

and Surveillance Facility, Virginia Capes (FACSFAC VACAPES), NAS Oceana, Virginia Beach, VA” and inserting the words “Using agency. U.S. Navy, Fleet Area Control and Surveillance Facility, Virginia Capes (FACSFAC VACAPES), Virginia Beach, VA.”

* * * * *

Issued in Washington, DC, on November 4, 2010.
Edith V. Parish,
Manager, Airspace, Regulations and ATC Procedures Group.
[FR Doc. 2010-28388 Filed 11-9-10; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

[Docket No. FDA-2010-N-0002]

New Animal Drugs; Change of Sponsor’s Name

AGENCY: Food and Drug Administration, HHS.
ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor’s name from North American Nutrition Companies, Inc., to Provimi North America, Inc.
DATES: This rule is effective November 10, 2010.

FOR FURTHER INFORMATION CONTACT: Steven D. Vaughn, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 240-276-8300, E-mail: steven.vaughn@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: North American Nutrition Companies, Inc., 6531 State Rte. 503, Lewisburg, OH 45338, has informed FDA that it has changed its name to Provimi North America, Inc. Accordingly, the Agency is amending the regulations in 21 CFR 510.600 to reflect this change.

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 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

■ 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 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600, in the table in paragraph (c)(1), remove the entry for “North American Nutrition Companies, Inc.”; and alphabetically add a new entry for “Provimi North America, Inc.”; and in the table in paragraph (c)(2), revise the entry for “017790” to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *
(c) * * *
(1) * * *

Firm name and address	Drug labeler code
* * * * *	
Provimi North America, Inc., 6531 State Rte. 503, Lewisburg, OH 45338	017790
* * * * *	

(2) * * *	
Drug labeler code	Firm name and address
* * *	
017790	Provimi North America, Inc., 6531 State Rte. 503, Lewisburg, OH 45338.
* * *	

Dated: October 28, 2010.
Steven D. Vaughn,
Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
[FR Doc. 2010-28307 Filed 11-9-10; 8:45 am]
BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA-2010-N-0512]

Medical Devices; General and Plastic Surgery Devices; Classification of Tissue Adhesive With Adjunct Wound Closure Device Intended for Topical Approximation of Skin

AGENCY: Food and Drug Administration, HHS.
ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the tissue adhesive with adjunct wound closure device intended for topical approximation into class II (special controls). The special control that will apply to the device is the guidance document entitled “Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Tissue Adhesive With Adjunct Wound Closure Device Intended for the Topical Approximation of Skin.” The agency is classifying the device into class II (special controls) in order to provide reasonable assurance of safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a guidance document that will serve as the special control for this device type.

DATES: This final rule is effective December 10, 2010. The classification was effective April 30, 2010.

FOR FURTHER INFORMATION CONTACT: George J. Mattamal, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, Rm. 4617, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-6396.

SUPPLEMENTARY INFORMATION:

I. What is the background of this rulemaking?

The Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 301 *et seq.*) as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94-295), the Safe Medical Devices Act of 1990 (Pub. L. 101-629), and the Food and Drug Administration Modernization Act (Pub. L. 107-250) established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 306c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and

effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

FDA refers to devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), as postamendments devices. Postamendments devices are classified automatically by statute (section 513(f) of the FD&C Act) into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless: (1) FDA reclassifies the device into class I or II; (2) FDA issues an order classifying the device into class I or class II in accordance with section 513(f)(2) of the FD&C Act; or FDA issues an order finding the device to be substantially equivalent, under section 513(i), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

Section 513(f)(2) of the FD&C Act provides that any person who submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, request FDA to classify the device under

the criteria set forth in section 513(a)(1). FDA will, within 60 days of receiving this 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 this classification.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on February 25, 2009, classifying the PRINEO Skin Closure System into 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 which was subsequently reclassified into class I or class II. On March 23, 2009, Closure Medical Corp. submitted a petition requesting classification of the tissue adhesive with adjunct wound closure device for topical approximation of skin under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act. FDA classifies devices 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 determined that tissue adhesive with adjunct wound closure device intended for topical approximation of skin can be classified into class II with the establishment of special controls. FDA believes these special controls will provide reasonable assurance of the safety and effectiveness of the device.

