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.

2. Section 558.485 is amended by revising paragraphs (e)(2)(i) introductory text, (e)(2)(i)(A), and the first sentence of paragraph (e)(2)(i)(B), and by adding and reserving paragraph (e)(2)(ii) to read as follows:

§ 558.485 Pyrantel tartrate.

* * * * *

(e) * * *

(2) *Horses*—(i) *Amount.* Feed continuously at the rate of 1.2 milligrams per pound (2.64 milligrams per kilogram) of body weight.

(A) *Indications for use.* Prevention of *Strongylus vulgaris* larval infections; control of adult large strongyles (*S. vulgaris*, and *S. edentatus*), adult and 4th stage larvae small strongyles (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp., *Cylicodontophorus* spp., *Poteriostomum* spp., and *Triodontophorus* spp.), adult and 4th stage larvae pinworms (*Oxyuris equi*), and adult and 4th stage larvae ascarids (*Parascaris equorum*).

(B) *Limitations.* Administer either as a top-dress (not to exceed 20,000 grams per ton) or mixed in the horse's daily grain ration (not to exceed 1,200 grams per ton) during the time that the animal is at risk of exposure to internal parasites. * * *

(ii) [Reserved]

Dated: September 9, 1999.

Melanie R. Berson,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 99–25773 Filed 10–4–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. 78N–2646]

General and Plastic Surgery Devices; Classification of the Nonresorbable Gauze/Sponge for External Use, the Hydrophilic Wound Dressing, the Occlusive Wound Dressing, and the Hydrogel Wound Dressing

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the nonresorbable gauze/sponge for external use, the hydrophilic wound dressing, the occlusive wound dressing, and the hydrogel wound dressing into class I (general controls). FDA is also exempting these devices from premarket notification procedures. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA).

EFFECTIVE DATE: November 4, 1999.

FOR FURTHER INFORMATION CONTACT: Gail G. Gantt, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 19, 1989 (54 FR 38600) (hereinafter referred to as the September 19, 1989 proposal), FDA issued a proposed rule to classify the following 11 devices: The nonabsorbable gauze surgical sponge for external use, the hydrophilic wound and burn dressing, the interactive wound and burn dressing, the porcine burn dressing, the intravascular catheter securement device, the medical adhesive tape, the medical adhesive bandage, the adhesive wound closure, the occlusive wound and burn dressing, the burn sheet, and the hydrogel wound and burn dressing. Four of the eleven devices (the liquid bandage, the intravascular catheter securement device, the medical adhesive tape and bandage, and the burn sheet) were already classified as general hospital and personal use devices (45 FR 1739, October 21, 1980).

In the September 19, 1989 proposal, FDA proposed that: (1) The four general hospital and personal use devices, identified above, be recodified in the Code of Federal Regulations (CFR) with the general and plastic surgery devices; (2) the medical adhesive tape and bandage be divided into four generic devices; (3) the liquid bandage be divided into two generic devices; and (4) the porcine burn dressing for short-term use be classified into class I and the porcine burn dressing for long-term use be classified into class III as the interactive wound and burn dressing. The proposals were not finalized. Based on the comments of the September 19, 1989 proposed rule, the General and Plastic Surgery Devices Panel's (the panel) recommendations, and current wound care and product use, FDA is finalizing the classification of the following four wound care devices: The nonresorbable gauze/sponge for external use, the hydrophilic wound dressing, the occlusive wound dressing, and the hydrogel wound dressing.

These final rules do not address wound dressings that contain added drugs such as antimicrobial agents, added biologics such as growth factors, or are composed of materials derived from animal sources. These are preamendments devices that FDA intends to classify in the future.

II. Comments and FDA's Responses

Interested persons were given until November 20, 1989, to comment on the September 19, 1989 proposed rule. During the comment period, FDA received following comments.

1. Two comments requested that an additional classification category be added for the nonsterile hydrogel wound and burn dressing. The nonsterile device would be for conditions such as minor cuts, scrapes, burns, and sunburn. The comment stated that components of this type of hydrogel wound and burn dressing cannot withstand sterilization.

FDA agrees that the hydrogel wound and burn dressing may be either sterile or nonsterile and has revised the final rule accordingly.

2. One comment requested that the health risk information be printed on the wrappings of the devices.

FDA believes that it is adequate that the health risk information be provided in the outer labeling of the device.

3. One comment stressed the need for price control because low-income persons generally have little or no health insurance coverage.

