~guideline~~ *guidance*. If the secretary  
31 extends the time period for reregistration, the extension shall not  
32 be later than the federal implementation date of the guidance.

33 (b) If revisions to the veterinary feed directive ~~causes~~ *cause* the  
34 FDA to revise the Guidance for Industry #213, the secretary shall  
35 have the authority to promulgate regulations to ensure that  
36 California law is consistent with the revisions to the guidance.

37 SEC. 3. No reimbursement is required by this act pursuant to  
38 Section 6 of Article XIII B of the California Constitution because  
39 the only costs that may be incurred by a local agency or school  
40 district will be incurred because this act creates a new crime or

1 infraction, eliminates a crime or infraction, or changes the penalty  
2 for a crime or infraction, within the meaning of Section 17556 of  
3 the Government Code, or changes the definition of a crime within  
4 the meaning of Section 6 of Article XIII B of the California  
5 Constitution.

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