Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120, EO 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9D, Airspace Designations and Reporting Points, dated September 4, 1996, and effective September 16, 1996, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ASO FL E5 Sebastian, FL [New]

Sebastian Municipal Airport, FL
(Lat. 27°48′46″ N, long. 80°29′44″ W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Sebastian Municipal Airport, excluding that airspace within the Vero Beach, FL, Class E airspace area.

* * * * *

Issued in College Park, Georgia, on August 6, 1997.

Nancy B. Shelton,

Manager, Air Traffic Division, Southern Region.

[FR Doc. 97–23603 Filed 9–4–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 312

[Docket No. 95N–0138]

Disqualification of a Clinical Investigator

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the investigational new drug regulation that provides for disqualification of clinical investigators who submit false information. The revision is intended to clarify the agency's authority to reach sponsor-investigators under the regulation.

EFFECTIVE DATE: November 4, 1997.

FOR FURTHER INFORMATION CONTACT: Thomas C. Kuchenberg, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1046.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is amending the regulations governing the disqualification of clinical investigators to clarify that § 312.70 (21 CFR 312.70) reaches sponsor-investigators.

Part 312 (21 CFR part 312) requires sponsors to monitor the progress of clinical investigations, to review and evaluate evidence relating to the safety and effectiveness of the drug under investigation, and to report to FDA information based on these monitoring and review activities. Clinical investigators conduct clinical trials on new drugs and submit the resulting data to individual or corporate sponsors. Data generated by the clinical investigators are the subject of the reports submitted by sponsors to FDA.

In the **Federal Register** of February 16, 1996 (61 FR 6177), FDA proposed amending § 312.70 by adding language that would clarify that FDA can disqualify clinical investigators, including sponsor-investigators, for submitting to sponsors or to FDA false information in any required report. Under current § 312.70(b), the agency may disqualify an investigator who has ''deliberately or repeatedly submitted false information to the sponsor in any required report.'' However, unlike investigators, sponsor-investigators, who both directly conduct investigations and report data to FDA, submit information directly to FDA and not to a separate sponsor. Because § 312.3(b) specifically states that the ''requirements applicable to a sponsor-investigator under this part include both those applicable to an investigator and a sponsor,'' § 312.70(b) encompasses the disqualification of sponsor-investigators. This has been the agency's long-standing interpretation for clinical investigator disqualifications for drugs, animal drugs, and devices. However, for clarity, the agency is amending this regulation to make specific reference to FDA and to sponsor-investigators. FDA also intends in the near future to review and harmonize the clinical investigator disqualification provisions under device and animal drug regulations (21 CFR 812.119 and 511.1(c)) with the changes made in this final rule.

II. Comments on the Proposed Rule

FDA received one comment on the proposed rule. The comment commended FDA for the proposed amendment to § 312.70, stating that it is imperative that data supporting the safety and efficacy of pharmaceuticals be accurate and reliable. The comment noted that it was in the best interest of patients, investigators, pharmaceutical companies, and the Government that FDA be able to assure the integrity of data. The comment also expressed support for the disqualification of a clinical investigator who has deliberately or repeatedly supplied false information to a sponsor or to FDA.

FDA welcomes comments and suggestions from all persons interested in protecting the integrity of clinical data. The deliberate submission of false information by those directly responsible for administering or dispensing an investigational new drug subverts the integrity of the review process. At worst, such actions may endanger public health and safety and, at a minimum, will challenge public confidence in a review process that is conducted with honesty by the vast majority of investigators and sponsor-investigators.

III. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) 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.

IV. 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). 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.