3. Memorandum from J. Madden, FDA, to the Biotechnology Policy Branch, FDA, October 20, 1995.
4. Memorandum from R. D. Benz, FDA, to K. C. Raffaele, FDA, July 20, 1995.
5. Memorandum from the Division of Health Effects Evaluation, FDA, to R. H. Alrefai, FDA, May 4, 1999.
6. *Food Chemicals Codex*, 1996, 4th ed., National Academy Press, Washington, DC, pp. 133–134.
7. Memorandum from the Division of Health Effects Evaluation, FDA, to R. H. Alrefai, FDA, August 20, 1999.

List of Subjects in 21 CFR Part 173

Food additives, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 173 is amended as follows:

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

2. Section 173.115 is added to subpart B to read as follows:

§ 173.115 Alpha-acetolactate decarboxylase (α-ALDC) enzyme preparation derived from a recombinant Bacillus subtilis.

The food additive alpha-acetolactate decarboxylase (α-ALDC) enzyme preparation, may be safely used in accordance with the following conditions:

(a) The food additive is the enzyme preparation derived from a modified *Bacillus subtilis* strain that contains the gene coding for α-ALDC from *Bacillus brevis*.

(b)(1) The manufacturer produces the additive from a pure culture fermentation of a strain of *Bacillus subtilis* that is nonpathogenic and nontoxigenic in man or other animals.

(2) The manufacturer may stabilize the enzyme preparation with glutaraldehyde or with other suitable approved food additives or generally recognized as safe substances.

(3) The enzyme preparation must meet the general and additional requirements for enzyme preparations in the *Food Chemicals Codex*, 4th ed., 1996, pp. 133–134, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20055, or may be examined at the Center for Food Safety and Applied Nutrition, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) The additive is used in an amount not in excess of the minimum required to produce its intended effect as a processing aid in the production of alcoholic malt beverages and distilled liquors.

Dated: May 4, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–12225 Filed 5–15–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use in Animal Feeds; Narasin, Nicarbazin, and Bambermycins

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Elanco Animal Health. The NADA provides for use of approved narasin/nicarbazin and bambermycins Type A medicated articles to make three-way combination Type C medicated feeds used for prevention of coccidiosis, increased rate of weight gain, and improved feed efficiency in broiler chickens.

DATES: This rule is effective May 16, 2001.

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–1600.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed NADA 140-942 that provides for use of Maxiban® (36 grams per pound (g/lb) each of narasin and nicarbazin) and Flavomycin® (2, 4, or 10 g/lb of bambermycins activity) Type A medicated articles to make three-way combination Type C medicated feeds for use in broiler chickens. The combination Type C medicated feeds contain 27 to 45 g/ton narasin and 27 to 45 g/ton nicarbazin (in a fixed 1:1 ratio) and 1 to 2 g/ton bambermycins, and are used for prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, and *E. mivati*, and for increased rate of weight gain and improved feed efficiency. The NADA is approved as of March 8, 2001, and the regulations are amended in 21 CFR 558.95 and 558.363 to reflect the approval. The basis of approval is discussed in the freedom of information summary

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.95 [Amended]

2. Section 558.95 *Bambermycins* is amended in paragraph (d)(5)(iv) by adding ''nicarbazin or'' following ''with'', and in paragraph (d)(5)(v) by removing ''Nicarbazine'' and adding in its place ''Nicarbazin''.

3. Section 558.363 is amended by adding paragraph (d)(1)(xii) to read as follows:

§ 558.363 Narasin.

* * * * *

(d) * * *

(1) * * *

(xii) *Amount per ton.* Narasin, 27 to 45 grams; nicarbazin, 27 to 45 grams; and bambermycins, 1 to 2 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and for increased rate of weight gain and improved feed efficiency.

(B) *Limitations.* Feed continuously as the sole ration. Do not allow adult turkeys, horses, or other equines access to formulations containing narasin. Ingestion of narasin by these animals has been fatal. Do not feed to laying hens. Withdraw 5 days before slaughter. Narasin and nicarbazin as provided by 000986, bambermycins by 012799 in § 510.600(c) of this chapter.

* * * * *

Dated: April 23, 2001.

Linda Tollefson,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 01–12229 Filed 5–15–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 864 and 876

[Docket No. 01P–0087]

Gastroenterology-Urology Devices; Classification of Tissue Culture Media for Human Ex Vivo Tissue and Cell Culture Processing Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying tissue culture media for human ex vivo tissue and cell culture processing applications into class II (special controls). The special control that will apply to this device is a guidance document entitled ''Class II Special Controls Guidance Document: Tissue Culture Media for Human Ex Vivo Tissue and Cell Culture Processing Applications; Final Guidance for Industry and FDA Reviewers.'' The agency is taking this action in response to a petition submitted under the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, and the Food and Drug Administration Modernization Act of 1997. The agency is classifying these devices into class II (special controls) in order to provide a reasonable assurance of the safety and effectiveness of the devices.

DATES: This rule is effective May 16, 2001.

FOR FURTHER INFORMATION CONTACT: Carolyn Y. Neuland, Center for Devices and Radiological Health (HFZ–473), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1220.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the act (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976, generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the FDA regulations.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification.

In accordance with section 513(f)(1) of the act, FDA issued an order on December 5, 2000, classifying the Dulbecco's Modified Eagle medium for human ex vivo tissue and cell culture processing applications in class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device that was subsequently reclassified into class I or class II.

On December 19, 2000, FDA filed a petition submitted by Life Technologies, Inc., requesting classification of the Dulbecco's Modified Eagle medium for human ex vivo tissue and cell culture processing applications into class II under section 513(f)(2) of the act. After review of the information submitted in the petition, FDA determined that the Dulbecco's Modified Eagle medium for human ex vivo tissue and cell culture processing applications can be classified in class II with the establishment of special controls. The solutions are indicated for use in human ex vivo tissue and cell culture processing applications. FDA believes that class II special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device for this intended use.

In addition to the general controls of the act, the Dulbecco's Modified Eagle medium for human ex vivo tissue and cell culture processing applications is subject to a special control guidance document entitled ''Class II Special Controls Guidance Document: Tissue Culture Media for Human Ex Vivo Tissue and Cell Culture Processing Applications; Final Guidance for Industry and FDA Reviewers.''

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of this type of device for this intended use and, therefore, the device is not exempt from the premarket notification requirements. FDA review of bench data and labeling will ensure that minimum levels of performance for both safety and effectiveness are addressed before marketing clearance. Thus, persons who intend to market this device for this intended use must submit to FDA a premarket notification submission containing information on the device before marketing the device.

On February 16, 2001, FDA issued an order to the petitioner classifying the Dulbecco's Modified Eagle medium for human ex vivo tissue and cell culture processing applications, and substantially equivalent devices of this generic type, into class II under the generic name, tissue culture media for