The device is assigned the generic name "Tissue Adhesive with Adjunct Wound Closure Device Intended for Topical Approximation of Skin" and it is identified as tissue adhesive with adjunct wound closure device intended for topical approximation of skin. FDA has identified the following risks to health associated specifically with this type of device and the recommended measures to mitigate these risks.

A. Unintentional bonding of device due to misapplication of device, device leaking or running to unintended areas, etc.

B. Wound dehiscence

C. Adverse tissue reaction and chemical burns

D. Infection

E. Applicator malfunction

F. Weak bonding leading to loss of approximation

G. Delayed polymerization

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES

Identified risk	Recommended mitigation measures
Unintentional bonding of device due to misapplication of device, device leaking or running to unintended areas, etc.	Bench Testing, Labeling.
Wound dehiscence	Bench Testing, Shelf Life Testing, Animal Testing, Clinical Studies, Labeling.
Adverse tissue reaction and chemical burns	Biocompatibility Animal Testing, Clinical Studies.
Infection	Bench Testing, Biocompatibility Animal Testing, Clinical Studies, Sterility.
Applicator malfunction	Bench Testing.
Weak bonding leading to loss of approximation	Bench Testing, Animal Testing, Clinical Studies.
Delayed polymerization	Bench Testing, Animal Testing.

FDA believes that the special controls guidance document, in addition to general controls, addresses the risks to health identified in table 1 of this document and provides reasonable assurance of the safety and effectiveness of the device. Therefore, on April 30, 2010, FDA issued an order to the petitioner classifying the device into class II. FDA is codifying this device by adding § 878.4011 to 21 CFR part 878.

Following the effective date of this final classification rule, any firm submitting a 510(k) premarket

notification for tissue adhesive with adjunct wound closure device intended for topical approximation of skin will need to address the issues covered in the special controls guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurance of safety and effectiveness.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirement under section 510(k) of the

FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device and, therefore, the type of device is not exempt from premarket notification requirements. 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 tissue adhesive with adjunct wound closure intended for topical approximation of skin that they intend to market.

II. What is the environmental impact of this rule?

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. What is the analysis impact of this rule?

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 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 as defined by 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 this device from class III to class II will relieve manufacturers of the device of cost of complying with the premarket approval requirements of section 515 of the FD&C 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 \$135 million, using the most current (2009) 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. Does this final rule have Federalism Implications?

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires agencies to “construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.” Federal law includes an express preemption provision that preempt certain State requirements “different from or in addition to” certain Federal requirements applicable to devices. 21 U.S.C. 360k; *See Medtronic v. Lohr*, 518 U.S. 470 (1996); *Riegel v. Medtronic*, 552 U.S. 312 (2008). The special controls established by this final rule create “requirements” to address each identified risk to health presented by these specific medical devices under 21 U.S.C. 360k, even though product sponsors have some flexibility in how they meet those requirements. Cf. *Papike v. Tambrands, Inc.*, 107 F.3d 737, 740–42 (9th Cir. 1997).

V. How does this rule comply with the Paperwork Reduction Act of 1995?

This final rule contains no new collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 is not required. Elsewhere in this issue of the **Federal Register**, FDA is issuing a notice announcing the availability of a guidance for the final rule. The guidance, “Class II Special Controls Guidance Document: Tissue Adhesive with Adjunct Wound Closure Device Intended for the Topical Approximation of Skin,” references previously approved collections of information found in FDA’s regulations.

VI. What references are on display?

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Closure Medical Corp., March 23, 2009.

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, 3601, 371.

■ 2. Section 878.4011 is added to subpart E to read as follows:

§ 878.4011 Tissue adhesive with adjunct wound closure device for topical approximation of skin.

(a) *Identification.* A tissue adhesive with adjunct wound closure device intended for the topical approximation of skin is a device indicated for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations. It may be used in conjunction with, but not in place of, deep dermal stitches. Additionally, the adjunct wound closure device component maintains temporary skin edge alignment along the length of wound during application of the liquid adhesive.

(b) *Classification.* Class II (special controls). The special control for this device is FDA’s “Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Tissue Adhesive with Adjunct Wound Closure Device Intended for the Topical Approximation of Skin.” See § 878.1(e) for the availability of this guidance document.

Dated: November 4, 2010.

Nancy K. Stade,

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

[FR Doc. 2010–28356 Filed 11–9–10; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2010–0998]

Drawbridge Operation Regulation; Upper Mississippi River, Rock Island, IL

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.