

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.

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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:

Authority: 8 U.S.C. 1101(a)(15)(j), 1182, 1258; 22 U.S.C. 1421-1442, 2451-2460; Reorganization Plan No. 2 of 1977, 42 FR 62461, 3 CFR, 1977 Comp. p. 200; E.O. 12048, 43 FR 13361, 3 CFR, 1978 Comp. p. 168; USIA Delegation Order No. 85-5 (50 FR 27393).

2. Section 514.31 paragraph (e), (f), (h), (i), and (m) are revised to read as follows:

§ 514.31 Au pairs.

* * * * *

(e) *Au pair placement.* Sponsors shall secure, prior to the au pair's departure from the home country, a host family placement for each participant. Sponsors shall not:

(1) Place an au pair with a family unless the family has specifically agreed that a parent or other responsible adult will remain in the home for the first three days following the au pair's arrival;

(2) Place an au pair with a family having a child aged less than three months unless a parent or other responsible adult is present in the home;

(3) Place an au pair with a host family having children under the age of two, unless the au pair has at least 200 hours of documented infant child care experience;

(4) Place an au pair with a host family having a special needs child, as so identified by the host family, unless the au pair has specifically identified his or her prior experience, skills, or training in the care of special needs children and the host family has reviewed and acknowledged in writing the au pair's prior experience, skills, or training so identified;

(5) Place the au pair with a family unless a written agreement between the au pair and host family outlining the au pair's obligation to provide not more than 45 hours of child care services per week has been signed by both;

(6) Place the au pair with a family who cannot provide the au pair with a suitable private bedroom; and

(7) Place an au pair with a host family unless the host family has interviewed the au pair by telephone prior to the au pair's departure from his or her home country.

(f) *Au pair orientation.* In addition to the orientation requirements set forth at § 514.10, all sponsors shall provide au pairs, prior to their departure from the home country, with the following information:

(1) A copy of all operating procedures, rules, and regulations, including a grievance process, which govern the au

pair's participation in the exchange program;

(2) A detailed profile of the family and community in which the au pair will be placed;

(3) A detailed profile of the educational institutions in the community where the au pair will be placed, including the financial cost of attendance at these institutions;

(4) A detailed summary of travel arrangements; and

(5) A copy of the Agency's written statement and brochure regarding the au pair program.

* * * * *

(h) *Host family selection.* Sponsors shall adequately screen all potential host families and at a minimum shall:

(1) Require that the host parents are U.S. citizens or legal permanent residents;

(2) Require that host parents are fluent in spoken English;

(3) Require that all adult family members resident in the home have been personally interviewed by an organizational representative;

(4) Require that host parents and other adults living full-time in the household have successfully passed a background investigation including employment and personal character references;

(5) Require that the host family have adequate financial resources to undertake all hosting obligations;

(6) Provide a written detailed summary of the exchange program and the parameters of their and the au pair's duties, participation, and obligations; and

(7) Provide the host family with the prospective au pair participant's complete application, including all references.

(i) *Host family orientation.* In addition to the requirements set forth at § 514.10 sponsors shall:

(1) Inform all host families of the philosophy, rules, and regulations governing the sponsor's exchange program and provide all families with a copy of the Agency's written statement and brochure regarding the au pair program;

(2) Provide all selected host families with a complete copy of Agency-promulgated Exchange Visitor Program regulations, including the supplemental information thereto;

(3) Advise all selected host families of their obligation to attend at least one family day conference to be sponsored by the au pair organization during the course of the placement year. Host family attendance at such a gathering is a condition of program participation

and failure to attend will be grounds for possible termination of their continued or future program participation; and

(4) Require that the organization's local counselor responsible for the au pair placement contacts the host family and au pair within forth-eight hours of the au pair's arrival and meets, in person, with the host family and au pair within two weeks of the au pair's arrival at the host family home.

* * * * *

(m) *Reporting requirements.* Along with the annual report required by regulations set forth at § 514.17, sponsors shall file with the Agency the following information:

(1) A summation of the results of an annual survey of all host family and au pair participants regarding satisfaction with the program, its strengths and weaknesses;

(2) A summation of all complaints regarding host family or au pair participation in the program, specifying the nature of the complaint, its resolution, and whether any unresolved complaints are outstanding;

(3) A summation of all situations which resulted in the placement of au pair participant with more than one host family;

(4) A report by a certified public accountant, conducted pursuant to a format designated by the Agency, attesting to the sponsor's compliance with the procedures and reporting requirements set forth in this subpart;

(5) A report detailing the name of the au pair, his or her host family placement, location, and the names of the local and regional organizational representatives; and

(6) A complete set of all promotional materials, brochures, or pamphlets distributed to either host family or au pair participants.

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 200

Introduction to FHA Programs

CFR Correction

In Title 24 of the Code of Federal Regulations, parts 200 to 499, revised as of Apr. 1, 1999, on page 73, the editorial note following § 200.1302 is removed.

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