FDA notes that the agency has no control over the price of medical

devices and whether devices are covered by health insurance.

4. Two comments suggested that the proposed classifications were too restrictive. One comment stated that an effect of the September 19, 1989 proposed rule is that many products will have no classification and other classified devices would become unclassified. The other comment requested that the device descriptions be more generalized to include other wound dressings that do not specifically meet the proposed descriptions.

FDA is only classifying the four devices identified above at this time. While it is true that some wound dressings remain unclassified, no devices that have already been classified will ''become unclassified'' as a result of this action. The agency will consider additional wound dressing classification categories in the future.

5. Three comments suggested that nonwoven materials be included in the description of nonabsorbable gauze surgical sponge for external use.

FDA agrees with the comment and has included nonwoven materials in the nonresorbable gauze/sponge for external use identification.

6. One comment recommended that synthetic materials also be included in the description of nonabsorbable gauze surgical sponge for external use.

FDA disagrees with the comment. The agency has included synthetic materials in the identification of the hydrophilic wound dressing identification.

III. Recommendations of the Panel

Although the panel discussed wound dressings at the July 17, 1995 meeting, the panel did not make classification recommendations for any of the wound dressing devices. At the November 17, 1998 meeting, the panel discussed the classification of four of the wound dressings proposed for classification in 1989, the nonresorbable gauze/sponge for external use, the hydrophilic wound dressing, the occlusive wound dressing, and the hydrogel wound dressing. The panel unanimously recommended that these four wound dressing devices be classified into class I (general controls) and that they be exempted from premarket notification procedures (section 510(k) of the act) (21 U.S.C. 360(k)) (Ref. 1). The panel concluded that the safety and effectiveness of the four wound dressing devices can be reasonably ensured by the following general controls: (1) Registration and Listing (21 CFR part 807), (2) General Provisions of the Quality System Regulation (21 CFR part 820), (3) General Requirements for Reports (21 CFR 820.180), and Complaint Files (21 CFR 820.198).

IV. Risks to Health

The panel identified the following risks for two of the wound dressing devices: (1) The nonresorbable gauze/sponge for external use may become incorporated into a wound if its use is not monitored; and (2) the occlusive dressing may cause formation of an abscess if it is placed on an infected wound. The panel identified no specific risks to health for the hydrogel wound dressing and the hydrophilic wound dressing.

V. Summary of the Data Upon Which the Recommendation Is Based

The panel based its recommendations on expert testimony presented to the panel and on the panel members' personal knowledge of and clinical experience with the nonresorbable gauze/sponge for external use, the hydrophilic wound dressing, the occlusive wound dressing, and the hydrogel wound dressing.

VI. FDA's Conclusion

FDA has concluded that the nonresorbable gauze/sponge for external use, the hydrophilic wound dressing, the occlusive wound dressing, and the hydrogel wound dressing do not present unreasonable risks to the public health and that general controls would provide reasonable assurance of the safety and effectiveness of the devices.

On November 21, 1997, the President signed the FDAMA into law. Section 206 of the FDAMA added a new section 510(l) to the act (21 U.S.C. 360(l)), which became effective on February 19, 1998. It states that a class I device is exempt from the premarket notification requirements under section 510(k) of the act, unless the device is intended for a use which is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury (hereinafter referred to as ''reserved criteria''). FDA has determined that the nonresorbable gauze/sponge for external use, the hydrophilic wound dressing, the occlusive wound dressing, and the hydrogel wound dressing do not meet the reserved criteria and, therefore, they should be exempt from the premarket notification requirements.

FDA has determined that the four general hospital and personal use devices (the liquid bandage, the intravascular catheter securement device, the medical adhesive tape and bandage, and the burn sheet) should remain codified as general hospital and personal use devices (21 CFR part 880). FDA will finalize classifications of the porcine wound dressing and the interactive wound and burn dressing in the future.

VII. Reference

The following reference has been placed on display in the Dockets Management Branch, 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. General and Plastic Surgery Devices Panel Meeting Transcript, November 17, 1998, pp. 1–119.

VIII. 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.

IX. 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 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. As noted previously, FDA may classify devices into one of three regulatory classes according to the degree of control needed to provide reasonable assurance of safety and effectiveness. FDA is classifying these four devices into class I, the lowest level of control allowed. Under the final rule, they will be exempt from premarket notification. As unclassified preamendments devices, these devices are already effectively regulated as class

I devices. Therefore, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

X. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

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. 4014 is added to subpart E to read as follows:

§ 878.4014 Nonresorbable gauze/sponge for external use.

