(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

human ex vivo tissue and cell culture processing applications. FDA identifies this generic type of device as tissue culture media for human ex vivo tissue and cell culture processing applications consisting of cell and tissue culture media and components that are composed of chemically defined components (e.g., amino acids, vitamins, inorganic salts) that are essential for the ex vivo development, survival, and maintenance of tissues and cells of human origin. The solutions are indicated for use in human ex vivo tissue and cell culture processing applications. This order also identified as a special control applicable to this device 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.''

FDA is codifying this device by adding § 876.5885. FDA is also amending 21 CFR 864.2220 *Synthetic cell and tissue culture media and components*, to clarify that the device described in that section does not include tissue culture media for human ex vivo tissue and cell culture processing applications.

II. Electronic Access

In order to receive the 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'' via your fax machine, call the CDRH Facts-on-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number 1325. Then follow the remaining voice prompts to complete your request. Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the 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,'' device safety alerts,**Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at www.fda.gov/cdrh.

III. Environmental Impact

The agency has determined under 21 CFR 25.34(b) 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.

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4)). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final rule is not a significant regulatory action as defined by the Executive order and so it is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. FDA knows of only one manufacturer of this type of device. Classification of these devices in class II will relieve this manufacturer of the device of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e) and may permit small potential competitors to enter the market place by lowering their costs. The agency, therefore, certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation). The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for the final rule, because the final rule is not expected to result in any 1-year expenditure that would exceed$100 million.

V. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, or on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

VI. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects

21 CFR Part 864

Biologics, Blood, Laboratories, Medical devices, Packaging and containers.

21 CFR Part 876

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 864 and 876 are amended as follows:

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

1. The authority citation for 21 CFR part 864 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 864.2220 is amended by revising paragraph (a) to read as follows:

§ 864.2220 Synthetic cell and tissue culture media and components

(a) *Identification*. Synthetic cell and tissue culture media and components are substances that are composed entirely of defined components (e.g., amino acids, vitamins, inorganic salts) that are essential for the survival and development of cell lines of humans and other animals. This does not

include tissue culture media for human ex vivo tissue and cell culture processing applications as described in § 876.5885 of this chapter.

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PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

1. The authority citation for 21 CFR part 876 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Section 876.5885 is added to subpart F to read as follows:

§ 876.5885 Tissue culture media for human ex vivo tissue and cell culture processing applications.

(a) *Identification.* Tissue culture media for human ex vivo tissue and cell culture processing applications consist of cell and tissue culture media and components that are composed of chemically defined components (e.g., amino acids, vitamins, inorganic salts) that are essential for the ex vivo development, survival, and maintenance of tissues and cells of human origin. The solutions are indicated for use in human ex vivo tissue and cell culture processing applications.

(b) *Classification.* Class II (special controls): FDA guidance document, ''Class II Special Controls Guidance Document: Tissue Culture Media for Human Ex Vivo Processing Applications; Final Guidance for Industry and FDA Reviewers.''

Dated: May 7, 2001.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 01–12227 Filed 5–15–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD08–01–002]

RIN 2115–AE47

Drawbridge Operating Regulation; Inner Harbor Navigation Canal, New Orleans, LA

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is changing the regulation governing the operation of the SR 46 (St. Claude Avenue) bridge, mile 0.5 (GIWW mile 6.2 East of Harvey Lock), the SR 39 (Judge Seeber/Claiborne Avenue) bridge, mile 0.9 (GIWW mile 6.7 East of Harvey Lock), and the Florida Avenue bridge, mile 1.7 (GIWW mile 7.5 East of Harvey Lock), across the Inner Harbor Navigation Canal in New Orleans, Orleans Parish, Louisiana. This rule allows for the uninterrupted flow of commuter traffic while still providing for the reasonable needs of navigation.

DATES: This rule is effective June 15, 2001.

ADDRESSES: Comments and materials received from the public, as well as documents indicated in this preamble as being available in the docket, will be available for inspection or copying at the office of the Eighth Coast Guard District, Bridge Administration Branch, Hale Boggs Federal Building, Room 1313, 501 Magazine Street, New Orleans, Louisiana 70130–3396 between 7 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. David Frank, Bridge Administration Branch, Commander (obc), Eighth Coast Guard District, 501 Magazine Street, New Orleans, Louisiana, 70130–3396, telephone number 504–589–2965.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On February 22, 2001, a notice of proposed rulemaking (NPRM) entitled Drawbridge Operating Regulation; Inner Harbor Navigation Canal, New Orleans, Louisiana, was published in the **Federal Register** (66 FR 11129). Sixteen letters of comment were received on the proposed rule. No public hearing was requested, and none was held.

Background and Purpose

To meet the needs of commuters who cross these three bridges in the morning and afternoon en route to and from work in the Lower Ninth Ward area of New Orleans and in St. Bernard Parish, the Coast Guard proposed to codify the historic accommodation with marine interests that allows the bridges to remain closed-to-navigation and open to vehicular traffic during the morning and afternoon rush hours.

During the past several years, although no regulation has ever been established, all parties have accepted the spirit of the ''closure'' during morning and afternoon rush hours and the bridges have not opened during these time periods. The Coast Guard proposes to codify the accepted historic practices of these three bridges. Another factor we considered is the relocation of the Industrial Canal Lock previously discussed in detail in the Notice of Proposed Rulemaking.

The rule would establish the same operation schedules for all three draws to facilitate the flow of vehicular traffic during rush hours while still meeting the reasonable needs of navigation.

Discussion of Comments and Changes

Sixteen letters were received containing signatures in support of or commenting on the NPRM published in the **Federal Register** and reprinted in a local Coast Guard Public Notice CGD08–05–01 mailed on March 8, 2001. Thirteen respondents, one being the Louisiana Department of Transportation and Development, wrote in support of the proposal with no changes requested. One response was received containing forty-nine signatures in support of the proposal. Two respondents wrote letters in support of the project but requested that a modification be made to the proposed hours of closure. These respondents were individual commuters who wanted the hours of the closure to begin earlier in the morning to accommodate their work hours. However, the Port of New Orleans and the Louisiana Department of Transportation and Development provided traffic counts with the proposal and the traffic counts indicated that the proposed hours of closure correspond to the peak traffic crossing the bridges for the majority of the commuters. Therefore, no changes to the proposal were made based upon these responses. No changes have been incorporated into the Final Rule.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, l979).

We expect the economic impact of this proposed temporary rule to be so minimal that a full Regulatory Evaluation under paragraph 10(e) of the regulatory policies and procedures of DOT is unnecessary.

This rule maintains the existing historically accepted curfews with a minor change allowing the bridge to remain closed-to-navigation an additional 30 minutes.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard considers whether this rule would have a significant economic impact on a