

Model Bills and Regulations Committee Report

February 12, 2021 – March 2, 2021 E-Meeting

Committee Recommendations:

The Model Bills and Regulations Committee recommends the following revisions be made to the Model Bills and Regulations, and that the AAFCO Board of Directors review the proposed revisions for future consideration by the Association membership.

Guidelines for Making Therapeutic Diet Claims

AAFCO supports and recommends the following guidelines, as based on FDA CPG 690.150, for dog and cat food products that are intended for use to diagnose, cure, mitigate, treat, or prevent diseases and that are also labeled and/or marketed to provide all or most of the nutrients in support of meeting an animal's total daily nutritional requirements by serving as the pet's sole diet.

1. The product is made available to the public only through a valid veterinarian-client-patient relationship (VCPR) or through retail or internet sales to individuals purchasing the product under the direction of a veterinarian.
2. The product does not present a known safety risk when used as labeled (e.g., when a product labeled for use in dogs or cats with a particular disease would be unsafe in such animals).
3. The product *label* does not include representations that it can be used to treat or prevent disease (e.g., obesity, renal failure).
4. Distribution of labeling and other manufacturer communications that contain representations that the product is intended for treatment or prevention of disease is limited so that it is provided only to veterinary professionals.
5. Electronic resources for the dissemination of labeling information and other manufacturer communications related to the intended use of the product are secured so that they are available only to veterinary professionals.
6. The label and labeling of the product is not false or misleading in other respects (e.g., dog food labeled and promoted for the treatment of cancer with no basis for the claim).
7. The product is not marketed as an alternative to approved new animal drugs.
8. The manufacturer is registered under section 415 of the FD&C Act.
9. The product is manufactured in accordance with CGMPs applicable to animal food (see 21 CFR part 507 subpart B) and other regulations applicable to animal food manufacturing.
10. The product's labeling complies with the current AAFCO Model Regulations and all other food labeling requirements for such products (see 21 CFR part 501).
11. The product contains only ingredients that are GRAS ingredients, approved food additives, or ingredients defined in the most recent version of the *Official Publication*.

The Model Bills and Regulations Committee recommends publishing these guidelines in the AAFCO OP following the guidelines for “human grade” claims on page 157 of the 2021 AAFCO Official Publication.

Board Recommendations:

Association Actions:

Committee Report and Minutes:

Model Bills and Regulations Committee Chairman Doug Lueders called the meeting to order on Feb. 12, 2021.

Chairman Lueders had announced at the Mid-year meeting that he would convene an e-meeting to address the AAFCO Pet Food Committee submitted Guidelines for Products Making Therapeutic Diet Claims. The request had not arrived in time for review and discussion at the mid-year MBRC meeting. The Chair electronically distributed the Pet Food Committee proposal with minor editorial edits (text attached at the bottom of this document).

On February 16, 2021 Kristen Green moved to approve the Guidelines for Making Therapeutic Diet Claims as distributed and forward to the Board of Directors indicating that there was no conflict with the Model Bills and the request to publish the guidelines in the AAFCO OP following the guidelines for “human grade” claims on page 157 of the 2021 AAFCO Official Publication.

Ben Jones seconded the motion.

On February 17, 2021 Chairman Lueders opened the floor to e-discussion asking to conclude by February 28, 2021.

There were no comments received and on March 2, 2021 Chairman Lueders called for the vote indicating that voting would be open for one week or until a majority was obtained. Chairman Lueders further explained that failure to cast a vote was the same as a Nay vote and since there are 14 committee members the motion needed 8 Aye votes for the motion to pass. By 7:11 PM CST nine Aye votes were received from Ken Bowers, Dan King, Eric Brady, Kristen Green, Scott Ziehr, David Dressler, Ben Jones, George Ferguson and Tim Tyson. Chairman Lueders declared the motion carried.

Adjournment

Since the Guidelines for Making Therapeutic Diet Claims was the single item for the meeting, the announcement of a majority vote to accept the motion effectively adjourned the meeting on March 2 at 7:11 PM CST. Chairman Lueders thanked everyone for their prompt responses.

On behalf of the Model Bills and Regulations Committee, I respectfully submit this report and request acceptance of the report by the AAFCO Board of Directors.

Guidelines for Making Therapeutic Diet Claims

AAFCO supports and recommends the following guidelines, as based on FDA CPG 690.150, for dog and cat food products that are intended for use to diagnose, cure, mitigate, treat, or prevent diseases and that are also labeled and/or marketed to provide all or most of the nutrients in support of meeting an animal's total daily nutritional requirements by serving as the pet's sole diet.

12. The product is made available to the public only through a valid veterinarian-client-patient relationship (VCPR) or through retail or internet sales to individuals purchasing the product under the direction of a veterinarian.
13. The product does not present a known safety risk when used as labeled (e.g., when a product labeled for use in dogs or cats with a particular disease would be unsafe in such animals).
14. The product *label* does not include representations that it can be used to treat or prevent disease (e.g., obesity, renal failure).
15. Distribution of labeling and other manufacturer communications that contain representations that the product is intended for treatment or prevention of disease is limited so that it is provided only to veterinary professionals.
16. Electronic resources for the dissemination of labeling information and other manufacturer communications related to the intended use of the product are secured so that they are available only to veterinary professionals.
17. The label and labeling of the product is not false or misleading in other respects (e.g., dog food labeled and promoted for the treatment of cancer with no basis for the claim).
18. The product is not marketed as an alternative to approved new animal drugs.
19. The manufacturer is registered under section 415 of the FD&C Act.
20. The product is manufactured in accordance with CGMPs applicable to animal food (see 21 CFR part 507 subpart B) and other regulations applicable to animal food manufacturing.
21. The product's labeling complies with the current AAFCO Model Regulations and all other food labeling requirements for such products (see 21 CFR part 501).
22. The product contains only ingredients that are GRAS ingredients, approved food additives, or ingredients defined in the most recent version of the *Official Publication*.