

and the Regulatory Flexibility Act (5 U.S.C. 601-612). 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. Because this regulation does not impose reporting, recordkeeping, or other economic burdens, the agency certifies that the 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.

**List of Subjects in 21 CFR Part 312**

Drugs, Exports, Imports, Investigations, Labeling, Medical research, Reporting and recordkeeping requirements, Safety.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 312 is amended as follows:

**PART 312—INVESTIGATIONAL NEW DRUG APPLICATION**

1. The authority citation for 21 CFR part 312 continues to read as follows:

**Authority:** Secs. 201, 301, 501, 502, 503, 505, 506, 507, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371); sec. 351 of the Public Health Service Act (42 U.S.C. 262).

2. Section 312.70 is amended by revising the first sentences of paragraphs (a) and (b) to read as follows:

**§ 312.70 Disqualification of a clinical investigator.**

(a) If FDA has information indicating that an investigator (including a sponsor-investigator) has repeatedly or deliberately failed to comply with the requirements of this part, part 50, or part 56 of this chapter, or has submitted to FDA or to the sponsor false information in any required report, the Center for Drug Evaluation and Research

or the Center for Biologics Evaluation and Research will furnish the investigator written notice of the matter complained of and offer the investigator an opportunity to explain the matter in writing, or, at the option of the investigator, in an informal conference. \* \* \*

(b) After evaluating all available information, including any explanation presented by the investigator, if the Commissioner determines that the investigator has repeatedly or deliberately failed to comply with the requirements of this part, part 50, or part 56 of this chapter, or has deliberately or repeatedly submitted false information to FDA or to the sponsor in any required report, the Commissioner will notify the investigator and the sponsor of any investigation in which the investigator has been named as a participant that the investigator is not entitled to receive investigational drugs. \* \* \*

\* \* \* \* \*

Dated: August 29, 1997.

**William B. Schultz,**

*Deputy Commissioner for Policy.*

[FR Doc. 97-23587 Filed 9-4-97; 8:45 am]

BILLING CODE 4160-01-F

**UNITED STATES INFORMATION AGENCY**

**22 CFR 514**

**Exchange Visitor Program**

**AGENCY:** United States Information Agency.

**ACTION:** Final rule.

**SUMMARY:** The Agency adopts as final and without change the interim final rule governing au pair program participation adopted June 27, 1997.

**DATES:** This rule is effective September 5, 1997.

**FOR FURTHER INFORMATION CONTACT:** Exchange Visitor Program Services, Program Designation Branch, United States Information Agency, 301 4th Street, SW., Washington DC 20547; Telephone (202) 401-9810.

**SUPPLEMENTARY INFORMATION:** The Agency adopted an interim final rule governing au pair program participation on June 27, 1997 (62 FR 34632.) This interim final rule amended existing au pair program regulations adopted February 15, 1995 (60 FR 8547.) Specifically, the interim rule further defined the selection and screening requirements for au pair participants and required that participants actually attend rather than merely enroll for six

hours of academic credit. Further, the number of hours that au pair may provide child care services was limited to no more than 10 hours per day and forty-five hours in any given week.

The Agency provided for a thirty day public comment period which ended July 27, 1997 and received forty-one comments. The Agency reviewed those comments and found that all comments received objected to the educational program component, the wage to be paid to the au pair participant, or the limitation on the number of hours an au pair participant may work. Due to the Agency's past review of these three specific areas of the au pair program, the Agency has determined that it is appropriate to adopt the interim final regulation as final and without modification notwithstanding these comments from interested members of the public.

**List of Subjects in 22 CFR Part 514**

Cultural exchange programs.

Dated: August 29, 1997.

**Les Jin,**

*General Counsel.*

**PART 514—EXCHANGE VISITOR PROGRAM**

Accordingly, the interim rule amending 22 CFR part 514 which was published at 62 FR 34633 on June 27, 1997 is adopted as a final rule without change.

[FR Doc. 97-23624 Filed 9-4-97; 8:45 am]

BILLING CODE 8230-01-M

**DEPARTMENT OF THE TREASURY**

**Internal Revenue Service**

**26 CFR Part 1**

[TD 8722]

RIN 1545-AV33

**Guidance Regarding Claims for Certain Income Tax Convention Benefits; Correction**

**AGENCY:** Internal Revenue Service, Treasury.

**ACTION:** Correction to temporary regulations.

**SUMMARY:** This document contains corrections to temporary regulations (TD 8722) which were published in the **Federal Register** on Wednesday, July 2, 1997 (62 FR 35673). The temporary regulations relate to the eligibility for benefits under income tax treaties for payments to entities.

**EFFECTIVE DATE:** July 2, 1997.