TETRAMED 324 HCA is approved as a generic copy of Boehringer Ingelheim Vetmedica, Inc.'s TETRASURE 324 (tetracycline hydrochloride), approved under NADA 65–496. The ANADA is approved as of September 13, 2005, and the regulations are amended in § 520.2345d (21 CFR 520.2345d) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, FDA has noticed that certain withdrawal times for other approved generic products are not reflected in § 520.2345d. At this time, the regulations are amended to reflect the correct withdrawal times in calves and swine. This action is being taken to improve the accuracy of the regulations.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 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 Division of Dockets Management (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.

FDA has determined under 21 CFR 25.33(a)(1) 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 520

Animal drugs.

■ 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 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

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

■ 2. Section 520.2345d is amended by revising the section heading, paragraphs (a) through (c), the heading and introductory text of paragraph (d), and paragraphs (d)(1)(iii) and (d)(2)(iii) to read as follows:

§ 520.2345d Tetracycline powder.

(a) *Specifications.* Each pound of powder contains 25, 102.4, or 324 grams tetracycline hydrochloride.

(b) *Sponsors.* See sponsors listed in § 510.600(c) of this chapter for conditions of use as in paragraph (d) of this section:

(1) No. 000069: 25 grams per pound as in paragraphs (d)(3) and (d)(4) of this section.

(2) Nos. 000010 and 046573: 102.4 and 324 grams per pound as in paragraph (d) of this section.

(3) No. 053501: 102.4 and 324 grams per pound as in paragraphs (d)(1) and (d)(2) of this section.

(4) No. 046573: 102.4 and 324 grams per pound as in paragraph (d)(3) of this section.

(5) Nos. 051259, 057561, 059130, and 061623: 324 grams per pound as in paragraph (d) of this section.

(c) *Related tolerances.* See § 556.720 of this chapter.

(d) *Conditions of use.* It is administered in drinking water as follows:

(1) * * *

(iii) *Limitations.* Administer for 3 to 5 days; do not slaughter animals for food within 4 days of treatment for sponsor No. 053501 and within 5 days of treatment for sponsor Nos. 000010, 046573, 051259, 057561, 059130, and 061623; prepare a fresh solution daily; use as the sole source of tetracycline. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) * * *

(iii) *Limitations.* Administer for 3 to 5 days; do not slaughter animals for food within 7 days of treatment for sponsor No. 053501 and within 4 days of treatment for sponsor Nos. 000010, 046573, 051259, 057561, 059130, and 061623; prepare a fresh solution daily; use as the sole source of tetracycline.

* * * * *

Dated: October 19, 2005.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 05–21889 Filed 11–4–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. 2005P–0366]

Medical Devices; General and Plastic Surgery Devices; Classification of the Low Energy Ultrasound Wound Cleaner

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the low energy ultrasound wound cleaner into class II (special controls). The special control that will apply to the device is the guidance document entitled ''Class II Special Controls Guidance Document: Low Energy Ultrasound Wound Cleaner.'' 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 (FDAMA). The agency is classifying this device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document that will serve as the special control for the class II device.

DATES: This rule is effective December 7, 2005. The reclassification was effective June 25, 2004.

FOR FURTHER INFORMATION CONTACT: David B. Berkowitz, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090, ext. 152.

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 (the amendments), 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 FDA's 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 April 8, 2004, classifying the Celleration MIST Therapy System™ 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 April 29, 2004, Celleration, Inc., submitted a petition requesting classification of the Celleration MIST Therapy System™ under section 513(f)(2) of the act. The manufacturer recommended that the device be classified into class II.

In accordance with 513(f)(2) of the act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in 513(a)(1) of the act. Devices are to be classified into class II if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition, FDA has determined that the low energy ultrasound wound cleaner intended for the cleaning and maintenance debridement of wounds can be classified in class II with the establishment of special controls. FDA believes that class II special controls provide reasonable assurance of the safety and effectiveness of the device.

The device is assigned the generic name ''Low energy ultrasound wound cleaner,'' and it is identified as a device that uses ultrasound energy to vaporize a solution and generate a mist that is used for the cleaning and maintenance debridement of wounds. Low levels of ultrasound energy may be carried to the wound by the saline mist.

The potential risks to health associated with the device are: Delayed wound healing, thermal damage, inflammation/foreign body response, infection, and electrical shock. The special control guidance document entitled ''Class II Special Controls Guidance Document: Low Energy Ultrasound Wound Cleaner'' aids in mitigating the risk by recommending performance characteristics, safety testing, and appropriate labeling.

