Prior to the effective date of the final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

List of Subjects in 21 CFR Part 54

Biologics, Drugs, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 54 is amended as follows:

PART 54—FINANCIAL DISCLOSURE BY CLINICAL INVESTIGATORS

1. The authority citation for 21 CFR part 54 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360, 360c–360j, 371, 372, 373, 374, 375, 376, 379; 42 U.S.C. 262.

2. Section 54.2 is amended by revising paragraphs (d) and (e) to read as follows:

§ 54.2 Definitions.

* * * * *

(d) *Clinical investigator* means only a listed or identified investigator or subinvestigator who is directly involved in the treatment or evaluation of research subjects. The term also includes the spouse and each dependent child of the investigator.

(e) *Covered clinical study* means any study of a drug or device in humans submitted in a marketing application or reclassification petition subject to this part that the applicant or FDA relies on to establish that the product is effective (including studies that show equivalence to an effective product) or any study in which a single investigator makes a significant contribution to the demonstration of safety. This would, in general, not include phase l tolerance studies or pharmacokinetic studies, most clinical pharmacology studies (unless they are critical to an efficacy determination), large open safety studies conducted at multiple sites, treatment protocols, and parallel track protocols. An applicant may consult with FDA as to which clinical studies constitute ''covered clinical studies'' for purposes of complying with financial disclosure requirements.

* * * * *

Dated: November 24, 1998.

Michael A. Friedman,

Lead Deputy Commissioner for the Food and Drug Administration.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 98–34546 Filed 12–30–98; 8:45 am]

BILLING CODE 4160–01–F

INTERNATIONAL DEVELOPMENT COOPERATION AGENCY

U.S. Agency for International Development

22 CFR Part 228

RIN 0412–AA40

Rules on Source, Origin and Nationality for Commodities and Services Financed by USAID: Special Source Rules Requiring Procurement from the United States

AGENCY: United States Agency for International Development (USAID), IDCA.

ACTION: Final rule.

SUMMARY: USAID is amending its regulation on source, origin and nationality for commodities and services financed by USAID by dropping the requirement that vehicles must be manufactured by, and bear the nameplates of, Chrysler, Ford or General Motors in order to be considered U.S.-manufactured vehicles eligible for USAID financing. The rule served little practical purpose since these are the only vehicles manufactured in the U.S. that are generally available for export from the United States. Foreign corporations manufacturing vehicles in the U.S. are doing so for U.S. consumption. Removing the requirement simplifies the rules and has no significant impact.

DATES: Effective March 1, 1999.

FOR FURTHER INFORMATION CONTACT: Kathleen O'Hara, Office of Procurement, Policy Division (M/OP/P) USAID, Washington, DC 20523–7801. Telephone: (202) 712–4759, facsimile: (202) 216–3395, e-mail address: koharausaid.gov.

SUPPLEMENTARY INFORMATION: This change is being published as a final rule since the regulation is being amended to reflect a change the Agency has made in its internal policy documents. However, we welcome any comments from the public. This rule will not have an impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* and is not a major rule under 5 U.S.C. 804. This regulatory action was not subject to Office of Management and Budget review under Executive Order 12866, dated September 30, 1993.

List of Subjects in 22 CFR Part 228

Administrative practice and procedure, Commodity procurement, Grant programs—foreign relations.

Accordingly 22 CFR part 228 is amended as follows:

PART 228—[AMENDED]

1. The authority citation continues to read as follows:

Authority: Sec. 621, Pub. L. 87–195, 75 Stat. 445 (22 U.S.C. 2381), as amended; E.O. 12163, Sept. 29, 1979, 44 FR 56673; 3 CFR 1979 Comp., p. 435.

§ 228.13 [Amended]

2. Sec. 228.13 is amended by removing the last two sentences in the paragraph (b).

Dated: November 17, 1998

Marcus L. Stevenson,

Procurement Executive.

[FR Doc. 98–34718 Filed 12–30–98; 8:45 am]

BILLING CODE 6116–01–M