



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

December 19, 2019

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Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that the FDA require foods treated with medically important antibiotics before harvest be labeled under the Federal Food, Drug and Cosmetic Act ("FFDCA" or "Act") in the manner detailed below:

Issuance of new regulations under 21 C.F.R. § 101 to require labeling for all food covered by the FFDCA that has been treated with medically important antibiotics before harvest. The regulations shall include the following:

a. Definitions

1. "Antibiotics" refers to any drug (except drugs for use in animals other than humans) composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other drug intended for human use containing any quantity of any chemical substance that is produced by a micro-organism, synthetically or semi-synthetically and that has the capacity to inhibit or destroy micro-organisms in dilute solution (including a chemically synthesized equivalent of any such substance) or any derivative thereof.

2. "Medically Important" means any drug from a class of drug or derivative of a class of drug that is:

(1)(i) Made from a mold or bacterium that kills or slows the growth of other microbes, specifically bacteria; and

(ii) Used in human beings or intended for use in human beings to treat or prevent disease or infection; or

(2) Listed in:

(i) Appendix A of the federal Food and Drug Administration's Guidance for Industry #152, including critically important, highly important, or important antimicrobial drugs; or (ii) A subsequent guidance document created by the federal Food and Drug Administration that ranks the medical importance of antimicrobial drugs.

3. "Foods" means (1) articles used for consumption or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

4. "Treat" means to apply a process or substance to something or give it particular characteristics. This includes any pesticide application process.

5. "Label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this chapter that any word, statement, or other information appearing on the label shall not be considered to have been complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

b. Packaged, or unpackaged food shall be considered misbranded, unless its nutritional information panel indicates which ingredients have been treated with medically important antibiotics as follows:

1. An asterisk appearing after each ingredient indicating it has been treated with medically important antibiotics.
 2. Directly below the list of ingredients, in bold typeface not less than twice the size of the typeface in the ingredients list, a notice as follows: **“Treated with Antibiotics.”**
- c. Any food treated with antibiotics shall be considered misbranded, unless it contains a label that provides notices in accordance with the following:
1. A notice as follows: **“Treated with Antibiotics.”**
 2. A notice as follows: **“United States Government Notice: This Product was Treated with Medically Important Antibiotics.”**
 3. The notice required in clause (1) must immediately precede the notice required in clause (2) and must be no less than twice the size of the notice required in clause (2).
 4. The notice required in clause (2) must be the same size as would apply if the notice provided nutritional information.
- d. Any food that has been treated with antibiotics shall be considered misbranded if the average consumer cannot reasonably tell that the product was treated with medically important antibiotics or contains ingredients that have been treated with medically important antibiotics.
- e. Foods that have never been treated with antibiotics may remain unlabeled or labeled as **“Antibiotics Free”**

Your petition was received by this office on 12/19/2019 and assigned docket number FDA-2019-P-5997. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Karen Malvin
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)