Thus, in addition to the general controls of the act, a low energy ultrasound wound cleaner is subject to the special controls guidance document. FDA believes that following the class II special controls guidance document generally addresses the risks to health identified in the previous paragraph of this document. Therefore, on June 25, 2004, FDA issued an order to the petitioner classifying the device as described previously into class II and is codifying this device by adding § 878.4410.

Following the effective date of this final rule classifying the device, any firm submitting a 510(k) premarket notification for the device will need to address the issues covered in the special controls guidance. However, the firm would need to show only that its device meets the recommendations of the guidance, or in some other way provides equivalent assurances of safety and effectiveness.

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 and, therefore, the type of device is not exempt from premarket notification requirements. Thus, persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the low energy ultrasound wound cleaner that they intend to market.

II. 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.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), 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 not a significant regulatory action 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. Because reclassification of these devices from class III to class II will relieve manufacturers 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 marketplace by lowering their costs, the agency certifies that the 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, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $115 million, using the most current (2003) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. 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, 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 Executive order and, consequently, a federalism summary impact statement is not required.

V. Paperwork Reduction Act of 1995

FDA concludes that this rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520) is not required.

FDA also concludes that the special controls guidance document does not contain new information collection provisions that are subject to review and clearance by OMB under the PRA. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing the availability of the guidance document entitled ''Class II Special Controls Guidance Document: Low Energy Ultrasound Wound Cleaner.''

List of Subjects in 21 CFR Part 878

Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for 21 CFR part 878 continues to read as follows:

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

■ 2. Section 878.4410 is added to subpart E to read as follows:

§ 878.4410 Low energy ultrasound wound cleaner.

(a) *Identification.* A low energy ultrasound wound cleaner is a device that uses ultrasound energy to vaporize a solution and generate a mist that is used for the cleaning and maintenance debridement of wounds. Low levels of ultrasound energy may be carried to the wound by the saline mist.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Low Energy Ultrasound Wound Cleaner.'' See § 878.1(e) for the availability of this guidance document.

Dated: September 28, 2005.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 05–22068 Filed 11–4–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9228]

RIN 1545–BE50

Low-Income Housing Credit Allocation and Certification; Revisions

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains regulations that reduce the burden for taxpayers filing Form 8609, ''Low-Income Housing Credit Allocation and Certification.'' The regulations affect owners of low-income housing projects who claim the low-income housing credit.

DATES: *Effective Date:* These regulations are effective November 7, 2005.

Date of Applicability: For date of applicability, see § 1.42–1(j).

FOR FURTHER INFORMATION CONTACT: Paul F. Handleman, (202) 622–3040 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On January 27, 2004, the Treasury Department and IRS published Treasury Decision 9112 in the **Federal Register** (69 FR 3826), which removed impediments to the electronic filing of Form 8609, ''Low-Income Housing Credit Allocation and Certification,'' by revising former § 1.42–1T(e)(1) and (h)(2) and adding § 1.42–1(h). Former § 1.42–1T(e)(1) and (h)(2) required an owner to include a third-party signature from an authorized State or local housing credit agency (Agency) official when filing the form with the owner's Federal income tax return for each year of the 15-year compliance period. Section 1.42–1(h) contains the filing requirement for Form 8609 and no longer requires the third-party signature when filing the form with the owner's Federal income tax return.

Explanation of Provisions

Section 42 provides for a low-income housing credit that may be claimed as part of the general business credit under section 38. In general, the credit is allowable only if the owner of a qualified low-income building receives a housing credit allocation from an Agency of the jurisdiction where the building is located.

Section 1.42–1(h) provides that a completed Form 8586, ''Low-Income Housing Credit,'' must be filed with the owner's Federal income tax return for each taxable year the owner of a qualified low-income building is claiming the low-income housing credit under section 42(a). A completed Form 8609 must be filed with the owner's Federal income tax return for each of the 15 taxable years of the compliance period. Failure to comply with the requirement of the preceding sentence for any taxable year after the first taxable year in the credit period will be treated as a mathematical or clerical error for purposes of section 6213(b)(1) and (g)(2).

The IRS plans to reduce taxpayer burden by allowing taxpayers to file Form 8609 one time, instead of filing the form with the same information for 15 consecutive years. Taxpayers currently file the form as part of their return with the Internal Revenue Service center that processes their return. Planned revisions to the form should improve administration of the low-income housing credit program by requiring taxpayers to send completed forms to the Philadelphia service center, where each Agency currently sends Part I of the form. The requirements for completing and filing Form 8609 will be addressed in the instructions to the form.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) and (d) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations. Because no notice of proposed rulemaking is required, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Internal Revenue Code, these regulations were submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Drafting Information

The principal author of these regulations is Paul F. Handleman, Office of the Associate Chief Counsel (Passthroughs and Special Industries),