(a) *Identification*. A nonresorbable gauze/sponge for external use is a sterile or nonsterile device intended for medical purposes, such as to be placed directly on a patient's wound to absorb exudate. It consists of a strip, piece, or pad made from open woven or nonwoven mesh cotton cellulose or a simple chemical derivative of cellulose. This classification does not include a nonresorbable gauze/sponge for external use that contains added drugs such as antimicrobial agents, added biologics such as growth factors, or is composed of materials derived from animal sources.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in part 807, subpart E of this chapter subject to the limitations in § 878.9.

3. Section 878.4018 is added to subpart E to read as follows:

§ 878.4018 Hydrophilic wound dressing.

(a) *Identification*. A hydrophilic wound dressing is a sterile or non-sterile device intended to cover a wound and to absorb exudate. It consists of nonresorbable materials with hydrophilic properties that are capable of absorbing exudate (e.g., cotton, cotton derivatives, alginates, dextran, and rayon). This classification does not include a hydrophilic wound dressing that contains added drugs such as antimicrobial agents, added biologics such as growth factors, or is composed of materials derived from animal sources.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in part 807, subpart E of this chapter subject to the limitations in § 878.9.

4. Section 878.4020 is added to subpart E to read as follows:

§ 878.4020 Occlusive wound dressing.

(a) *Identification*. An occlusive wound dressing is a nonresorbable, sterile or non-sterile device intended to cover a wound, to provide or support a moist wound environment, and to allow the exchange of gases such as oxygen and water vapor through the device. It consists of a piece of synthetic polymeric material, such as polyurethane, with or without an adhesive backing. This classification does not include an occlusive wound dressing that contains added drugs such as antimicrobial agents, added biologics such as growth factors, or is composed of materials derived from animal sources.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in part 807, subpart E of this chapter subject to the limitations in § 878.9.

5. Section 878.4022 is added to subpart E to read as follows:

§ 878.4022 Hydrogel wound dressing and burn dressing.

(a) *Identification*. A hydrogel wound dressing is a sterile or non-sterile device intended to cover a wound, to absorb wound exudate, to control bleeding or fluid loss, and to protect against abrasion, friction, desiccation, and contamination. It consists of a nonresorbable matrix made of hydrophilic polymers or other material in combination with water (at least 50 percent) and capable of absorbing exudate. This classification does not include a hydrogel wound dressing that contains added drugs such as antimicrobial agents, added biologics such as growth factors, or is composed of materials derived from animal sources.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in part 807, subpart E of this chapter subject to the limitations in § 878.9.

Dated: September 21, 1999.

Linda S. Kahan,

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

[FR Doc. 99–25791 Filed 10–4–99; 8:45 am]

BILLING CODE 4160–01–F

UNITED STATES INFORMATION AGENCY

22 CFR Part 514

Exchange Visitor Program

AGENCY: United States Information Agency.

ACTION: Final rule.

SUMMARY: By notice published April 13, 1999 (64 FR 17988) the Agency proposed amendment of existing au pair regulations in order to strengthen the oversight and general accountability of the au pair program and to identify and reduce the potential risk of injury to program participants. The proposed amendments will provide greater specificity regarding the selection and orientation of both host family and au pair participants, thereby enhancing the prospect for more informed participation by both parties. Further proposed program enhancements would require disclosure of prior experience for au pair participants providing child care for special needs children. An amendment to provide for uniform program audits was also proposed. A thirty day public comment period was provided and twenty comments were received by the Agency. These twenty comments all supported the proposed rule as written. Accordingly, the proposed rule is hereby adopted as final without change.

DATES: This rule is effective October 5, 1999.

FOR FURTHER INFORMATION CONTACT: Sally Lawrence, Branch Chief, Program Designation Branch, Exchange Visitor Services, 301 4th Street, S.W., Washington, D.C. 20547; telephone, (202) 401–9800.

List of Subjects in 22 CFR Part 514

Cultural exchange program, Reporting and recordkeeping requirements.

Dated: September 28, 1999.

Les Jin,

General Counsel.

Accordingly, 22 CFR part 514 is amended as follows:

PART 514—EXCHANGE VISITOR PROGRAM

1. The authority citation for part 514 continues to read as follows: